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Adam Mossoff

**Antonin Scalia Law School,
George Mason University**

Kevin R. Madigan

**Antonin Scalia Law School, George Mason University,
Center for the Protection of Intellectual Property**

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

Kevin Madigan* & Adam Mossoff**

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 1,400 patent applications covering the same invention that were recently filed in the U.S., China, and the European Union, 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. All 1,400 patent applications were granted in both China and the E.U., but the same applications were all rejected in the U.S. as ineligible for patent protection. The cause of these rejections is the U.S. Supreme Court’s recent spat 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 now mired in 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 inventions from the database of 1,400 applications, this Essay discusses this uncertainty in U.S. patent law, 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 E.U. 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,¹ regulatory actions,² and numerous

* Legal Fellow, Center for the Protection of Intellectual Property, Antonin Scalia Law School at George Mason University. The authors would like to thank Robert Sachs and David Kappos for providing them with the database of patent applications that is reported on in this Essay.

** Professor of Law, Antonin Scalia Law School at George Mason University.

¹ See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 248 (2011).

² See *FTC Finalizes Settlement in Google Motorola Mobility Case*, FEDERAL TRADE COMMISSION (July 24, 2013), <https://www.ftc.gov/news-events/press-releases/2013/07/ftc-finalizes-settlement-google-motorola-mobility-case> (discussing the FTC’s approval of Google/Motorola merger in which Google made concessions on enforcement of 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,

decisions by the United States Supreme Court addressing all areas of patent doctrine. These widespread and systematic changes have affected, among many others, infringement remedies,³ licensing activities,⁴ and what types of inventions and discoveries are eligible for patent protection.⁵ 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,⁶ 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.⁷ This concern is particularly salient in patent eligibility doctrine. In four decisions over the past seven years, the

Esq., Dorsey & Whitney LLP (Feb. 2, 2015), <https://www.justice.gov/atr/response-institute-electrical-and-electronics-engineers-incorporated> (refusing to challenge the Institute of Electrical and Electronics Engineers’ (“IEEE”) adoption of controversial changes to its Intellectual Property Rights (“IPR”) policies).

³ See eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006) (determining that an injunction should not be automatically issued based on a finding of infringement); see also Samsung Electronics Co. v. Apple, No. 15-777 (holding that damages must be limited to infringing components, rather than the final device as a whole).

⁴ See MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007) (holding that a licensee does not forfeit the right to challenge a licensed patent by signing a license agreement); Stanford University v. Roche Molecular Systems, Inc., 563 U.S. 776 (2011) (holding that the Bayh-Dole Act does not automatically vest title to federally funded inventions in federal contractors).

⁵ See Alice Corp. v. CLS Bank International, 134 U.S. 2347 (2014) (holding that a computer program that facilitated financial transactions and mitigated risk was an abstract idea and not eligible for patent protection); see also Assn. for Molecular Pathology v. Myriad Genetics, 133 U.S. 2107 (2013) (determining that claims related to isolated pieces of naturally-occurring DNA, and diagnostic methods using them, are naturally occurring phenomena and excluded from patentable subject matter); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012) (holding that claims directed to the treatment of an immune-related disorder were not directed to patentable subject matter); Bilski v. Kappos, 561 U.S. 593 (2010) (determining that a business method patent on hedging investment risk was not eligible for patent protection).

⁶ 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. (2015-2016); Innovation Act, H.R.9, 114th Cong. (2015-2016); Innovation Act, H.R.3309, 113th Cong. (2013-2014); Saving High-Tech Innovators from Egregious Legal Disputes Act of 2013, H.R.845, 113th Cong. (2013-2014).

