

TURNING GOLD INTO LEAD:  
HOW PATENT ELIGIBILITY DOCTRINE IS UNDERMINING U.S.  
LEADERSHIP IN INNOVATION

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Compared to other countries, the United States has long had a “gold standard” patent system. The U.S. has led the world in securing stable and effective property rights in cutting-edge innovation; most recently, in protecting biotech and computer software inventions. Presenting information from a database of 17,743 patent applications recently filed in the U.S., China, and Europe, this Essay explains how this “gold standard” designation is now in serious doubt. Many of these applications represent pioneering, life-saving inventions, such as treatments for cancer and diabetes. Although all 17,743 patent applications were rejected in the U.S. as ineligible for patent protection, 1,694 of them were granted by the European Patent Office, by China, or both. The cause of the U.S. rejections is the Supreme Court’s recent spate of decisions that upended patent eligibility doctrine, especially as it has been applied to high-tech and biotech innovation. The U.S. patent system is increasingly mired in legal uncertainty, except for the firm knowledge derived from data on the massive numbers of invalidations of issued patents and of rejections of patent applications. In addition to highlighting some of the 1,694 inventions that were denied patent protection in the U.S., this Essay discusses this new legal uncertainty in the U.S. patent system, how this is a key change from the innovation-spurring approach of the U.S. patent system in the past, and what this means for the U.S. as other jurisdictions like China and the European Union become forerunners in securing the new innovation that drives economic growth and flourishing societies.

INTRODUCTION

Over the past ten years, the United States patent system has been transformed by new legislation,<sup>1</sup> regulatory actions,<sup>2</sup> and numerous decisions by

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<sup>1</sup> See generally Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified in scattered sections of 35 U.S.C.).

<sup>2</sup> See Press Release, Fed. Trade Comm’n, FTC Finalizes Settlement in Google Motorola Mobility Case, (July 24, 2013), <https://www.ftc.gov/news-events/press-releases/2013/07/ftc-finalizes-settlement->

the United States Supreme Court addressing all areas of patent doctrine. These widespread and systematic changes have affected infringement remedies,<sup>3</sup> licensing activities,<sup>4</sup> and what types of inventions and discoveries are eligible for patent protection,<sup>5</sup> among many other patent rights and doctrines. Inventors, universities, and companies working in the U.S. innovation economy have faced more than a decade of extensive legal changes to the patent system,<sup>6</sup> and this constantly morphing legal landscape has created extensive uncertainty for all stakeholders.

These many disruptive legal changes raise the question whether the U.S. still can lay claim to being the “gold standard” patent system as compared to the rest of the world.<sup>7</sup> This concern is particularly salient in patent eligibility

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google-motorola-mobility-case (discussing the FTC’s approval of Google/Motorola merger, in which the FTC required Google to commit to the non-enforcement its standard essential patents); *see also* Letter from Renata B. Hesse, Acting Assistant Att’y Gen., U.S. Dep’t of Justice, Antitrust Division, to Michael A. Lindsay, Esq., Dorsey & Whitney LLP (Feb. 2, 2015), <https://www.justice.gov/atr/response-institute-electrical-and-electronics-engineers-incorporated> (approving under the antitrust laws the Institute of Electrical and Electronics Engineers, Inc. (“IEEE”)’s rules prohibiting enforcement of standard essential patents declared in this standard-setting organization).

<sup>3</sup> *See eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 392–93 (2006) (holding that an injunction is not presumptively available to patent-owners on a finding of infringement); *see also Samsung Elec. Co. v. Apple Inc.*, 137 S. Ct. 429, 434–36 (2016) (holding that damages must be limited to the particular value of a component, and not the market value of a device comprising this component).

<sup>4</sup> *See Impression Prods, Inc. v. Lexmark Int’l, Inc.*, 137 S. Ct. 1523, 1533 (2017) (holding that any and all sales of a patented product by the patent-owner regardless of the conditions imposed on the sale automatically terminates all patent rights); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007) (holding that a licensee can challenge the validity of the licensed patent in court without having to be liable for infringement by first violating the license agreement).

<sup>5</sup> *See Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2360 (2014) (holding that a computer program for facilitating complex international financial transactions is an abstract idea and cannot be patented); *see also Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117 (2013) (holding that isolated DNA for laboratory and medical uses is an unpatentable natural phenomenon); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72–73 (2012) (holding that a diagnostic medical treatment for an autoimmune disorder is an unpatentable discovery of a law of nature); *Bilski v. Kappos*, 561 U.S. 593, 609 (2010) (holding that a business method for hedging investment risk is an abstract idea and not a patentable invention).

<sup>6</sup> There have also been numerous bills introduced in Congress each year, which have entailed extensive and expensive lobbying fights and policy debates. *See, e.g.*, Venue Equity and Non-Uniformity Elimination Act of 2016, S. 2733, 114th Cong. (2016); Innovation Act, H.R. 9, 114th Cong. (2015); Innovation Act, H.R. 3309, 113th Cong. (2013); Saving High-Tech Innovators from Egregious Legal Disputes Act of 2013, H.R. 845, 113th Cong. (2013).

<sup>7</sup> *See Ashley Gold et al., Lee Staying on as Patent Chief Under Trump Administration*, POLITICO (Jan. 19, 2017), <http://www.politico.com/blogs/donald-trump-administration/2017/01/michelle-lee-patent-office-chief-to-stay-on-233847> (quoting Adam Mossoff that “the U.S. has lost its ‘gold standard’ patent system—it no longer promises stable, effective property rights to innovators”); David Kappos et al., *From Efficient Licensing To Efficient Infringement*, N.Y. L.J. (Apr. 4, 2016), <http://www.newyorklawjournal.com/id=1202753754690/From-Efficient-Licensing-to-Efficient-Infringement?slreturn=20170307103946> (“The recent degradation of the U.S. patent system will test the long history of economic prosperity associated with strengthening, rather than weakening, intellectual property rights.”)

doctrine. In four decisions issued between 2010 and 2014, the Supreme Court created a new legal test for determining whether an invention or discovery fundamentally counts as a technological innovation worthy of a patent under § 101 of the Patent Act.<sup>8</sup> Unfortunately, as commentators have pointed out, this legal test is rife with indeterminacy, creating substantial doubt as to whether long-term research and development (“R&D”) expenditures can be recaptured through stable and effective property rights in technological innovation.<sup>9</sup>

This recent legal development raises an important question about whether the U.S. is surrendering its long-held position as the world leader in promoting and securing new technological innovation. This is significant, because other countries are neither standing still nor following the U.S. lead this time. Other jurisdictions, such as in Europe and China, are now granting patents for the same or related inventions and discoveries that are being rejected in the U.S. as ineligible for patent protection. This raises the question of whether these countries are positioning themselves to bypass the U.S. as the forerunners of innovation, especially in the research-intensive sectors of the innovation economy, such as in the life sciences, biotech, and high tech.

