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Protecting Real Innovations by Improving Patent Quality

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Patent Reality Checks
Eliminating Patents On Fake, Impossible And Other Inoperative Inventions

Abstract

The recent assertion of patents originally held by Theranos, the defunct blood analysis company whose founders are under federal indictment for fraud, highlights the existence of patents that claim non-existent and inoperative inventions. While such patents may ultimately be subject to validity challenges in court, their issuance nevertheless has harmful effects on markets and innovation. I propose several modest administrative and legislative measures directed toward the elimination of patents on inoperative inventions including (1) increasing PTO efforts to detect potentially inoperable inventions, (2) heightening examination requirements, including a certification of enablement, for certain inventions, (3) enabling greater public input into the examination process, and (4) increasing penalties for fraudulent conduct before the PTO. In addition to addressing inoperative inventions, some of these reforms could help to alleviate broader enablement concerns that have been identified by scholars over the past decade. Given the serious consequences that these issues have on markets and innovation, such measures merit serious consideration by the PTO and Congress.

Mr. Chairman and distinguished members of the committee: thank you for the opportunity to testify before you today. My name is Jorge Contreras and I am a professor of law at the University of Utah with a secondary appointment in the Department of Human Genetics. In addition to my JD degree, I hold an undergraduate degree in electrical and computer engineering, and prior to entering academia I spent seventeen years practicing transactional intellectual property law at a major international law firm. As an academic, I have written extensively on issues surrounding intellectual property quality, transactions and licensing. As such, I am intimately familiar with the topic of today's hearings.

Introduction

On March 9, 2020, two days before the World Health Organization (WHO) declared COVID-19 to be a global pandemic, a little-known patent assertion entity (PAE) named Labrador Diagnostics sued BioFire, a medical device manufacturer that was about to release a diagnostic test for COVID-19.[1] Labrador alleged that BioFire and its French parent bioMérieux infringed two U.S. patents[2] that claimed various features of microfluidic testing devices. In addition to monetary damages, Labrador sought to enjoin the manufacture and sale of the infringing devices in the U.S.

It was bad enough that Labrador sued one of the first companies to develop a COVID-19 test just as the disease was taking hold in the United States.[3] But even more surprising was the

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[1] Labrador Diagnostics LLC v. BioFire Diagnostics, LLC, No. 1:20-cv-00348 (D. Del. filed Mar. 9, 2020). The suit also named as a defendant BioFire's French parent company, bioMérieux S.A. For additional discussion of the case see Jorge L. Contreras, *Patent Fakes – How Fraudulent Inventions Threaten Public Health, Innovation and the Economy*, BILL OF HEALTH (2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3663477.

[2] U.S. Pat. Nos. 8,283,155 and 10,533,994.

[3] Press coverage of the lawsuit sparked a backlash that quickly persuaded Labrador's parent company, Fortress Investments, to end the lawsuit against BioFire and bioMérieux and to offer royalty-free licenses to anyone conducting COVID-19 testing. *See* Craig Clough, *Fortress Offers IP Rights to Fight COVID-19 After Backlash*,

source of the patents that Labrador asserted. They were two of more than one thousand patents originally assigned to Theranos,[4] the now defunct blood analysis company founded by Stanford dropout Elizabeth Holmes in 2003. Holmes, who left the company in 2018 after settling charges brought by the Securities and Exchange Commission (SEC),[5] is currently under federal indictment for multiple counts of criminal conspiracy and wire fraud.[6] Holmes is named as the lead inventor on both patents asserted by Labrador.

But as journalist John Carreyrou first reported in 2015,[7] Theranos never produced the blood testing devices that brought it to national prominence and enabled it to raise hundreds of millions of dollars from investors and business partners. If this is true, 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 technology. In other words, how could the U.S. Patent and Trademark Office (PTO) issue multiple patents for a technology that was, at a minimum, incomplete, and at worst, fraudulent?

LAW360 (Mar. 17, 2020, 5:14 PM EDT) https://www.law360.com/articles/1254102/fortress-offers-ip-rights-to-fight-covid-19-after-backlash.

[4] Richard Lloyd, *Theranos back to the fore with Fortress assertion campaign against diagnostics business*, Intell. Asset Mgt., Mar. 10, 2020, https://www.iam-media.com/litigation/theranos-back-the-fore-fortress-assertion-campaign-against-diagnostics-business

[5] Securities & Exch. Comm. (SEC), Press Release: Theranos, CEO Holmes, and Former President Balwani Charged With Massive Fraud, Mar. 14, 2018. In her settlement of the securities fraud charges brought by the SEC in March, 2018, Holmes agreed to pay a $500,000 penalty, be barred from serving as an officer or director of a public company for 10 years, and return a significant portion of the equity she received from Theranos. She did not, however, admit guilt to the charges.