⁷ See Joff Wild, *Sadly, Michelle Lee is Wrong to Believe the US IP System is Gold Standard and That it Works for the Little Guy*, INTELLECTUAL ASSET MANAGEMENT (Dec. 15, 2013), www.iam-media.com/blog/Detail.aspx?g=ce27a358-7b3f-4fe5-b8fe-4cc7e73fd515 (discussing USPTO 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”); Ashley Gold, Nancy Scola, Li Zhou, and Tony Romm, *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 one of the co-authors that the new Director of the PTO should “fix the very real problem that the U.S. has lost its “gold standard” patent system—it no longer promises stable, effective property rights to innovators”); cf. David Kappos, Richard Ludwin, and Marc Ehrlich, *From Efficient Licensing To Efficient Infringement*, NYLJ, Vol. 255, No. 63 (Apr. 4, 2016) (“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.”).

Supreme Court has 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.⁸ Unfortunately, as commentators have widely 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.⁹

This recent legal development raises an important question about whether the United States 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 the European Union (“E.U.”) and China, are now granting patents for the exact same inventions and discoveries that are being abandoned and rejected in the U.S. as patent ineligible. It raises the legitimate 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 providing much-needed empirical data: 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 1,400 recently filed patent applications in the U.S., the E.U., and China.¹⁰ In each instance, the application was for the exact same invention, and while the patent was granted in the E.U. and in China, it was rejected in the U.S. on the ground that the invention is patent ineligible under § 101.¹¹ These 1,400 patent applications 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.¹²

In addressing this concern about the U.S. conceding its gold standard patent system, increasingly voiced by many lawyers and

⁸ See *supra* note 5.

⁹ See, e.g., Brief of 19 Law Professors as Amici Curiae in Support of Petition for Writ of Certiorari, *Sequenom, Inc. v. Ariosa Diagnosis, Inc. et al.* (2016) (No. 15-1182) (detailing how the Supreme Court’s test for patent eligibility suffers from both legal indeterminacy and over-restrictiveness in application).

¹⁰ This database is on file with the authors. It was compiled by Robert Sachs, a Partner at Fenwick & West, and David Kappos, former Director of the U.S. PTO and now a Partner at Cravath, Swaine & Moore LLP.

¹¹ The applications were rejected as of [get date from Bob or Dave], but may have since been abandoned or granted after rebuttal.

¹² See *infra* note 72 and accompanying chart.

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 1,400 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.¹³ 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.¹⁴ 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.

A. *Biotechnology*

In 1980, the Supreme Court held in *Diamond v. Chakrabarty* that a genetically modified bacterium is a patentable innovation under § 101 of the Patent Act.¹⁵ 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.¹⁶ The *Chakrabarty* Court

¹³ 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) (discussing the development of IP institutions in the United States and 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, 79 (2014) (“The American patent system has succeeded because it has secured property rights in the new innovation that has come about with each new era—and it has secured the same property rights for all types of new inventions, whether in the Industrial Revolution or in the Digital Revolution.”).

¹⁴ See Kahn, *Trolls and Other Patent Inventions*, *supra* note 13, at 854-855 (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 and led to “many countries voluntarily adopting the distinctive U.S. rules and standards”).

¹⁵ *Diamond v. Chakrabarty*, 447 U.S. 303, 316 (1980).

¹⁶ *Id.* (detailing a parade of horrors from Nobel Laureates and other scientists about the dangers of biotech research, who thus argued that it should not be patentable).

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.¹⁷ 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.¹⁸

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 "oncomouse" controversy in the 1980s and 1990s. 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 treatments for cancer.¹⁹ Following the *Chakrabarty* precedent, the U.S. was the first country to secure a patent in this radical biotech innovation in 1988.²⁰

The genetic modification of living organisms has been controversial,²¹ 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 ("EPO") through 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.²² After similar multi-decade legal disputes, other

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.* 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 an example of the purpose of the patent system to secure unpredictable innovation precisely because innovation is unpredictable).

¹⁸ See, e.g., See Robert P. Merges & John F. Duffy, *Patent Law and Policy* 77 (4th ed., Lexis 2007) (noting how *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)).

¹⁹ *Bioethics and Patent Law: The Case of the Oncomouse*, WIPO MAGAZINE (June, 2006), http://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html.

²⁰ Patent No. 4,736,866 (issued Apr. 12, 1988).