This Essay contributes to this critical policy question by offering some empirical data on the impact of the new patent eligibility doctrines on existing patents and on patent applications. It presents statistics on patent-eligibility decisions in U.S. courts and at the United States Patent and Trademark Office (“PTO”), and it presents for the very first time information from a database of 17,743 recently filed patent applications in the U.S., the European Patent Office (“EPO”), and China.<sup>10</sup> All of these patent applications

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(footnote omitted)); Joff Wild, *Sadly, Michelle Lee is Wrong to Believe the US IP System is Gold Standard and That it Works for the Little Guy*, INTELL. ASSET MGMT. (Dec. 15, 2013), [www.iam-media.com/blog/Detail.aspx?g=ce27a358-7b3f-4fe5-b8fe-4cc7e73fd515](http://www.iam-media.com/blog/Detail.aspx?g=ce27a358-7b3f-4fe5-b8fe-4cc7e73fd515) (discussing PTO Director Michelle Lee’s designation of the US patent system as the “gold standard” and stating that “[w]hen Lee talks about the amount of innovation the US produces showing that the US system is the gold standard, she is talking about the past.”).

<sup>8</sup> See cases cited *supra* note 5.

<sup>9</sup> See, e.g., Brief of 19 Law Professors as *Amici Curiae* in Support of Petition for Writ of Certiorari at 13, *Sequenom, Inc. v. Ariosa Diagnosis, Inc.*, 136 S. Ct. 2511 (2016) (No. 15-1182), 2016 WL 1605521 (detailing how the Supreme Court’s new test for patent eligibility is both indeterminate and overly restrictive).

<sup>10</sup> This database was compiled by Robert Sachs, a Partner at Fenwick & West, and David Kappos, a Partner at Cravath, Swaine & Moore LLP and former Director of the PTO. An earlier version of this database obtained by the authors was limited in scope, and this resulted in previous drafts mistakenly reporting that 1,728 patent applications had been granted in China and by the EPO but had been denied in the U.S. The database has since been updated and the correct numbers are reported here. The 17,743 patent applications is a subset of 48,586 total patent applications that received a § 101 rejection in initial or final office actions and then were abandoned between August 1, 2014 and September 27, 2017. The 17,743 applications received *final rejections* by the PTO as patent ineligible. The database can be accessed here: <https://cpip.gmu.edu/wp-content/uploads/sites/31/2017/10/Madigan-Mossoff-Turning-Gold-to->

were rejected (and then abandoned) in the U.S. on the ground that they are ineligible for patent protection under § 101, but 1,694 of them were granted by the EPO, in China, or by both. These 1,694 patent applications rejected by the PTO raise the specter of the U.S. losing its gold standard status, as many of these patent applications represent innovative and life-saving inventions in the life sciences and biotech, such as diagnostic cancer treatments, medical devices, and ultrasound imaging.<sup>11</sup>

In addressing this concern about the U.S. conceding its gold standard patent system to China and Europe, increasingly voiced by many lawyers and commentators, this Essay explains how and why this matters. First, it details why the U.S. has been referred to as having a gold-standard patent system relative to other countries. Second, it briefly explains the four recent patent-eligibility decisions by the U.S. Supreme Court. Third, it presents statistics and other empirical data on how the Court's patent-eligibility doctrine has been applied by the PTO and the courts, with reference to some examples from the database of 17,743 patent applications.

## I. THE GOLD STANDARD PATENT SYSTEM IN THE U.S.

The U.S. has long been regarded as the world leader in securing property rights in technological innovation, granting patents for the next wave of discoveries when the rest of the world hesitates. Professor Zorina Kahn, a leading economic historian, concludes that the U.S. patent system has been successful precisely because it consistently secured legal protection for the fruits of inventors' labors.<sup>12</sup> This truth is confirmed by the spread of patent laws across the world throughout the nineteenth and early twentieth centuries that were explicitly modeled on the U.S. system.<sup>13</sup> This pattern of U.S. leadership in securing patents in the next wave of innovation continued up through the two most recent technological revolutions of our modern era: the biotechnology and high-tech revolutions.

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Lead-Final-Dataset.pdf. For questions about the database, please contact Robert Sachs at RSachs@fenwick.com.

<sup>11</sup> See *infra* note 82 and accompanying chart.

<sup>12</sup> B. Zorina Kahn, *Trolls and Other Patent Inventions: Economic History and the Patent Controversy in the Twenty-First Century*, 21 GEO. MASON L. REV. 825, 855 (2014) (describing how “[i]ntellectual property institutions were successful in the United States largely because they ensured open access to creative individuals, decentralized decision making and extensive markets for technology, and strong legal enforcement of such rights”); see also Adam Mossoff, *A Brief History of Software Patents (and Why They're Valid)*, 56 ARIZ. L. REV. SYLLABUS 62 (2014) (explaining how the U.S. patent system has succeeded because it secured property rights in the new innovation that has come about with each new era, whether in the Industrial Revolution or in the Digital Revolution).

<sup>13</sup> See Kahn, *supra* note 12, at 854–55 (discussing how intellectual property rights played a prominent role in the nineteenth century in the U.S. overtaking other nations as a leader in industry and technology, which led to “many countries voluntarily adopting the distinctive U.S. rules and standards”).

### A. *Biotechnology*

In 1980, the Supreme Court held in *Diamond v. Chakrabarty*<sup>14</sup> that a genetically modified bacterium is a patentable innovation under § 101 of the Patent Act.<sup>15</sup> Although largely forgotten today, this was a time in which the patentability of the cutting-edge, innovative discoveries in the nascent biotech revolution was highly controversial.<sup>16</sup> The *Chakrabarty* Court definitively settled the question in the U.S.: pioneering work by scientists and innovators in the U.S. should be promoted and protected by the patent system.<sup>17</sup> Commentators widely recognize that *Chakrabarty* was a key factor in spurring the explosive growth in the biotech industry in the ensuing decade in the U.S.<sup>18</sup>

The *Chakrabarty* Court's recognition that the products of biotech research are patentable, especially when such products are living organisms or represent the building blocks of life, paved the way for dramatic advances in the life sciences and in medical treatment, such as in cancer research. One prominent example is the invention of the "oncomouse" in the 1980s. After the *Chakrabarty* decision, researchers at Harvard Medical School created a mouse that was genetically prone to cancer by giving it a gene that causes tumor growth, leading to invaluable opportunities to research new treatments for cancer.<sup>19</sup> Following the *Chakrabarty* precedent, the U.S. was the first country to secure a patent in this radical biotech innovation in 1988.<sup>20</sup>

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<sup>14</sup> 447 U.S. 303 (1980).

<sup>15</sup> *Id.* at 310.

<sup>16</sup> *Id.* at 316 (detailing a "parade of horrors" from Nobel Laureates and other scientists about the dangers of biotech research, who argued that it should not be patentable).

<sup>17</sup> *Id.* at 316–17. The Court recognized that biotech innovation like the genetically modified bacteria at issue in this case is a patentable invention "precisely because such inventions are often unforeseeable." *Id.* at 316. This was a significant insight by the Court, because this is the function of the patent system—to promote and secure dynamic innovation. See Adam Mossoff, *A Simple Conveyance Rule for Complex Innovation*, 44 TULSA L. REV. 707, 729 (2009) (discussing *Chakrabarty* and other cases as exemplifying the purpose of the patent system in securing unpredictable innovation precisely because innovation is unpredictable).

<sup>18</sup> See, e.g., ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY* 76 (5th ed. 2011) (noting that *Chakrabarty* was "extremely important for the then-nascent biotechnology industry because it established that the fruits of the industry's research . . . would be eligible for patenting"); see also John Edward Schneider, *Microorganisms and the Patent Office: To Deposit or Not to Deposit, That is the Question*, 52 FORDHAM L. REV. 592, 592, 594 (1984) (noting that the "revolution in biotechnology is one of the most important developments affecting industry in the twentieth century" and that *Chakrabarty* "spurred the increased commercial interest in biotechnology" (footnotes omitted)).