[6] United States v. Holmes, Indictment (N.D. Cal., filed Jun. 14, 2018).

[7] See John Carreyrou, *Hot Startup Theranos Has Struggled With Its Blood-Test Technology*, WALL ST. J., Oct. 16, 2015. Carreyous's book BAD BLOOD: SECRETS AND LIES IN A SILICON VALLEY STARTUP (2018), and Alex Gibney's film THE INVENTOR: OUT FOR BLOOD IN SILICON VALLEY (HBO 2019) offer a compelling account of the sordid Theranos affair.

A. Three Flavors of Inoperative Invention

The Labrador litigation sheds light on a disturbing reality about patents: more than a few of them cover inventions that were never made, or at least never worked. These non-existent inventions are referred to as "inoperative",[8] and for lack of a better term, I call the patents that cover these inoperative inventions as "bad" (as in rotten, not evil) patents. I divide the world of inoperative inventions into three basic categories: Fakes, Fictions and Mistakes.

Fakes – some claimed inventions are simply fraudulent – their inventors know that they don't work, yet they seek patent protection anyway. Theranos is only one of numerous examples of this practice. Another involved the claim by the Korean research team led by Dr. Hwang Woo Suk that it had created a human embryonic stem cell line derived from a cloned human embryo. Shortly after publishing this stunning finding in the journal *Science*, it was revealed that Hwang had falsified key data.[9] Despite his conviction for fraud and embezzlement, Hwang's biotech company continued prosecution of patents on the cell line and succeeded in getting at least one U.S. patent issued.[10] And as recently as last week, STAT reported that the CEO of Athira Pharma was placed on leave for allegedly falsifying data in four scientific papers that formed the basis for the company's patents on treatments for Alzheimer's and other neurodegenerative diseases.[11]

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[8] *See* Manual of Patent Examining Procedure (MPEP), § 2107.01, Part II, "Wholly Inoperative Inventions; 'Incredible' Utility" (9th ed., Rev. 10.2019, last revised Jun. 2020).

[9] *See* Barry Fox, *Disgraced cloning pioneer could keep his patents*, NEW SCIENTIST, Jan. 18, 2006, https://www.newscientist.com/article/dn8601-disgraced-cloning-pioneer-could-keep-his-patents/.

[10] U.S. Pat. No. 8,647,872, Human Embryonic Stem Cell Line Prepared By Nuclear Transfer Of A Human Somatic Cell Into An Enucleated Human Oocyte (Issued Feb. 11, 2014). *See also* Andrew Pollack, *Disgraced Scientist Granted U.S. Patent for Work Found to be Fraudulent*, N.Y. Times, Feb. 14, 2014

[11] Olivia Goldhill, *Athira Pharma CEO placed on leave amid allegations of altered images in her research papers*, STAT, Jun. 17, 2021, https://www.statnews.com/2021/06/17/athira-pharma-ceo-placed-on-leave-amid-allegations-of-altered-images-in-research-papers/ (referencing U.S. Pat. No. 8,598,118 assigned to Washington State University and exclusively licensed to Athira).

Fictions – rather than perpetrating fraud, some inventors honestly, but incorrectly, believe that they have made an important new discovery. These applicants have claimed inventions from cold fusion and panacea cures to warp drive and flying saucers. But not all fictional inventions are so farfetched. As Professor Janet Freilich has recently observed, a full 17% of the experiments described in recent U.S. chemistry and biology patents were never performed.[12] Rather, they were made up to illustrate potential, hoped-for uses of a patented invention. Surprisingly, these so-called "prophetic examples" are perfectly legal and can help to establish additional protected uses of a patented invention, even if those uses do not in fact work.

Mistakes -- The problem of patents covering non-existent technologies does not end with applicants who are fraudulent or overly-creative. The PTO also receives a large number of applications from inventors who believe that they have made a legitimate discovery, only to find out later – sometimes after their patents have issued -- that they did not actually discover what they claimed, or anything at all. The problem arises, in part, from "gun jumping" – claiming a discovery before it is validated.[13] Of course, such mistakes occur in science as well. The difference is that in science, when a published finding is revealed to be incorrect or based on flawed or incomplete data,[14] the scientific paper making the claim can be retracted or

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[12] Janet Freilich, *Prophetic Patents*, 53 U.C. DAVIS L. REV. 663, 668 (2019). Over the past fifteen years, numerous scholars have criticized the practice of using prophetic examples in patent applications. *See id*. at 666-67 n. 10 (collecting literature).