²¹ See *Bioethics and Patent Law*, *supra* note 20 (discussing two key ethical issues regarding transgenic technology including (1) "should patents be granted at all for animals or animal varieties, particularly for higher-order animals such as mammals, even if they do otherwise meet patentability criteria (novelty, industrial applicability/usefulness, inventive step etc.)?" and (2) "how should moral implications be addressed in relation to specific cases, e.g. the question of suffering caused to the transgenic animal?").

²² See *Id.* (In order to address an exception that excludes patents for inventions "the publication or exploitation of which would be contrary to *ordre public* or morality," the EPO developed a utilitarian

countries eventually rejected the patent application on the oncomouse.²³ Despite Europe's ultimate acceptance of the patenting of this innovation, the decision decades earlier by U.S. authorities to secure property rights in the fruits of biotech research ensured that the U.S. became the birthplace of the biotech revolution.²⁴ Europe lost a competitive and commercial edge in biotechnology to the United States, 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.²⁵

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.²⁶ This confusion was obvious in 1972 in *Gottschalk v. Benson* 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.²⁷ Given that the digital revolution had begun only about ten years earlier, digital computers were still in their infancy as consumer products, and it was a decade before the Personal Computer ("PC") Revolution of the 1980s, this confusion about the nature of software innovation was perhaps understandable.²⁸ Still, Justice William Douglas's opinion in *Benson* was unfortunate, because it inserted a fundamental misunderstanding about computer programs into the legal foundations for defining how this important, modern innovation should be secured to its creators. It would be

balancing test to assess the potential benefits of a claimed invention against negative aspects and eventually "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.").

²³ See *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 SCR 45 at para 155 (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).

²⁴ See generally 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).

²⁵ See *Life Sciences and Biotechnology: A Strategy for Europe*, European Commission (2002) (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.").

²⁶ See generally Mossoff, *supra* note 18 (discussing this early history and controversy).

²⁷ *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972).

²⁸ See Mossoff, *supra* note 18, at 67 n.29.

nearly ten years before a more careful and informed Court corrected this initial misstep.

In 1981, the Supreme Court definitively held in *Diamond v. Diehr* that a computer program was not automatically an “abstract idea” or “algorithm” that precluded patent protection.²⁹ 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, it was a manufacturing process for curing rubber—was a valid component of a technological innovation deserving of legal protection in the patent system.³⁰ The key was recognizing how the software program functioned in creating a new technological innovation itself; in the legalese of patent parlance, the *Diehr* Court reaffirmed a basic precept of patent law that all patentable inventions must be evaluated by the PTO and courts *as a whole* as to their nature and function as new, useful, and nonobvious inventions.³¹

Following 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 innovation in software programs represented the equivalent of a digital machine.³² 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 digital machine in the High-Tech Revolution of the late twentieth century. In their technological and commercial context, each is a valuable machine that serves a specific function for end-users, and as cutting-edge innovation, each is precisely what the patent system is supposed to promote and secure to inventors and the companies that deploy these products and services in the marketplace.³³

The court decisions in *Diehr*, *Chakrabarty*, and *Alappat*, among others, meant that innovators knew the fruits of their inventive labors

²⁹ *Diamond v. Diehr*, 450 U.S. 175 (1981).

³⁰ *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.”).

³¹ *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.”).

³² *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994).

³³ *See* Brief of Ten Law Professor as Amici Curiae in Support of Plaintiff-Appellee, Trading Techs. Int’l, Inc. v. CQG, Inc., No. 2016-1616 (2016), 2016 WL 4017117, at 9; Mossoff, *supra* note 18, 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.”).

would be secured to them under U.S. law. Despite fluctuations over time in the strength of legal protection provided to innovators in the U.S., the patent system generally has secured stable and effective property rights in the new innovation that drove the Industrial Revolution, the Biotech Revolution, and the High-Tech Revolution.³⁴ For this reason, it rightly earned the “gold standard” designation compared to the rest of the world. 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