<sup>19</sup> *Bioethics and Patent Law: The Case of the Oncomouse*, WIPO MAGAZINE, June 2006, at 16, [http://www.wipo.int/export/sites/www/wipo\\_magazine/en/pdf/2006/wipo\\_pub\\_121\\_2006\\_03.pdf](http://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2006/wipo_pub_121_2006_03.pdf).

<sup>20</sup> U.S. Patent No. 4,736,866 (issued Apr. 12, 1988).

The genetic modification of living organisms has been controversial,<sup>21</sup> and as a result of this controversy, other countries initially refused to secure this innovation with patents. For fifteen years, the oncomouse patent application languished in the European Patent Office, mired in a legal quagmire of a series of rejections, court appeals, and remands back to the EPO for re-examination of the patent application; the EPO finally relented and granted the patent in 2004, almost two decades after the U.S. patent had been issued.<sup>22</sup> Even worse, after a similar multi-decade legal fight, some countries rejected outright the patent application on the oncomouse, such as Canada's final rejection of the patent application in 2002.<sup>23</sup> Although the EPO ultimately ceded to the patenting of this innovation, its decision to do so decades after the U.S. was significant for the development of a domestic biotech industry in the U.S. By first securing property rights in the fruits of biotech research, the U.S. became the birthplace of the biotech revolution.<sup>24</sup> Europe lost the competitive and commercial edge in biotechnology to the U.S., which had the foresight to protect a new and innovative industry. This new industry both revolutionized modern medical research and healthcare treatments and brought economic growth to the many U.S. cities in which these new companies sprouted and flourished.<sup>25</sup>

## B. *Software Programs*

In the early days of digital computing, there was great uncertainty surrounding what exactly constituted a software program and whether these programs represented a patentable invention.<sup>26</sup> This confusion was obvious in

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<sup>21</sup> See, e.g., *Bioethics and Patent Law*, *supra* note 19 (discussing ethical concerns regarding transgenic technology).

<sup>22</sup> See *id.* at 17 (explaining how in 2004 the EPO “concluded that the usefulness of the oncomouse in furthering cancer research satisfied the likelihood of substantial medical benefit, and outweighed moral concerns about suffering caused to the animal”).

<sup>23</sup> See *Harvard Coll. v. Canada* (Commissioner of Patents), [2002] 4 S.C.R. 45, 46, 122 (Can.) (finding that “[a] higher life form is not patentable because it is not a ‘manufacture’ or ‘composition of matter’ within the meaning of ‘invention’ in [Canada’s] Patent Act”).

<sup>24</sup> See *Life Sciences and Biotechnology—A Strategy for Europe: Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions*, at 14–15, (2002) [hereinafter *Life Sciences and Biotechnology*]; see also CLAUDE BARFIELD & JOHN E. CALFEE, *BIOTECHNOLOGY AND THE PATENT SYSTEM: BALANCING INNOVATION AND PROPERTY RIGHTS* 24–29 (2007) (discussing the especially crucial role patent protection has played in biotechnological innovation).

<sup>25</sup> See *Life Sciences and Biotechnology*, *supra* note 24, at 14–15 (discussing Europe’s “fragile” biotechnology sector and noting that “the US biotechnology industry started earlier, produces more than three times the revenues of the European industry, employs many more people (162,000 against around 60,000), is much more strongly capitalized and, in particular, has more products in the pipeline”).

<sup>26</sup> See generally Mossoff, *supra* note 17 (discussing this early history and controversy); see also MERGES & DUFFY, *supra* note 18, at 134–35, 154–58.

1972 in *Gottschalk v. Benson*<sup>27</sup> when the Supreme Court denied patent protection for a software program, asserting that the patent claimed merely a “mathematical formula” and thus was unpatentable as an “abstract idea.”<sup>28</sup> At the time of *Benson*, digital computers were still in their infancy as consumer products, as it was a decade before the Personal Computer (“PC”) Revolution of the 1980s. Thus, the legal and technological confusion reflected in *Benson* about the nature of software innovation was perhaps understandable.<sup>29</sup> Still, Justice William Douglas’s opinion in *Benson* was unfortunate, because it inserted into patent law a fundamental misunderstanding about computer programs. It would be nearly ten years before a more careful and better-informed Supreme Court corrected this initial misstep.

In 1981, the Supreme Court held in *Diamond v. Diehr*<sup>30</sup> that a computer program was not automatically an “abstract idea” or “algorithm” that precluded patent protection.<sup>31</sup> Consistent with the *Chakrabarty* decision the year before, the *Diehr* Court recognized that the use of a computer software program to operate a machine for a useful purpose—in this case, a manufacturing process for curing rubber—was technological innovation deserving of legal protection in the patent system.<sup>32</sup> The key was recognizing how the software program functioned in creating new technological innovation; in the technical terms of patent law, the *Diehr* Court reaffirmed a basic precept of patent law that all patent claims must be evaluated *as a whole* as to their nature and function as new, useful, and nonobvious inventions.<sup>33</sup>

In the ensuing PC Revolution in which software programs became separate commercial products that served particular and useful functions for consumers who purchased them in the marketplace, the courts’ understanding of the nature of software innovation and its patent eligibility also evolved. In the 1990s, the Court of Appeals of the Federal Circuit thus recognized that software programs represented the equivalent of a digital machine.<sup>34</sup> If a mechanical typewriter was a patentable invention in the analog world of the Industrial Revolution in the nineteenth century, then a word processor is a patentable invention as a digital machine in the high-tech revolution of the late twentieth century. In their specific technological and commercial contexts, a typewriter and a word processor program are each a valuable machine that

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<sup>27</sup> 409 U.S. 63 (1972).

<sup>28</sup> *Id.* at 71–72.

<sup>29</sup> See Mossoff, *supra* note 12, at 70 n.29.

<sup>30</sup> 450 U.S. 175 (1981).

<sup>31</sup> *Id.* at 184–89.

<sup>32</sup> See *id.* at 187 (“[A] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer.”).

<sup>33</sup> *Id.* at 192 (finding that “when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (*e. g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101”).

<sup>34</sup> *In re Alappat*, 33 F.3d 1526, 1545 (Fed. Cir. 1994).

serves a specific function for end-users. Thus, as cutting-edge innovation, each invention is precisely what the patent system is supposed to promote and secure to inventors and to the companies that deploy these products and services in the marketplace.<sup>35</sup>

The court decisions in *Diehr*, *Chakrabarty*, and *Alappat*, among others, meant that innovators knew the fruits of their inventive labors would be secured to them under U.S. law. Despite fluctuations over time in the specific legal protections provided to innovators in the U.S., the patent system has generally secured stable and effective property rights in the new innovation that drove the Industrial Revolution, the Biotech Revolution, and the Digital Revolution.<sup>36</sup> For this reason, it rightly earned the “gold standard” designation compared to the rest of the world. But this “gold standard” designation is now open to question, as the U.S. has retreated in recent years from ensuring that its patent system is properly forward looking in promoting and securing new technological innovation in the twenty-first century.