[13] Numerous scholars have identified this problem. *See, e.g.,* Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. REV. 1171 (2016) ("In an important class of cases—those in which the inventor has an idea but does not yet know if it will work—the patent system encourages the inventor to patent first and figure it out later, if at all"); Lisa L. Ouellette, *Pierson, Peer Review, and Patent Law*, 69 VANDERBILT L. REV. 1825, 1832 (2016) ("in practice, patents often are awarded too early"), Mark A. Lemley et al., *Life After Bilski*, 63 STAN. L. REV. 1315, 1330-31 (2011) (introducing "gun jumping" terminology), Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65 (2009) ("The United States patent system is intentionally structured to encourage patent filing early in an invention's development.")

[14] Some retractions result from the uncovering of scientific fraud or other unethical practices – these fall under the category of "Fakes", discussed above. In the category of "Mistakes", I address retractions resulting from the discovery of experimental design flaws, lapses in data or other inadvertent, yet invalidating, occurrences.

corrected. The same is not true of patents, which, as Professor Freilich has observed, seem impervious to subsequent corrections of technical understanding.[15]

B. Why Bad Patents Matter

Why does any of this matter? Some have argued that no harm is done by patents on inoperative inventions. Commenting on one 2005 patent claiming an improbable antigravity-driven spacecraft, a senior PTO advisor opined that "It doesn't cause any problems because the patents are useless."[16] Similarly, one patent attorney said of Dr. Hwang's fraudulent stem cell technology, "Does it really matter if the man made up his results? Let him try and sell it."[17] The prevailing view, both at the PTO and the patent bar, seems to be that patents on non-existent and impossible inventions are mere curiosities: unfortunate but ultimately harmless.

But Labrador's suit against BioFire is stark evidence to the contrary. The following are examples of the very real harms that can flow from bad patents.

1. A bad patent can act as prior art preventing later inventors from getting a patent they deserve after actually developing the claimed technology.[18]
2. The holder of a bad patent can enforce the patent against others who are more successful at developing the technology (i.e., a bad patent isn't necessarily an unenforceable

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[15] Professor Freilich and Soomi Kim studied patents matched to disclosures in scientific papers, which are common in the biotechnology field. They report in a forthcoming article that retraction of the underlying paper had little or no effect on the examination, issuance or later citation of those patents, notwithstanding the withdrawal of the scientific claims underlying them. Janet Freilich & Soomi Kim, *Is the Patent System Sensitive to Information Quality?* (working paper, 2021). This phenomenon is well-illustrated by the case of Dr. Hwang, who continued to cite two retracted *Science* papers in his patent application, which was eventually granted.

[16] Philip Ball, *Antigravity craft slips past patent officers*, 438 NATURE 139 (2005) (quoting Alan Cohan, an adviser at the PTO Inventors Assistance Center).

[17] Fox, *supra* note 9 (quoting George Schlich, a patent attorney and counsel for Stem Cell Sciences).

[18] This outcome may have occurred with respect to one of Theranos's patents. *See* Freilich & Kim, *supra* note 15, at 1.

patent). Exacerbating this problem: an issued patent is presumed to be valid,[19] making it nontrivial to challenge when asserted.

3. Even if a bad patent can eventually be invalidated in court (and not all can), patent litigation is costly, especially for small and medium sized enterprises (SMEs). Some may prefer to settle infringement claims rather than incur the cost of litigation, leaving the bad patent on the books for assertion against others.[20]
4. The existence of bad patents can itself chill new research and innovation, thus reducing market entry, technology development and competition.

More than half a century ago, the Supreme Court recognized in *Lear v. Atkins* the threat that bad patents pose to the market and innovation and identified "the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain."[21] In short, bad patents allow unscrupulous actors to put fences around not-yet-invented technologies that should still be part of the public domain.

Just imagine what might have happened in the early twentieth century if the Patent Office had allowed German aviation pioneer Otto Lilienthal, French-born engineer Octave Chanute or Sir Hiram Maxim, the English inventor of the machine gun, to patent the idea of a fixed-wing piloted aircraft before Wilbur and Orville Wright had actually reduced this monumental

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[19] 35 U.S. Code § 282 ("A patent shall be presumed valid ... The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.")