Since 2010, four equally influential Supreme Court decisions have dramatically restricted the scope of inventions that can receive patent protection: *Bilski v. Kappos* (2010), *Mayo Labs v. Prometheus* (2012), *AMP v. Myriad* (2013), and *Alice Corp. v. CLS Bank* (2014).³⁵ These four decisions have significantly impacted the U.S. patent system. First, they substantively restricted the scope of patentable inventions, and thereby chipped away incrementally at the innovation gains achieved by *Chakrabarty*, *Diehr*, and other decisions. Second, and far worse, they have injected tremendous uncertainty into the U.S. patent system, undermining the ability of inventors, universities, venture capitalists, and companies to make long-term investment decisions in R&D.³⁶ This Part will briefly review these decisions and detail their impact on the U.S. innovation economy.

A. *Bilski v. Kappos*, 561 U.S. 593 (2010)

In 2010, the Supreme Court addressed whether new and useful business methods are patentable inventions as a “process” under § 101 of the Patent Act.³⁷ Despite an extensive legal and policy debate about the

³⁴ See Stephen Haber, *Patents and the Wealth of Nations*, 23:4 GEORGE MASON L. REV. 811, 825 (2016), (identifying historical and economic research that overwhelmingly proves that patents are a key factor in promoting innovation and economic growth).

³⁵ See *supra* note 5.

³⁶ See Joan Farre-Mensa, Deepak Hegde, and Alexander Ljungqvist, *The Bright Side of Patents*, USPTO Economic Working Paper 2015-5 (2016), available at:

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).

³⁷ 35 U.S.C § 101 (“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.)

patent eligibility of business methods,³⁸ the *Bilski* Court held that they are an invented process capable of being patented (as long as they met the other patentability requirements).³⁹ While the *Bilski* Court emphasized that business method patents are not unpatentable per se, provoking a strident dissent from Justice John Stevens, the *Bilski* Court ultimately concluded that the business method in this case was in fact an “abstract idea” and thus unpatentable. 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 definitive 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 many patents on software, business methods, and diagnostic methods,⁴⁰ which only picked up speed in the ensuing years.

B. *Mayo v. Prometheus*, 132 S. Ct. 1289 (2012)

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 claimed a “law of nature.”⁴¹ 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 condition is merely a “law of nature” and thus unpatentable.⁴² Repeating the

³⁸ Compare Michael Risch, *Everything is Patentable*, 75 TENN. L. REV. 591, 609-611 (2008) (business methods are patentable) and 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 (1999) (business methods should not be patentable).

³⁹ *Id.* at 604 (“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.’”).

⁴⁰ See, e.g., Daniel A. Tysver, *Are Software and Business Methods Still Patentable After the Bilski Decisions?*, BITLAW (last visited Dec. 9, 2016), <http://www.bitlaw.com/software-patent/bilski-and-software-patents.html> (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* decision” 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”); Edward Van Gieson and Paul Stelman, *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 High Tech. L.J. 403, 404 (2010) (“The amorphous U.S. Supreme Court decision in *Bilski v. Kappos* . . . has now set the stage for years of Federal Circuit litigation defining the scope of patentable subject matter for software and business method patents under 35 U.S.C. § 101. New tests will likely be created, and old tests will likely be refined.”).

⁴¹ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1291 (2012).

⁴² *Id.* at 1294, 1305.

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.”⁴³

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.⁴⁴ More importantly, 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.”⁴⁵ The one-two punch of the doctrinal confusion and the lack of guidance as to assessing whether patent methods claim an invalid “law of nature” has resulted in extensive uncertainty and high invalidation rates in the biotech and pharmaceutical industries.⁴⁶

C. *AMP v. Myriad Genetics*, 133 U.S. 2107 (2013)

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 § 101.⁴⁷ 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 correlated with a woman’s proclivity to contract breast cancer (BRCA1 and BRCA2).⁴⁸

⁴³ *Id.* at 1294, 1305.

⁴⁴ 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.”).

⁴⁵ *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.”).

⁴⁶ Robert 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-alicestorm.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*.”).