## II. THE NEW PATENT ELIGIBILITY JURISPRUDENCE

Between 2010 and 2014, the Supreme Court issued four decisions that dramatically restricted the scope of inventions that can receive patent protection: *Bilski v. Kappos*,<sup>37</sup> *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,<sup>38</sup> *Association for Molecular Pathology (“AMP”) v. Myriad Genetics*,<sup>39</sup> and *Alice Corp. v. CLS Bank International*.<sup>40</sup> These four decisions have significantly impacted the U.S. patent system. First, they each respectively restricted the scope of patentable inventions, and thereby incrementally chipped away at the innovation gains achieved by *Chakrabarty*, *Diehr*, and other prior court decisions. The totality of these four decisions is a substantial restriction on the scope of what counts as a patentable invention. Second, and far worse, they have injected tremendous legal uncertainty into the U.S. pa-

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<sup>35</sup> See Brief of Ten Law Professor as *Amici Curiae* in Support of Plaintiff-Appellee at 9–10, *Trading Techs. Int’l, Inc. v. CQG, Inc.*, 675 Fed. App’x 1001 (Fed. Cir. 2017) (No. 2016-1616), 2016 WL 401711; Mossoff, *supra* note 12, at 80 (warning that “[t]o restrict the patent system to only the valuable analog machines and processes of the nineteenth century is to turn the patent system on its head—denying today’s innovators the protections of the legal system whose purpose is to promote and secure property rights in innovation”).

<sup>36</sup> See generally Stephen Haber, *Patents and the Wealth of Nations*, 23 GEO. MASON L. REV. 811 (2016) (surveying all of the historical and economic research that overwhelmingly proves that patents are a key factor in promoting innovation and economic growth).

<sup>37</sup> 561 U.S. 593 (2010).

<sup>38</sup> 566 U.S. 66 (2012).

<sup>39</sup> 133 S. Ct. 2107 (2013).

<sup>40</sup> 134 S. Ct. 2347 (2014).

tent system, undermining the ability of inventors, universities, venture capitalists, and companies to make long-term investment decisions in R&D.<sup>41</sup> This Part will briefly review these decisions and detail their impact on the U.S. innovation economy.

#### A. *Bilski v. Kappos*

In 2010, the Supreme Court addressed for the first time whether new and useful business methods are patentable inventions as a “process” under § 101 of the Patent Act.<sup>42</sup> Despite an extensive legal and policy debate about the patent eligibility of business methods,<sup>43</sup> the *Bilski* Court held that they are an invented process capable of being patented (as long as they met the other patentability requirements).<sup>44</sup> While the *Bilski* Court emphasized that business method patents are not unpatentable per se, provoking a strident “dissent” on this issue by Justice John Stevens,<sup>45</sup> the Court ultimately concluded that the business method in this case was in fact an “abstract idea” and thus unpatentable.<sup>46</sup> In reaching this decision, the Court provided no legal guidance on how to determine what counts as an unpatentable “abstract idea,” creating an ambiguous legal precedent that has provided no guidance to stakeholders in the high-tech industry as to how it might be applied to their inventive work-product. Unsurprisingly, commentators bemoan how *Bilski* started a legal practice of mass invalidation of patents on software, business

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<sup>41</sup> See generally Joan Farre-Mensa et al., *What is a Patent Worth?: Evidence from the U.S. Patent “Lottery”*, (Nat’l Bureau of Econ. Research, Working Paper No. 23268, 2017), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2704028](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2704028) (finding causal connection between a startup’s ownership of a patent and its ability to obtain venture capital funding, and thus finding a causal connection between patents and the ultimate market success of a startup company).

<sup>42</sup> 35 U.S.C. § 101 (2012) (“Whoever invents or discovers any new and useful *process*, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” (emphasis added)).

<sup>43</sup> Compare Michael Risch, *Everything is Patentable*, 75 TENN. L. REV. 591, 609–11 (2008) (arguing that business methods are patentable) with 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, 581 (1999) (arguing that business methods should not be patentable).

<sup>44</sup> *Bilski v. Kappos*, 561 U.S. 593, 604 (2010) (“This Court’s precedents establish that the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101. The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible ‘process.’”).

<sup>45</sup> See *id.* at 613–57 (Stevens, J., concurring). Justice Stevens’ opinion is nominally styled as a concurrence, because he agreed with the decision that the patent in this case was an unpatentable abstract idea, but the substance of his opinion is a lengthy, wide-ranging dissent from the *Bilski* Court’s holding that business methods are patentable inventions.

<sup>46</sup> *Id.* at 611.

methods, and diagnostic methods with vague or conclusory court opinions,<sup>47</sup> which only picked up speed in the ensuing years.

B. *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*

Two years later, the Supreme Court further narrowed the scope of patentable subject matter in the life sciences and biotech industry when it held that a patent on a medical treatment method was invalid because it was a “law of nature.”<sup>48</sup> Unlike in *Bilski*, the *Mayo* Court was not faced with a fundamental question as to whether medical treatment methods are patentable inventions—they clearly are—but the *Mayo* Court concluded in this case that the patented method for treating an immune-deficiency illness is merely a “law of nature” and thus unpatentable.<sup>49</sup> Repeating the same pattern in *Bilski*, the *Mayo* Court did not explain *how* it reached its conclusion that the patented method in this case is a “law of nature” other than asserting only that the method was “well-understood, routine conventional activity previously engaged in by researchers in the field.”<sup>50</sup>

Commentators immediately recognized the destructive potential of this decision, especially given the conflation of patent eligibility with the other patentability requirements of novelty and nonobviousness.<sup>51</sup> More important, any invented method, especially diagnostic methods and therapeutic treatments, can be analytically dissected into component parts that are easily characterized as merely “laws of nature.”<sup>52</sup> The one-two punch of the doctrinal

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<sup>47</sup> See, e.g., Edward Van Gieson & Paul Stellman, *Killing Good Patents to Wipe out Bad Patents: Bilski, the Evolution of Patentable Subject Matter Rules, and the Inability to Save Valuable Patents Using the Reissue Statute*, 27 SANTA CLARA COMPUTER & HIGH TECH. L.J. 403, 404 (2010) (referring to the *Bilski* decision as “amorphous” and thus predicting that it “has now set the stage for years of Federal Circuit litigation defining the scope of patentable subject matter for software and business method patents”); Daniel A. Tysver, *Are Software and Business Methods Still Patentable After the Bilski Decisions?*, BITLAW, <http://www.bitlaw.com/software-patent/bilski-and-software-patents.html> (last visited Aug. 13, 2017) (claiming that “some of the software and business method patents issued by the U.S. Patent and Trademark Office over the last twenty years are no longer valid under the *Bilski* decisions” and that “[u]nfortunately, we don't have a clear understanding of the dividing line between patentable software and business method inventions and unpatentable ideas”).

<sup>48</sup> *Mayo*, 132 S. Ct. at 1305.

<sup>49</sup> *Id.* at 1294, 1305.

<sup>50</sup> *Id.* at 1294.

<sup>51</sup> See Gene Quinn, *Killing Industry: The Supreme Court Blows Mayo v. Prometheus*, IP WATCHDOG (March 20, 2012), <http://www.ipwatchdog.com/2012/03/20/supreme-court-mayo-v-prometheus/id=22920/> (discussing the courts' confusion and warning that “the fact that they have either through ignorance or intent conflated patent eligibility with novelty and non-obviousness will be a plague on the entire patent system for years to come”).