[20] This preference is, in fact, the motivating business rationale behind many patent suits brought by PAEs. *See, e.g.*, Mark A. Lemley & A. Douglas Melamed, *Missing the Forest for the Trolls*, 113 COLUM. L. REV. 2117, 2126 (2013) ("a growing number of trolls are interested in quick, low-value settlements for a variety of patents. These plaintiffs do not want to go to trial and are thus not particularly interested in the quality of their patents or whether they are infringed. Rather, they rely on the high cost of patent litigation—a median of $5.5 million for substantial cases that go to trial, by one recent estimate—to induce the parties they sue to settle for small amounts of money rather than pay millions to their lawyers.")

[21] Lear v. Atkins, 395 U.S. 653 (1969).

achievement to practice?[22] Would the historic flight at Kitty Hawk have happened? Maybe not, and American technological progress might have suffered.

For all of these reasons, there is a strong societal interest in preventing patents on fraudulent, imaginary and non-existent inventions from being issued and released into the market.

C. Existing Methods to Address Inoperative Inventions

The threat of inoperative inventions is well-known, and several existing legal mechanisms have been used, with differing degrees of success, to prevent their patenting.

1. Inequitable Conduct. Every patent applicant has "a duty of candor and good faith in dealing with the [PTO], which includes a duty to disclose … all information known to that individual to be material to patentability."[23] The failure to comply with this duty of candor is referred to as inequitable conduct, and the PTO's rules provide that "no patent will be granted on an application in connection with which fraud on the [PTO] was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct."[24] While these rules are necessary, few cases of inequitable conduct are identified or pursued during

[22] *See* DAVID MCCULLOUGH, THE WRIGHT BROTHERS 28, 32 (2015).

[23] 36 CFR § 1.56(a).

[24] 36 CFR § 1.56(a).

prosecution.[25] Such cases are difficult for examiners to identify,[26] and because prosecution is largely an *ex parte* proceeding, examiners are not aided by opposing parties with broad discovery powers. Even when potential inequitable conduct is identified during prosecution, most cases relate only to an applicant's failure to disclose prior art that could preempt some or all of its claims.

Cases of outright fraud involving the patenting of inoperative inventions appear to be much rarer.[27] And even when such cases emerge, the PTO appears to adopt a lenient approach that allows applicants to correct inaccurate or omitted statements without penalty.[28] For example, during the prosecution of an application claiming Dr. Hwang's discredited stem cell invention, the examiner noted that "a post-filing investigation … discovered that [the] applicant falsified data resulting from the claimed method," citing a news exposé titled "Disgraced Cloning Pioneer Could Keep His Patents".[29] Nevertheless, the examiner helpfully suggested that "A declaration filed under 35 U.S.C. § 1.132 attesting to data demonstrating … the claimed method

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[25] *See* 6A CHISUM ON PATENTS § 19.03[6][a] ("The question of fraud or inequitable conduct has been most commonly raised after a patent issues"). If a patent obtained through fraud is enforced, the infringer may raise inequitable conduct as an affirmative defense and, if successful, the patent will be held unenforceable. See Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co., 324 U.S. 806 (1945) (patent obtained through fraud or inequitable conduct is not enforceable). In addition, an antitrust claim may be brought with respect to the attempted enforcement of a patent obtained through fraud. *See* Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965) ("the enforcement of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act provided the other elements necessary to a § 2 case are present.")

[26] This is among the many problems that arise from what Professor Freilich identifies as examiners' failure to "dig" adequately into the information that they obtain about an application. See Janet Freilich, *Ignoring Information Quality*, 89 FORDHAM L. REV. 2113 (2021).

[27] Judge Randall Rader notes the expansion of the inequitable conduct doctrine from one originally directed to cases of "egregious fraud, perjury, and extortion" to its more common use today as an overarching mechanism for "eliciting prior art from a patent applicant". Randall R. Rader, *Always at the Margin: Inequitable Conduct in Flux*, 59 AM. U. L. REV. 777, 781 (2010). Judge Rader's sentiments have been echoed by numerous commentators. *See, e.g.*, David O. Taylor, *Patent Fraud*, 83 TEMPLE L. REV. 49 (2010) (arguing that the doctrine of inequitable conduct should be reduced to one of patent fraud).

[28] *See* CHISUM, *supra* note 25, at § 19.03[6][a][iii] (Curing Inequitable Conduct).