⁴⁷ 35 U.S.C § 101 (“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.”) (emphases added.)

⁴⁸ Board of Appeal of the European Patent Office, No. T 1213/05 at 69-70 (2007), www.epo.org/law-practice/case-law-appeals/pdf/t051213eu1.pdf (describing *Myriad*’s discovery as a “major

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.⁴⁹ 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.⁵⁰

As in *Bilski* and *Mayo*, the *Myriad* Court concluded that isolated DNA is a "product of nature" that is unpatentable under § 101 of the Patent Act.⁵¹ Following the same pattern of decision-making in *Bilski* and *Mayo*, the *Myriad* Court again provided no specific guidance for the PTO or courts to assess the patentability of the tens of thousands of existing patents and 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.⁵²

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 pioneering effort that went into Myriad's success).

⁴⁹ Brief in Opposition at 3-5, *Assn. for Molecular Pathology v. Myriad Genetics, Inc.*, 133 U.S. 2107, (2012) (No. 12-398).

⁵⁰ See Adam Mossoff, *A Century-Old Form of Patent*, N.Y. TIMES ROOM FOR DEBATE (June 6, 2013), at <http://www.nytimes.com/roomfordebate/2013/06/06/can-the-human-blueprint-have-owners/a-century-old-form-of-patent>; Christopher Beauchamp, *Patenting Nature: A Problem of History*, 16 STANFORD TECH. L. REV. 257, 296-99 (2013) (discussing patents on adrenalin and insulin in early twentieth century).

⁵¹ *Assn. of Molecular Pathology v. Myriad Genetics, Inc.*, 133 U.S. 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").

⁵² See Scott Gottlieb, *Supreme Court's Ruling on Genetic Tests Will Make a Bad Business Worse*, AMERICAN ENTERPRISE INSTITUTE (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 King, *Will the Supreme Court's decision on "gene patents" stifle medical innovation?*, VECTOR: BOSTON CHILDREN'S HOSPITAL'S SCIENCE 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."); Statement on U.S. Supreme Court Review of Isolated DNA Patents, BIO (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 on *Myriad*, "the Supreme Court's decision today

D. *Alice Corp. v. CLS Bank*, 134 U.S. 2347 (2014)

In 2014, the Supreme Court again took on patent eligibility, tackling the last remaining field of modern innovation that it had not addressed in its prior three decisions: the patent eligibility of software programs. The *Alice* Court framed the legal issue it would decide very broadly—whether computer-implemented inventions are directed to patent-eligible subject matter within the meaning of 35 U.S.C. § 101⁵³—but the opinion it ultimately issued 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 the large and complex software program for managing intricate international financial transactions is an “abstract idea” and thus ineligible for patent protection.⁵⁴

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 two-step framework first set forth in *Mayo* and *Myriad*, which was used in those earlier cases to invalidate the patents. This two-step framework, which one of us has termed the “*Mayo-Alice* test,”⁵⁵ is a very generalized inquiry framed at a high level of abstraction.⁵⁶ Thus, *Alice* is a capstone, or what some in the innovation industries might consider 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 the analysis section of 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

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”).

⁵³ *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2350 (2014).

⁵⁴ *Id.* at 2352 (2014) (“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.”).

⁵⁵ Brief of 19 Law Professors as Amici Curiae in Support of Petition for Writ of Certiorari, *Sequenom, Inc. v. Ariosa Diagnosis, Inc. et al.*, at 2 (2016) (No. 15-1182).

⁵⁶ The two-prong inquiry is (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 Corp. Pty. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1296-97 (2012).

known” processes.⁵⁷ Despite not even mentioning the word “software” once in its opinion, some commentators concluded that the *Alice* Court rejected all software patents,⁵⁸ 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 form statement that merely recited the *Alice* opinion.⁵⁹ In the ensuing years, courts began invalidating at astronomical rates patents covering innovation in the biotech, pharmaceutical, and high-tech sectors of the economy.⁶⁰ 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 over-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.”⁶¹ 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,⁶² 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, the Court has consistently invalidated patented inventions and failed to provide any meaningful legal guidance in

⁵⁷ *Alice Corp.*, 134 S. Ct. at 2354-60.