<sup>52</sup> *Id.* (“The Supreme Court also further specifically ignored the Government's objective, reasonable and until today correct assertion that any step beyond a statement of a law of nature transforms the claim into one that displays patent eligible subject matter, with issues of whether those steps are known to be properly resolved by 102 and 103.”).

confusion and the lack of guidance as to assessing whether patents claim an invalid “law of nature” has resulted in extensive uncertainty and high invalidation rates in the biotech and pharmaceutical industries.<sup>53</sup>

### C. Association for Molecular Pathology (“AMP”) v. Myriad Genetics

One year later, the Supreme Court again weighed in on the issue of what counts as a patentable invention or discovery under § 101 of the Patent Act. This time, the question was whether DNA that was separated and isolated in a medical laboratory and used in a diagnostic process was a patentable discovery of a “composition of matter” under § 101.<sup>54</sup> The patent at the heart of the *Myriad* case was an exemplar of the biotech revolution that had fundamentally transformed medical treatment and saved countless lives: the discovery of the specific DNA that directly correlate with a woman’s proclivity to contract breast cancer (BRCA1 and BRCA2).<sup>55</sup> Myriad’s discovery was the result of many years of R&D, comprising thousands of hours of research and investments of hundreds of millions of dollars.<sup>56</sup> In fact, the isolation of molecules and other organic elements that were of valuable use in medical treatments, such as adrenalin and insulin, had long been recognized as patentable discoveries, confirming how the forward-looking U.S. patent system was central to promoting and securing the benefits of medical research from its very beginnings in the early twentieth century.<sup>57</sup>

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<sup>53</sup> Robert R. Sachs, *The One Year Anniversary: The Aftermath of #AliceStrom*, BILSKI BLOG (June 20, 2015), <http://www.bilskiblog.com/blog/2015/06/the-one-year-anniversary-the-aftermath-of-alice-storm.html> (discussing the patent rejection trends after *Mayo* and noting that “[o]verall, data shows that in 2012 subject matter rejections were mainly in the computer related Tech Centers (2100, 2400) and began declining thereafter, while escalating in biotechnology (1600) and so-called ‘business methods’ Tech Center, TC 3600, following *Mayo* and *Alice*”).

<sup>54</sup> 35 U.S.C. § 101 (2012) (“Whoever invents or *discovers* any new and useful process, machine, manufacture, or *composition of matter*, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” (emphasis added)).

<sup>55</sup> See Case T 1213/05, Univ. Utah Research Found. v. Sozialdemokratische Partei der Schweiz, ¶ 80, at 69–70 (EPO Boards of Appeal, 2007), [www.epo.org/law-practice/case-law-appeals/pdf/t051213eu1.pdf](http://www.epo.org/law-practice/case-law-appeals/pdf/t051213eu1.pdf) (describing Myriad’s discovery as a “major breakthrough”); Natalie Angier, *Fierce Competition Marked Fervid Race for Cancer Gene*, N.Y. TIMES (Sept. 20, 1994), <http://www.nytimes.com/1994/09/20/science/fierce-competition-marked-fervid-race-for-cancer-gene.html?pagewanted=all> (discussing the pivotal discovery of BRCA1 and the extensive, multi-year research effort that resulted in the successful isolation and identification of the BRCA genes).

<sup>56</sup> Brief for Respondents at 5, Ass’n. for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, (2012) (No. 12-398), 2013 WL 860315.

<sup>57</sup> See Christopher Beauchamp, *Patenting Nature: A Problem of History*, 16 STAN. TECH. L. REV. 257, 296–99 (2013) (discussing patents on adrenalin and insulin in early twentieth century); Adam Mossoff, *A Century-Old Form of Patent*, N.Y. TIMES ROOM FOR DEBATE (June 6, 2013), <http://www.nytimes.com/roomfordebate/2013/06/06/can-the-human-blueprint-have-owners/a-century-old-form-of-patent> (discussing how the U.S. patent system has long secured biomedical discoveries like the isolated genes discovered today).

Following the pattern of *Bilski* and *Mayo*, the *Myriad* Court concluded that isolated DNA is a “product of nature” that is unpatentable under § 101 of the Patent Act.<sup>58</sup> Just like in *Bilski* and *Mayo*, the *Myriad* Court also provided no specific guidance on either how courts should assess the validity of the tens of thousands of existing patents on DNA or how the PTO should assess the thousands of pending patent applications that claimed isolated molecules or other organic compounds of valuable use in diagnosing or treating diseases, such as antibiotics, anti-venoms, chemotherapies, etc. This fundamental legal uncertainty, the threat of zero legal protection, and the inability to recoup hundreds of millions of dollars in R&D expenditures, has placed the biotech and pharmaceutical industries in a quagmire that will swallow up and stifle future innovation like the discovery of the BRCA1 and BRCA2 genes.<sup>59</sup>

#### D. Alice Corp. v. CLS Bank International

In 2014, the Supreme Court again took on patent eligibility, tackling the last remaining field of modern innovation that it had not yet addressed in its prior three decisions: the patent eligibility of software programs. The Court initially framed the legal issue it would decide very broadly—whether computer-implemented inventions are patent eligible within the meaning of § 101 of the Patent Act<sup>60</sup>—but the *Alice* opinion ultimately punted on this fundamental question. Instead, the *Alice* Court answered only the narrow question of whether the specific patent in this case is invalid under § 101; it concluded

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<sup>58</sup> Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013) (holding that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated”).

<sup>59</sup> See Press Release, Biotechnology Innovation Org., Statement on U.S. Supreme Court Review of Isolated DNA Patents (June 13, 2013), <https://www.bio.org/media/press-release/statement-us-supreme-court-review-isolated-dna-patents> (quoting BIO President and CEO Jim Greenwood that “the Supreme Court’s decision today [in *Myriad*] represents a troubling departure from decades of judicial and Patent and Trademark Office precedent supporting the patentability of DNA molecules that mimic naturally-occurring sequences” and “could unnecessarily create business uncertainty for a broader range of biotechnology inventions”); Scott Gottlieb, *Supreme Court’s Ruling on Genetic Tests Will Make a Bad Business Worse*, AM. ENTERPRISE INST. (June 13, 2013), <http://www.aei.org/publication/supreme-courts-ruling-on-genetic-tests-will-make-a-bad-business-worse/> (warning that “[i]n the end, if the technology can’t be protected in this field, and the IP reimbursed with above market rates of return on invested capital, then the diagnostics industry will mostly function as a service business, not one led by innovation and new IP”); Nicole Kling, *Will the Supreme Court’s Decision on “Gene Patents” Stifle Medical Innovation?*, VECTOR: BOSTON CHILDREN’S HOSP. SCI. AND CLINICAL INNOVATION BLOG (July 8, 2013), <https://vector.childrenshospital.org/2013/07/will-the-supreme-courts-decision-on-gene-patents-stifle-medical-innovation/> (questioning the uncertainty created by *Myriad* and warning that “[a]dding new, poorly defined rules in the middle of the game leads to confusion that may inhibit the development of next-generation advances in medicine and biotechnology”).

<sup>60</sup> *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2351–52 (2014).

the large and complex software program for managing intricate international financial transactions is an “abstract idea” and thus ineligible for patent protection.<sup>61</sup>

Despite its seemingly narrow scope, *Alice* is extremely significant and thus deserves greater treatment in this brief review than the three prior patent-eligibility decisions. First and foremost, *Alice* reaffirmed the highly generalized two-step framework first set forth in *Mayo* and *Myriad*, and which was used in those earlier cases to invalidate the patents. This two-step framework, termed the “*Mayo-Alice* test,”<sup>62</sup> is a very generalized inquiry framed at a high level of abstraction.<sup>63</sup> Thus, *Alice* is a capstone—or what some in the innovation industries would consider as a nadir—to the three prior decisions, cementing the Court’s approach in all of its recent patent-eligibility cases as the definitive judicial interpretation of § 101.