[29] Office Action, Application/Control Number 13/316,199 at 5 (Oct. 3, 2012) (citing Fox, *supra* note 9).

may be sufficient to overcome the above rejection."[30] Not surprisingly, Hwang supplied the suggested declaration and his claims were allowed without further inquiry.

2. Utility. Section 101 of the Patent Act requires that an invention be "useful" in order to be patented, and longstanding judicial precedent has established that inoperative inventions are not useful.[31] However, as explained by the PTO, "Situations where an invention is found to be 'inoperative' and therefore lacking in utility are rare, and rejections maintained solely on this ground by a federal court even rarer." [32] In order to meet this standard, an invention must be "totally incapable of achieving a useful result"[33] and it is seldom applied outside of facially "incredible" claims to inventions such as perpetual motion machines.[34]

3. Enablement. The most frequently-cited mechanism for avoiding the issuance of bad patents is the so-called "enablement" requirement under Section 112 of the Patent Act.[35] It provides that each patent application must contain sufficient detail to enable one skilled in the art to practice the invention. It is (supposedly) not enough to say, "it would be 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 inform the PTO, and the world, how to make the claimed invention. The theory is that if the specification adequately instructs others how to make the invention, then we can assume that the inventor was able to make it, and the invention is not inoperative.

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[30] *Id*. at 6.

[31] *See* MPEP, *supra* note 8, at § 2107.01, Part II (citing Newman v. Quigg, 877 F.2d 1575, 1581 (Fed. Cir. 1989); In re Harwood, 390 F.2d 985, 989 (CCPA 1968)).

[32] *See* MPEP, *supra* note 8, at § 2107.01, Part II.

[33] Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571 (Fed. Cir. 1992).

[34] *See* MPEP, *supra* note 8, at § 2107.01, Part II. *See also* Cotropia, *supra* note 13, at 75-76.

[35] 35 U.S.C. § 112(a) ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.").

There are two general ways that patents fail to meet the enablement requirement: the invention was never successfully reduced to practice, or the specification fails to describe the invention in sufficient detail. The latter of these stems from deficient drafting, often for inventions that do, actually, work, at least under some circumstances. This type of failure is often referred to as a failure under the "written description" requirement of Section 112.[36] I will focus not on written description problems, but on what I view as the more serious enablement problem: inventions that were never actually reduced to practice by their inventors.

The enablement requirement and its failings have been the subject of significant scholarly criticism in recent years.[37] The root of the problem is that a patent application must merely describe the steps involved in making an invention, but need not show, or even aver, that the invention will work or achieve the expected results. And the patent examiner who evaluates the application need not perform any tests to verify what the applicant claims. 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 merit.

It is reasonable not to require an applicant to have created every possible variant of its invention before obtaining a patent. Some later experimentation and fine-tuning is expected before a patented device is ready for the market. Yet we may have gone too far in the direction of leniency. Today, applicants can seek patents before they have actually reduced *any* version of their invention to practice, including through the use of prophetic examples – experiments that were never conducted.[38] In a bizarre twist of logic, the filing of a patent application itself is

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[36] *See* Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010).

[37] *See, e.g.*, Ouellette, *Peer Review*, *supra* note 13; Lemley, *Ready, supra* note 13; Sean Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621 (2010); Cotropia, *supra* note 13.

[38] *See, e.g.*, Freilich, *Prophetic Patents, supra* note 12.

viewed by the courts and the PTO as a "constructive" reduction of the invention to practice,[39] a doctrine that has attracted significant criticism.[40] As observed by Professor Mark Lemley, "An inventor is better off filing a patent application as early as possible, before—or perhaps instead of— building a prototype or testing the invention… As against the inventor who went straight to the patent office, those who seek to build and test their inventions are at a disadvantage".[41]

Is any of this the fault of the PTO or its examiners? Probably not. We can't reasonably expect patent examiners to do their own confirmatory experiments – most of them work under intense time pressure; they don't have laboratories, equipment or reagents at their disposal to verify every applicant's assertions, nor even the luxury to read much of the scientific literature in the field. So what can be done?

D. Patent Reality Checks

The problem of bad patents is a broad and varied one, but one thing that can help to address it is a greater focus at the patent examination stage on whether claimed inventions are real. To that end, I offer a few modest "reality checks" to help examiners more closely align patent allowances to technical realities, and to deter fraudulent behavior at the PTO.