⁵⁸ See, e.g., Gene Quinn, *SCOTUS Rules Alice Software Claims Patent Ineligible*, IPWATCHDOG (June 19, 2014, 10:54 AM), <http://www.ipwatchdog.com/2014/06/19/scotus-rules-alice-software-claims-patent-ineligible/id=50120/> (“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.”).

⁵⁹ See Robert Plotkin, *Software Patents are Only as Dead as Schrödinger’s Cat*, IPWATCHDOG (Oct. 6, 2014, 10:49 AM), <http://www.ipwatchdog.com/2014/10/06/software-patents-are-only-as-dead-as-schrodingers-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”).

⁶⁰ Steven Callahan, *Alice: The Death of Software-Related Patents?*, NORTHERN DISTRICT OF TEXAS 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”).

⁶¹ Robert 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-alicestorm.html>.

⁶² *Alice* at 2354.

all four of its recent patent-eligibility decisions. The result of the specific decisions (invalid patents) and the lack of actual guidance to the PTO and courts has been 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 brute facts. A look inside the staggering numbers of post-*Alice* rejections and invalidations exposes an unprecedented imbalance in the U.S. patent system, raising the serious question whether the U.S. has lost its gold standard patent system.

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

In the year following the Court's decision in *Alice*, patent law expert Robert Sachs reported that there were 106 Federal Circuit and district court §101 decisions, 76 of which invalidated the patents at issue in whole or in part.⁶³ In these 106 cases, 65% of all challenged patents were found to be invalid, while a remarkable 76.2% of all claims were invalidated.⁶⁴ Looking to the Federal Circuit specifically, 18 of 19 patents were invalidated, resulting in a shocking 95% "kill rate."⁶⁵

⁶³ Sachs, *supra* note 54.

⁶⁴ *Id.* (in addition to the staggering final decision numbers, Sachs' data revealed that "[t]he success rate of motions on the pleadings (including motions to dismiss and judgments on the pleadings) is extremely impressive: 67% of defense motions granted, invalidating 54% of asserted patents.").

⁶⁵ *Id.* (Sachs points out that while one case - *DDR Holdings, LLC v. Hotels.com, L.P.* - held in favor of the patentee, "only nine district court opinions have relied upon *DDR* to find patent eligibility, with over 30 court opinions distinguishing *DDR* as inapplicable.").

Figure 1: Federal Circuit 101 Invalidations (June 2014 to June 2015)

	Total	Invalid	Percent Invalid
Fed. Circuit Decisions	13	12	92%
Patents	19	18	95%
Claims	468	441	94%

Using detailed datasets of PTO rejections and issuances of patent applications from 2013-2015, Sachs tracked the percentages of §101 rejections before and after *Alice* and found that the rates nearly doubled after the *Alice* Court’s decision.⁶⁶ Not surprisingly, the most significant increases in rejections were found in the areas of biotech 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*, *Alice*).

Figure 2: USPTO 101 Rejections (through May 2016)

Tech Center	Before Alice	6/14 Preliminary Guidance	12/14 Interim Guidance	7/15 Update	5/16 Examiner Memos
1600 Biotech & Chem	10.4%	13.7%	13.1%	10.9%	10.0%
1700 Chem. Eng.	1.5%	1.5%	1.5%	3.2%	0.9%
2100 Comp. Architecture	15.3%	15.4%	14.7%	11.9%	10.9%
2400 Networks & Video	10.2%	10.2%	13.3%	15.5%	13.1%
2600 Communications	7.8%	7.6%	8.8%	8.1%	8.6%
2800 Semiconductor, Elec., Opt.	1.9%	2.6%	2.9%	2.5%	3.0%
3600 Transportation & Construction	3.3%	4.3%	3.9%	3.7%	3.5%
3600 Business Methods	35.3%	76.6%	87.2%	86.3%	88.7%
3700 Mechanical	3.7%	6.1%	7.5%	6.1%	5.8%
Grand Total	6.8%	9.6%	10.5%	9.5%	8.6%

Perhaps the bleakest venue for patent owners has been the Patent Trial and Appeal Board (“PTAB”). 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 statistics are hard to deny.⁶⁷ In the first year after *Alice*,

⁶⁶ For a more detailed analysis of USPTO §101 rejections, see Sachs’ “*Alice* at the Office” section, available at: <http://www.bilskiblog.com/blog/2015/06/the-one-year-anniversary-the-aftermath-of-alicestorm.html>.