Second, and directly related to its express endorsement of the *Mayo-Alice* test, the *Alice* Court continued the same pattern of decision-making as in these three prior cases. More precisely, it continued the same pattern of *not* explaining its decision-making. In the six total pages of analysis in the *Alice* opinion, the Court did not explain *how* it reached its decision that the software program is “abstract,” offering only conclusory assertions that the patent covered “conventional” and “well known” software processes.<sup>64</sup> Despite not mentioning the word “software” at all in the entire opinion, some commentators concluded that the *Alice* Court rejected all software patents,<sup>65</sup> and with no substance to the opinion except for its conclusion that this software patent was abstract, it was hard to deny (or confirm) this claim.

Despite the ambiguities in *Alice*, many thought they heard a message loud and clear. The PTO immediately began rejecting patent applications with a one-paragraph boilerplate statement that merely recited the vague, conclusory language of the *Alice* opinion.<sup>66</sup> In the ensuing years, courts began

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<sup>61</sup> *Id.* at 2352 (“We hold that the claims at issue are drawn to the abstract idea of intermediated settlement, and that merely requiring generic computer implementation fails to transform that abstract idea into a patent eligible invention.”).

<sup>62</sup> Brief of 19 Law Professors, *supra* note 9, at 2.

<sup>63</sup> The two-prong inquiry requires a court to (1) determine whether the patent claim is directed to an abstract idea, natural phenomenon, or law of nature, and, if it is, then (2) determine whether the claim’s elements, considered both individually and as an ordered combination, contain an inventive concept that makes it patent eligible. *See Alice*, 134 S. Ct. at 2355; *Mayo*, 132 S. Ct. at 1296–97.

<sup>64</sup> *Alice*, 134 S. Ct. at 2354–60.

<sup>65</sup> *See, e.g.,* Gene Quinn, *SCOTUS Rules Alice Software Claims Patent Ineligible*, IPWATCHDOG (June 19, 2014), <http://www.ipwatchdog.com/2014/06/19/scotus-rules-alice-software-claims-patent-ineligible> (“Software claims as they have typically been writing now seems to result in patent ineligible claims . . . What this means is that companies like Apple, IBM, Microsoft, Google and others have had the value of their patent portfolios nearly completely erased today.”).

<sup>66</sup> *See* Robert Plotkin, *Software Patents are Only as Dead as Schrödinger’s Cat*, IPWATCHDOG (Oct. 6, 2014), <http://www.ipwatchdog.com/2014/10/06/software-patents-are-only-as-dead-as-schrodinger>

invalidating at astronomical rates patents covering innovation in the biotech, pharmaceutical, and high-tech sectors of the economy.<sup>67</sup> The generality and vagueness in the *Mayo-Alice* test has produced the seemingly perverse effect of it being both *indeterminate*, as no one is certain how it will be applied in any particular case, and *overly restrictive*, as it has been applied to invalidate patents covering “everything from computer animation to database architecture to digital photograph management and even to safety systems for automobiles.”<sup>68</sup> The *Alice* Court alleged that the PTO and courts were to tread carefully so as not to “swallow all of patent law” with the § 101 prohibitions against patenting of abstract ideas, natural phenomena, and laws of nature,<sup>69</sup> but this is exactly what is happening, as will be detailed in the next Part.

### III. TURNING GOLD TO LEAD: THE EVIDENCE ON HOW THE U.S. IS LOSING ITS INNOVATION LEADERSHIP

As detailed in Part II, in four recent cases, the Court consistently invalidated patents on the grounds that they claimed inventions or discoveries that are ineligible for patent protection under § 101, and in doing so, it failed to provide any meaningful legal guidance as to how it reached these results. The follow-on impact has been unsurprisingly predictable: extreme indeterminacy for inventors, universities, and companies working in the innovation industries in predicting how § 101 might be applied to a future patent application, and massive over-restrictiveness when it is applied to both patent applications and issued patents. Like the Four Horsemen, *Bilski*, *Mayo*, *Myriad*, and *Alice* have cut through the innovation industries, striking down wide swaths of patent applications and issued patents. Inventors, investors, and companies working in the innovation industries have little to no understanding how to create and commercialize the medical and high-tech innovation that everyone the world over has come to rely on in the twenty-first century.

This is not hyperbole, although it would be welcome news if it could be dismissed as such. Unfortunately, it refers to the undeniable facts. A look inside the numbers of post-*Alice* rejections and invalidations exposes a serious imbalance in the U.S. patent system today, raising the question whether the U.S. is losing its gold standard patent system.

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ers-cat (reporting that the Patent Office “started withdrawing Notices of Allowance from patent applications—even in cases in which the issue fee had been paid—and issuing patent eligibility rejections based on *Alice*, using nothing more than a standard form paragraph”).

<sup>67</sup> See Steven Callahan, *Alice: The Death of Software-Related Patents?*, N. DIST. TEX. BLOG (May 1, 2015), <http://www.ndtblog.com/?p=3550> (discussing *Alice*'s influence on lower courts and noting that “despite not categorically precluding software patents, [*Alice*] has spawned numerous lower court decisions invalidating patents” and observing that “since *Alice*, of the 76 decisions dealing with *Alice* challenges, 57 have invalidated patents; only 16 have upheld them on the merits”).

<sup>68</sup> Sachs, *supra* note 53.

<sup>69</sup> *Alice*, 134 S. Ct. at 2354.

A. *The Statistics on § 101 Rejections and Invalidations After Alice*

In the three years following the Court's last § 101 decision in *Alice*, Robert Sachs reports that there have been 473 Federal Circuit and district court §101 decisions, 317 of which invalidated the patents at issue in whole or in part.<sup>70</sup> In these 473 cases, 60% of all challenged patents were found to be invalid, while 66.4% of all claims were invalidated.<sup>71</sup> Looking to the Federal Circuit specifically, 80 of 88 patents were invalidated, resulting in a shocking 90.9% "kill rate."<sup>72</sup>

**Figure 1:** Total § 101 Invalidations (June 2014 to March 2017)<sup>73</sup>

	Total Invalid		
	Total	Under §101	% Invalid
Fed. Ct. Decisions	473	317	67.0%
Federal Circuit	88	80	90.9%
District Courts	385	237	61.6%
Patents	837	502	60.0%
Claims	23597	15661	66.4%
Motions on Pleadings	248	154	62.1%

Using detailed datasets of PTO rejections and issuances of patent applications from 2013-2015, Sachs tracked the §101 rejections before and after *Alice* and found significant increases after the *Alice* Court's decision.<sup>74</sup> As Sachs summarizes in Figure 2 below, rejections of patent applications in the field of chemical engineering (tech center 1700) more than doubled from 1.5% before *Alice* to 3.2% after *Alice*. Likewise, business methods (tech center 3600) went from a pre-*Alice* rejection rate of 35.3% to a post-*Alice* rejection rate of 86.3%. Other fields of innovation were similarly affected. Rejection rates for patent applications covering inventions in networks and video technology (tech center 2400) increased more than one-third from 10.2% before *Alice* to 15.5% after *Alice*. Surprisingly, rejections of patent applications covering inventions in the mechanical arts (tech center 3700) almost doubled from a 3.7% rate pre-*Alice* to a 6.1% rate post-*Alice*. Unsurprisingly, though, the most significant increases in rejections have been in the areas of biotech

<sup>70</sup> Robert Sachs, *ALICESTORM UPDATE FOR Q1 2017*, BILSKIBLOG (Apr. 6, 2017), <http://www.bilskiblog.com/blog/2017/04/alicestorm-update-for-q1-2017.html>.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> For a more detailed analysis of the PTO's §101 rejections, see Sachs, *supra* note 53 (section titled "*Alice* at the Office"), <http://www.bilskiblog.com/blog/2015/06/the-one-year-anniversary-the-after-math-of-alicestorm.html>.

and high-tech, the key sectors of the twenty-first-century innovation economy that the Court addressed in three of its four decisions (*Mayo*, *Myriad*, and *Alice*).