1. *Increase Vigilance for Inoperable Inventions*

At the examination stage, the PTO should check inventor names against lists of retracted papers,[42] criminal indictments, securities investigations, disciplinary proceedings, scientific misconduct allegations and other forms of behavior that could give rise to questions about the

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[39] *See* Frazer v. Schlegel, 498 F. 3d 1283, 1288 (Fed. Cir. 2007) ("The filing of a patent application is a constructive reduction to practice of the invention disclosed therein.").

[40] *See, e.g.*, Seymore, *supra* note 37, at 628-30 (referring to constructive reduction to practice as a "legal fiction" and proposing alternatives); Cotropia, *supra* note 13, at 120 (proposing the abolition of the doctrine in favor of actual reduction to practice).

[41] Lemley, *Ready, supra* note 13, at 1178-79.

[42] Such lists are easily accessed via scientific watchdog sites such as retractionwatch.org.

assertions made in an application.[43] The PTO could also flag other questionable applications such as miracle cures, cold fusion and interstellar spacecraft.[44] Finally, as Professor Freilich has suggested, when examiners conduct an initial search concerning an application, they should seek information published both before and *after* the priority date of the application. Post-priority information may not be relevant for prior art purposes, but it could identify retracted papers as well as public allegations and controversy surrounding a particular invention.[45] An application flagged for any of these reasons could be subject to heightened examination (see below).[46]

2. ***Demonstrate Enablement***

If an application is flagged as potentially claiming an inoperative invention, an examiner should be able to request verification that the invention has actually been reduced to practice and adequately enabled. This verification could come in several forms. First, as several scholars have previously suggested, applicants could be required during prosecution to provide more information about the enablement of their inventions, either as a general rule or upon request of

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[43] See Contreras, *Patent Fakes*, *supra* note 1. Professor Freilich suggests that certain examiner searching tasks could be augmented with artificial intelligence. *See* Janet Freilich, *Ignoring Information Quality*, 89 FORDHAM L. REV. 2113, 2154-55 (2021).

[44] From 1994 to 2015 the PTO operated a "Sensitive Application Warning System" (SAWS) that 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. *See* Joe Mullin, *USPTO ends "warning system" for outlandish patents*, ARS TECHNICA, Mar. 5, 2015, https://arstechnica.com/tech-policy/2015/03/uspto-ends-program-for-patents-that-could-create-unwanted-media-coverage/.

[45] *See* Freilich, *Information Quality, supra* note 43, at 2146-47.

[46] The PTO's reintroduction of an application monitoring system such as SAWS (see note 44, *supra*) could also have the benefit of triggering heightened review of enabled yet stupefyingly obvious inventions, such as the notorious dog toy shaped like a stick. U.S. Pat. No. 6,360,693, "Animal Toy" (Issued Mar. 26, 2002). *See* Jorge L. Contreras, *Silly Patents, Common Knowledge and the Elusive Prior Art of Everyday Life* (2015) (abstract available at https://law.depaul.edu/about/centers-and-institutes/center-for-intellectual-property-law-and-information-technology/programs/ip-scholars-conference/Documents/ipsc_2015/abstracts-papers-presentation/ContrerasJ_abstract.pdf).

the PTO.[47] Yet this approach may be of limited value when inventors are less than forthright, as might occur with respect to fraudulent inventions. Thus, a more effective approach may be to require an applicant to demonstrate the practice of its invention to a third party auditor or peer reviewer, or to convince the reviewer that reduction to practice is both feasible and likely.[48] Among the benefits of such a review and certification, in addition to preventing the issuance of bad patents, is the possibility of giving patents that have received a positive certification a *presumption of enablement* if their validity is later challenged under § 112.[49] This gives the applicant an incentive to seek such certification, assuming that its invention is real.

3. ***Involve the Public***

Over the years, commentators have observed that members of the public (academics, industrial researchers, software developers, etc.) are more likely to appreciate the technical challenges faced by a given invention than examiners. As such, numerous proposals have been made to enable members of the public to offer input to the PTO with respect to particular patent

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[47] See Freilich, *Information Quality, supra* note 43, at 2145 ("Instead of requiring examiners to further dig into the quality of evidence in patent applications, the system should ask applicants to provide additional support for their statements"), Lemley, *Ready, supra* note 13, at 1191 ("We could, for instance, impose a stricter test for disclosing the invention to the world on an inventor who cannot point to working examples—perhaps requiring her to explain the principles behind her invention if she cannot prove that it works in practice" (thanking Josh Sarnoff for this suggestion)), Seymore, *supra* note 37, at 642-43 ("the examiner should have the authority to request working examples"). Professor Seymore also notes the PTO's seldom-exercised authority to request a *physical* working model of an invention. Seymore, *supra* note 37, at 642 n. 103.