⁶⁷ Rob Sterne and 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->

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 100% of the patents it reviewed.⁶⁸

Figure 3: PTAB CBM Invalidations (June 2014 – June 2015)

	Total Petitions	Petitions Granted	Percent Invalid
PTAB CBM Institution on § 101	72	64	89%
PTAB Final Decisions on § 101	27	27	100%

In the ensuing years, 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.⁶⁹ As Sachs notes in his most recent update on §101 rejections and invalidations after *Alice*, the Federal Circuit continues to invalidate patents under § 101 using the *Mayo-Alice* test in 91.4% of the appeals in which this legal claim is asserted, although the overall rejection rate for both the Federal Circuit and District Court is now 68%.⁷⁰ The PTAB, however, continues aggressively invalidating patents under §101 rejections, as its “kill rate” in the CBM program has dropped from 100% to 96.7%.⁷¹

B. *The New Comparative Disadvantage in Patented Innovation: U.S., E.U., 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 the E.U. and China, are stepping up to fill the void that has been created by the U.S. Supreme Court’s § 101 jurisprudence. Although further

[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”).

⁶⁸ Sachs, *supra* note 54.

⁶⁹ See Robert R. Sachs, *Alice Brings Mix of Gifts for 2016 Holidays*, BILSKI BLOG (Dec. 23, 2016), <http://www.bilskiblog.com/blog/2016/12/alice-brings-a-mix-of-gifts-for-2016-holidays.html> (tracking ineligibility decisions through 2016 and finding that although there was a slight decrease, invalidation rates remain high).

⁷⁰ *Id.*

⁷¹ *Id.* (noting the “PTAB’s aggressive rates of invalidating patents under Section 101 during Covered Business Method reviews, as shown above (96.7%)”).

empirical studies of this issue are necessary, the initial data is just as alarming as the shockingly high rejection and invalidation rates at the PTO and in the courts.⁷²

A database compiled by Robert Sachs and David Kappos confirms what was before mostly sporadic anecdotes: while applications in the U.S. are being rejected as ineligible for patent protection under § 101 and then abandoned by the applicants, the E.U. and China are granting patents on the exact same inventions and discoveries. These rejections are not a sporadic or occasional result, which are being emphasized solely for rhetorical effect. The database lists over *one thousand four hundred inventions* in which patent applications in the past several years were granted in the E.U. and China, but denied or abandoned in the U.S. solely on the basis of being patent ineligible.

A closer look at some of these inventions further shows just how much the U.S. is in danger of losing its gold standard patent system, a key driver of its innovation economy for over two hundred years. A selection from the database of 1,400 patent applications shows that 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 ovarian cancer, 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.

Figure 4: Some Patent Applications Rejected in the U.S., but Granted in China and the E.U.⁷³

Publication Date	Application Number	Title	Assignee – Current US
8/29/2013	US13829262A	METHODS AND COMPOSITIONS FOR DIAGNOSTIC USE IN CANCER PATIENTS	GENENTECH INC.

⁷² See *supra* Part IV.A.

⁷³ The highlighted applications were subject to final Office rejections, while the others received non-final rejections.