**Figure 2:** PTO § 101 Rejections (through May 2016)<sup>75</sup>

Tech Center	Before Alice	6/14 Preliminary Guidance	12/14 Interim Guidance	6/15 Update	5/16 Examiner Memos
1600 Biotech & Chem.	10.40%	13.70%	13.10%	10.90%	10.00%
1700 Chem. Eng.	1.50%	1.50%	1.50%	3.20%	0.90%
2100 Comp. Architecture	15.30%	15.40%	14.70%	11.90%	10.90%
2400 Networks & Video	10.20%	10.20%	13.30%	15.50%	13.10%
2600 Communications	7.80%	7.60%	8.80%	8.10%	8.60%
2800 Semiconductor, Elec., Opt.	1.90%	2.60%	2.90%	2.50%	3.00%
3600 Transportation & Construction	3.30%	4.30%	3.90%	3.70%	3.50%
3600 Business Methods	35.50%	76.60%	87.20%	86.30%	88.70%
3700 Mechanical	3.70%	6.10%	7.50%	6.10%	5.80%
<b>Grand Total</b>	<b>6.80%</b>	<b>9.60%</b>	<b>10.50%</b>	<b>9.50%</b>	<b>8.60%</b>

Perhaps the bleakest venue for patent owners has been the Patent Trial and Appeal Board (“PTAB”).<sup>76</sup> Former Chief Judge of the Court of Appeals for the Federal Circuit, Randall Rader, referred to the PTAB as “death squads killing property rights,” and while some may blanch at this strong rhetoric, the data supporting this rhetoric are undeniable.<sup>77</sup> In the years after *Alice*, the PTAB’s Covered Business Method (“CBM”) program—where software and business method patents can be challenged as invalid by any person willing to pay the filing fee—invalidated 97.8% of the patents it reviewed.<sup>78</sup>

<sup>75</sup> *Id.*

<sup>76</sup> See generally Alden Abbott, Erika Lietzan, et al., *Crippling the Innovation Economy: Regulatory Overreach at the Patent Office*, Regulatory Transparency Project of the Federalist Society (Aug. 14, 2017), <https://regproject.org/wp-content/uploads/RTP-Intellectual-Property-Working-Group-Paper.pdf>.

<sup>77</sup> Rob Sterne & Gene Quinn, *PTAB Death Squads: Are All Commercially Viable Patents Invalid?*, IP WATCHDOG (March 24, 2014), <http://www.ipwatchdog.com/2014/03/24/ptab-death-squads-are-all-commercially-viable-patents-invalid/id=48642> (discussing the unanticipated low success rate of patent owners in PTAB proceedings and noting that Judge Rader “was ‘troubled’ by the many differences between proceedings at the PTAB and in the district courts, particularly pointing to the disparities in the treatment of the same evidence concerning the same claims”).

<sup>78</sup> Sachs, *supra* note 53.

**Figure 3: PTAB CBM Invalidations (June 2014 – March 2017)**<sup>79</sup>

	<b>Total Petitions</b>	<b>Petitions Granted</b>	<b>Percent Invalid</b>
PTAB CBM Institution on § 101	152	129	84.9%
PTAB Final Decisions on § 101	89	87	97.8%

More recently, these extremely high invalidation rates have softened a bit, especially in the district courts, but they continue to remain high enough to give anyone pause, at least at first glance.<sup>80</sup> As Sachs notes in his most recent update on §101 rejections and invalidations after *Alice*, there were a record 24 patent *ineligible* decisions in just the first quarter of 2017, although the overall rejection rate for both the Federal Circuit and District Court is now 67%.<sup>81</sup> The PTAB, however, continues aggressively to invalidate patents with §101 rejections, as its “kill rate” in the CBM program remains a remarkable 97.8%.<sup>82</sup>

B. *The New Comparative Disadvantage in Patented Innovation: U.S., Europe, and China*

While high rejection and invalidation rates demonstrate an unbalanced patent system, there is a further troubling development: the U.S. is losing its comparative advantage in securing stable and effective property rights in new technological innovation. Other jurisdictions, such as in Europe and China, are stepping up to the fill the void that has been created by the U.S. Supreme Court’s § 101 jurisprudence.<sup>83</sup> Although further empirical studies of this issue

<sup>79</sup> Robert R. Sachs, *Alicestorm Update for Q1 2017*, BILSKI BLOG (Apr. 6, 2017), <http://www.bilskiblog.com/blog/2017/04/alicestorm-update-for-q1-2017.html>.

<sup>80</sup> *Id.* (tracking ineligibility decisions through the first quarter of 2017 and finding that although there was a slight decrease, invalidation rates remain high).

<sup>81</sup> *Id.*

<sup>82</sup> *Id.* (noting the “PTAB’s aggressive rates of invalidating patents under Section 101 during Covered Business Method reviews, as shown above (96.7%)”).

<sup>83</sup> See Rana Foroohar, *A Better US Patent System Will Spur Innovation*, FINANCIAL TIMES (Sep. 3, 2017), <https://www.ft.com/content/74114a6c-8f28-11e7-9084-d0c17942ba93?mhq5j=e6> (discussing how “the country’s top minds can no longer monetise their research” in the United States and “many investors say they are considering moving money away from the US, towards Europe and Asia”); Jack Ellis, *China Relaxes Rules on Software Patentability – and the United States Loses More Ground*, INTELLECTUAL ASSET MGMT. (Mar. 3, 2017), <http://www.iam-media.com/Blog/Detail.aspx?g=7c198725-2c5e-497e-bca8-8e89f4bc1327> (detailing China’s recent embrace of software patents which “stands in stark contrast to the situation in the United States,” and noting that “it is increasingly looking easier and more worthwhile to obtain patent protection on software inventions in China, as compared to the United

are necessary, the initial data presents a first glimpse of a comparative trend that is just as disturbing as the high rejection and invalidation rates at the PTO and in the courts.<sup>84</sup>

A database compiled by Robert Sachs and David Kappos confirms what was before mostly sporadic anecdotes. The total database includes all patent applications that received an initial or final rejection as patent ineligible under § 101 and were then abandoned by the applicant between August 1, 2014 and September 27, 2017. The database of total patent applications is 48,586. From this total, 17,743 applications received a final rejection from the PTO on the basis of § 101, and were subsequently abandoned. Of these 17,743 patent applications, 344 were appealed and abandoned after the Examiner filed an Answer to the applicant's appeal brief. Thus, no U.S. patent issued from these 17,743 applications, nor did any other patents issue on related inventions (what patent lawyers call a "family"). Among these 17,743 patent applications, 1,694 patent applications claiming the same or similar inventions were granted by the EPO, in China, or both. Given past U.S. leadership relative to other world economies in securing new innovation, this data represents a potentially disturbing trend for the future of the U.S. innovation economy.<sup>85</sup>

A closer look at some of the patent applications in the database underscores this concern. Some of these applications represent the cutting-edge, push-the-envelope innovation that the U.S. patent system is supposed to promote and secure to inventors, just as it did in 1980 when the *Chakrabarty* Court confirmed that the fruits of biotech research should be protected by the patent system. Now, it is life-saving treatments for breast cancer, diabetes, and other maladies that are being denied the same protections, reducing the key investment and research incentives that have made "miracle cures" a commonplace feature of twenty-first-century life for everyone.