[48] Unlike others, this proposal would not require every applicant to reduce its invention to practice. *See* Cotropia, *supra* note 13, at 120 (proposal "requiring all applicants to actually reduce their invention to practice -- that is, actually implement the invention and observe that it works for its intended purpose-before receiving a patent"). *But see* Lemley, *Ready, supra* note 13, at 1188 ("In some fields, such as semiconductor manufacturing, designers may not be able to actually build and test their inventions without a great deal of time and money—money that inventors may not be able to pay.") Rather, it would only be imposed in situations in which the likelihood of a non-existent invention is high.

[49] For a discussion of a proposed annotation system, see Jorge L. Contreras, *Shepardizing Patents*, Patently-O, Jun. 16, 2021, https://patentlyo.com/patent/2021/06/contreras-shepardizing-patents.html.

applications.[50] Between 2007 and 2011, the PTO and New York Law School operated a pilot program called "Peer to Patent", which allowed "citizen-experts" to review selected patent applications (mostly relating to computing, software and business methods), to identify and rate prior art, and to offer other input to the examination process.[51]

And, since the effectiveness of the America Invents Act in 2012, Section § 122(e) of the Patent Act has permitted members of the public to submit to the PTO prior art pertaining to any patent application for six months after its publication,[52] and Section § 311 has permitted members of the public to bring an *inter partes* review (IPR) proceeding to challenge the novelty or nonobviousness of an issued patent within nine months of its issuance.[53]

Curiously, however, neither of these procedures allows challenges to the *enablement* of a patented invention.[54] Therefore, what is needed is an expansion of the pre-issuance submission procedure under 35 U.S.C. § 122(e) that permits members of the public to raise enablement concerns with the PTO throughout the prosecution of a patent application, without requiring the expense or formality of a full IPR proceeding.[55]

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[50] *See, e.g.*, Ouellette, *Peer Review*, *supra* note 13, at 1842 ("it is worth experimenting with a robust peer review system to solicit input from those of extraordinary skill in the field of an application"), Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 614-15 (1999) ("We need to design a system that better taps into patent validity information, much of which is in private hands.")

[51] *See* Naomi Allen et al., Peer to Patent: First Pilot Final Results (2012). *See also* Ouellette, *Peer Review, supra* note 13, at 1839-40 (describing program).

[52] 35 U.S.C. § 122(e).

[53] 35 U.S.C. § 311.

[54] These omissions have previously been pointed out, respectively, by Ouellette, *Peer Review*, *supra* note 13, at 1840-41, and Janet Freilich, *The Replicability Crisis in Patent Law*, 95 INDIANA L.J. 431, 475 (2020).

[55] Professor Ouellette proposes a more extensive peer review system for patent applications. Ouellette, *Peer Review*, *supra* note 13, at 1842-43. Professor Freilich has questioned the usefulness of expanding the scope of IPR proceedings because these proceedings do not give members of the public effective discovery mechanisms, as do litigation proceedings; though with targeted discovery, she agrees that such proceedings might be more useful. Freilich, *Information Quality, supra* note 43, at 2144. In addition, an early draft of the Endless Frontier Act, S.1260

4. *Enhance Penalties for Fraud*

As noted in Part C.1, above, the principal penalties for inequitable conduct and fraud before the PTO are rejection of a patent application and unenforceability of an issued patent.[56] Claims under antitrust law and state fraud statutes may also be available. However, there is no explicit fraud remedy, either private or administrative, under the Patent Act.

In many cases, the remedy of patent unenforceability may be sufficient to deter an applicant from intentionally omitting relevant prior art references – the type of conduct most frequently challenged under the inequitable conduct doctrine.[57] However, merely rendering a patent unenforceable when it was procured through fraudulent means seems unduly lenient, particularly when compared to penalties for fraud in the context of other regulated industries.[58]

Accordingly, the penalties for fraud on the PTO should be expanded in the case of inoperative inventions (i.e., these procured through deception beyond the simple omission of prior art references) to include both criminal penalties and substantial fines.[59] Similar penalties, as well as civil punitive damages, should also be available against entities responsible for the post-

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(May 2021), would have expanded the grounds under which a person may initiate an *ex parte* reexamination under 35 U.S.C. § 302 to include "credible evidence that any claim was obtained through fraud." See Dennis Crouch, *Recordation Requirements and a Certificate of Unenforceability*, Patently-O, May 25, 2021, https://patentlyo.com/patent/2021/05/recordation-requirements-unenforceability.html#comments.