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States"); Preetika Rana, *Your Cancer Drugs May Soon Be Discovered in China*, WALL ST. J. (Apr. 11, 2017), <https://www.wsj.com/articles/china-emerges-as-powerhouse-for-biotech-drugs-1491816607> (discussing the shift of research and development investment to China as a result of the "shrinking pool of patent-protected biotech drugs" in the United States).

<sup>84</sup> See *supra* Part III.A.

<sup>85</sup> For more information on the database, including how to download it, see note 10, *supra*.

**Figure 4:** Some Patent Applications Rejected in the U.S., but Granted by the EPO, in China, or Both.<sup>86</sup>

<b>Publication Date</b>	<b>Application Number</b>	<b>Title</b>	<b>Assignee – Current US</b>
8/29/2013	US13829262A	METHODS AND COMPOSITIONS FOR DIAGNOSTIC USE IN CANCER PATIENTS	GENENTECH INC.
3/21/2013	US13420589A	APPARATUSES AND METHODS FOR USER INTERACTIONS DURING ULTRASOUND IMAGING	CHISON MEDICAL IMAGING CO
12/15/2011	US12674875A	METHOD FOR DETECTING GYNECOLOGIC CANCER	LSIP
6/30/2011	US12139753A	METHOD FOR GROWING PLANTS	HOLMAN E H A
3/17/2011	US12989795A	METHOD OF DETERMINING ALANINE TRANSAMINASE (ALT) ACTIVITY BY 13C-MR DETECTION USING HYPERPOLARISED 13C-PYRUVATE	UNIVERSITY OF CALIFORNIA
10/1/2009	US12378965A	METHOD FOR EARLY DETERMINATION OF RECURRENCE AFTER THERAPY FOR PROSTATE CANCER	IRIS INTERNATIONAL

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<sup>86</sup> The highlighted applications were subject to final Office rejections, while the others received non-final rejections.

Publication Date	Application Number	Title	Assignee – Current US
7/28/2011	US13011672A	ANALYTE TESTING METHOD AND SYSTEM FOR TREATING DIABETES-RELATED COMPLICATIONS	LIFESCAN INC.
2/11/2010	US11573487A	METHODS AND KIT FOR THE PROGNOSIS OF BREAST CANCER	UNIVERSITY COLLEGE CARDIFF CONSULTANTS LIMITED
12/10/2009	US11915374A	MEDICAL DEVICE FOR PERITONEAL DIALYSIS	NICOLA T (NICO-I); SCHMIDTLEIN M (SCHM-I)
12/8/2011	US12679794A	CONTROL APPARATUS AND CONTROL METHOD FOR INTERNAL COMBUSTION ENGINE	TOYOTA JIDOSHA KABUSHIKI KAISHA
1/26/2012	US13122967A	DIAGNOSIS OF ACUTE STROKES	ORSAN MEDICAL TECHNOLOGIES
8/29/2013	US13746180A	METHODS FOR DIAGNOSING AND TREATING PROSTATE AND LUNG CANCER	PICOBELLA LLC

One such invention in Figure 4 was a patent application for an innovative method for diagnosing injuries to or diseases of the liver (application US12989795). It was invented by researchers at the University of California, who filed a patent application in 2009 for their new diagnostic method for detecting and treating liver diseases and injuries. Several years later, they applied for patents on this same diagnostic method in the EPO and China; both granted patents for their newly invented medical treatment.<sup>87</sup> Unfortunately, the U.S. patent application was still pending when Supreme Court handed down its opinion in *Myriad* in 2013. The PTO immediately applied *Myriad* to all pending patent applications on diagnostic methods, and it summarily rejected this liver treatment as patent *ineligible* under § 101. Since this

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<sup>87</sup> *Id.*

patent was granted by the EPO and in China, the manufacturing, licensing and other key economic activities predicated on it will now occur in those jurisdictions, and not in the U.S.<sup>88</sup>

In addition to threatening homegrown companies and innovators, the disruption in the U.S. patent system resulting from the Supreme Court's patent eligibility jurisprudence is affecting foreign inventors who seek patent protection in the U.S. In 2012, for example, researchers at Chison Medical Imaging, a Chinese manufacturer, filed a patent application in the U.S. for their invention of a new ultrasound machine.<sup>89</sup> Despite receiving a patent for their innovative technology from the EPO, the PTO rejected the U.S. application as ineligible for patent protection under § 101.

These are just a few examples of hundreds of innovators in the database that are now being rebuffed by the U.S. patent system. These inventors assumed that, based on its past gold standard protections for innovators, the U.S. patent system would recognize and reward them for the fruits of their inventive labors. Unfortunately, following the "four horsemen" patent eligibility decisions (*Bilski*, *Mayo*, *Myriad*, and *Alice*), this assumption is no longer viable.

Even more important, the EPO and China are continuing to offer the security of property rights in inventions and discoveries that the U.S. used to provide to innovators. In a global economy, inventors are discovering this simple fact through their own patent applications in these three jurisdictions. Simply put, the U.S. is in danger of losing its gold standard patent system. With this loss, the U.S. is in danger of losing its competitive and innovative edge, as innovators are driven overseas to create and commercialize new technologies.

## CONCLUSION

This Essay highlights empirical data about extensive invalidations of patents by the courts and by the PTO, and hundreds of patent applications rejected in the U.S. but granted for the same or similar inventions in Europe and China. This data reflects a very disturbing trend that portends darkly for the future of the U.S. innovation economy. The data deserves to be mined further with rigorous statistical analysis, investigating more closely issues like technology classes and other relevant variables, but this is beyond the scope of this conference Essay.

Still, this data is important, as it takes us on the first steps beyond the anecdotal reports by many lawyers, businesspersons, and commentators that the Supreme Court's recent patent eligibility decisions have shut the door to the innovators long welcomed by the U.S. patent system. It raises the very

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<sup>88</sup> Cf. Rana, *supra* note 83.

<sup>89</sup> U.S. Patent Application No. US13420589A, Publication No. US20130072795A1 (published Mar. 21, 2013) (Mo Ruoli; Gong Dongliang; Zhao Mingchang; Zhao Danhua, applicants).

real concern that the U.S. is abandoning its gold standard patent system, as compared to those in Europe, China, and the rest of the world. The U.S. patent system earned its gold standard reputation by protecting inventors and encouraging innovation for over 200 years. Unfortunately, the evidence in recent years suggests that the U.S. is reversing course and is ceding this innovation leadership to other countries.