[56] *See* Part C.1, *supra*.

[57] Indeed, many observers view this remedy as excessive in the context of prior art omissions. *See, e.g.*, Aventis Pharma S.A. v. Amphastar Pharms., Inc., 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting) (referring to the unenforceability remedy as an "atomic bomb"); Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 725-26 (2009) (describing widespread concern with remedy).

[58] Penalties for securities fraud include prison sentences and fines of up to $5 million.

[59] *See* Taylor, *supra* note 27, at 89-90 (proposing awards of attorneys' fees against parties unable to prove allegations of inequitable conduct), Kyle R. Kroll, *Prosecuting Inequitable Conduct*, 102 MINN. L. REV. HEADNOTES 49 (2018) (proposing various mechanisms for criminal prosecution of patent inequitable conduct).

issuance enforcement of such patents.[60] Such enhanced penalties are likely to reduce the chance that applicants will seek patents on inoperative inventions and that they and their assignees (patent assertion entities, in particular) will seek to enforce them.

Conclusion

Patents are being issued for non-existent and inoperative inventions. While some of these patents may ultimately be subject to validity challenges, the issuance of such patents nevertheless has harmful effects on the market and innovation, as demonstrated by the ill-timed lawsuit against one of the first COVID-19 test vendors. Rather than waiting for these patents to be challenged in costly litigation, the PTO should exercise greater efforts to weed out bad patents before they are issued. Over the years, scholars have proposed various approaches to improving the utility and enablement doctrines under patent law. I join them with a few modest proposals specifically directed toward the elimination of patents on inoperative inventions, including (1) increasing PTO vigilance to detect potentially inoperable inventions, (2) heightening examination requirements, including a certification of enablement, for questionable inventions, (3) enabling greater public input into the examination process, and (4) increasing penalties for fraudulent conduct before the PTO. The first two proposals could be implemented through PTO administrative rulemaking, while the latter two would require modest adjustments to the Patent Act. In addition to addressing inoperative inventions, some of the above reforms could also help to alleviate the broader enablement concerns that have been identified by scholars over the past decade. Given the serious consequences that these issues have on markets and innovation, such measures are worth serious consideration by the PTO and Congress.

[60] *See* Kenneth R. Spector, *Remedies for Fraud on the Patent Office*, 41 UNIV. CHI. L. REV. 775, 785-87 (1974).

Biographical Information

Jorge L. Contreras is a Presidential Scholar at the University of Utah, a Professor of Law at the University of Utah S.J. Quinney College of Law, and an Adjunct Professor in the Department of Human Genetics at the University of Utah School of Medicine. He also serves as a Senior Policy Fellow at the Program on Information Justice and Intellectual Property at American University Washington College of Law. Before entering academia, Professor Contreras was a partner at the international law firm Wilmer Cutler Pickering Hale and Dorr LLP, where he practiced transactional and IP law in Boston, London and Washington DC. His academic research focuses, among other things, on intellectual property, antitrust law, technical standards and science policy. He is the author or editor of eleven books and has published more than 100 scholarly articles and chapters. His forthcoming book *The Genome Defense: Inside the Epic Legal Battle to Determine Who Owns Your DNA*, tells the story of the landmark Supreme Court case *Association for Molecular Pathology v. Myriad Genetics*, which ended the practice of gene patenting in the United States. Professor Contreras currently serves as Chair of the Art Law Section of the American Association of Law Schools (AALS), Co-Chair of the Interdisciplinary Division of the American Bar Association's Section of Science & Technology Law, and a member of the American Antitrust Institute's Board of Advisors. He has previously served as Co-Chair of the National Conference of Lawyers and Scientists (NCLS), and a member of the National Academy of Sciences (NAS) Committee on IP Management in Standard-Setting Processes, the National Institutes of Health (NIH) Council of Councils, and the Advisory Councils of the National Human Genome Research Institute (NHGRI) and the National Center for Advancing Translational Sciences (NCATS). Professor Contreras was one of the founders of the Open COVID Pledge, an open framework for the contribution of intellectual property to the COVID-19 response. He is the recipient of numerous awards and honors, including the University of Utah's Distinguished Research Award (2020). He is an honors graduate of Harvard Law School (JD) and Rice University (BSEE, BA), and clerked for Chief Justice Thomas R. Phillips of the Texas Supreme Court.