3/21/2013	US13420589A	APPARATUSES AND METHODS FOR USER INTERACTIONS DURING ULTRASOUND IMAGING	CHISON MEDICAL IMAGING CO
12/15/2011	US2010674875A	METHOD FOR DETECTING GYNECOLOGIC CANCER	LSIP
6/30/2011	US2010968726A	METHOD FOR GROWING PLANTS	HOLMAN E H A
9/30/2010	US2010676670A	MICRORNA SIGNATURES FOR DIAGNOSIS OF HUMAN OVARIAN CANCER	OHIO STATE UNIVERSITY
10/1/2009	US2009378965A	METHOD FOR EARLY DETERMINATION OF RECURRENCE AFTER THERAPY FOR PROSTATE CANCER	IRIS INTERNATIONAL
7/28/2011	US13011672A	ANALYTE TESTING METHOD AND SYSTEM FOR TREATING DIABETES-RELATED COMPLICATIONS	LIFESCAN INC.
2/11/2010	US2006573487A	METHODS AND KIT FOR THE PROGNOSIS OF BREAST CANCER	UNIVERSITY COLLEGE CARDIFF CONSULTANTS LIMITED

12/10/2009	US2007915374 A	MEDICAL DEVICE FOR PERITONEAL DIALYSIS	NICOLA T (NICO-I); SCHMIDTLEIN M (SCHM-I)
12/8/2011	US2010679794 A	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 treating ovarian cancer (application US 2010676670A). It was created by researchers at the Ohio State University (“OSU”), the home of the James Cancer Hospital and Solove Research Institute, a state-of-the-art comprehensive cancer research and treatment center, and, as of 2014, the third largest cancer hospital in the United States.⁷⁴ In 2008, these OSU researchers filed a patent application for a new method to diagnose the presence or risk of ovarian cancer by measuring microRNA levels.⁷⁵ They also applied for patent protection for this same diagnostic method in the E.U., China, and Japan, and between 2014 and 2016, all three foreign jurisdictions granted patents for the treatment.⁷⁶ In the U.S., the PTO rejected the application shortly after *Myriad*, which the PTO applied in this case and concluded that the invention was not patent eligible under § 101. The patent applications were granted in the E.U. and China, signaling that the manufacturing, licensing and other key economic activities predicated on these patents will occur in those jurisdictions, and not in the U.S.

⁷⁴ The James Cancer Hospital and Solove Research Institute, THE OHIO STATE UNIVERSITY (last visited Nov. 7, 2016), <https://cancer.osu.edu/about/locations/the-james-cancer-hospital-and-solove-research-institute>.

⁷⁵ U.S. Patent Application No. US12676670, Publication No. US20100249213A1 (published Sept. 30, 2010)(Ohio State University Research Foundation, applicant).

⁷⁶ *Id.*

In addition to threatening homegrown companies and innovators, the disruption in the U.S. patent system from just the Supreme Court's patent eligibility jurisprudence is affecting foreign inventors who seek patent protection in the United States. In 2012, Chison Medical Imaging, a manufacturer of ultrasound systems based in China, filed a patent application in the U.S. for a new and improved ultrasound machine.⁷⁷ Despite receiving a patent for this innovative technology in the E.U., the PTO rejected the U.S. application as patent ineligible under § 101.

These are just a representative few examples of untold stories of innovators being rebuffed by the U.S. patent system. They assumed that, based on its past gold standard protections for innovators, the U.S. patent system would recognize and reward them today for the fruits of their inventive labors. The U.S. patent system following the "four horsemen" patent eligibility decisions no longer supports this assumption. But the E.U. and China are continuing to offer the types of property rights in inventions and discoveries that the U.S. used to secure to innovators, and in our 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

Fourteen hundred inventions secured by patents in the E.U. and China but deprived of legal protection in the U.S. is a wake-up call. The data deserves to be mined further with rigorous statistical analysis, which is beyond the scope of this conference Essay, but at this early stage, it appears to confirm the assessments by many lawyers and commentators that the Supreme Court's interpretation of patent eligibility under § 101 of the Patent Act is over-restrictive. In addition to the well-known concerns about excessively high rates of rejections of applications and invalidations of issued patents as ineligible under § 101, this data further shows that these "kill rates" are also undermining the longstanding "gold standard" status of the U.S. patent system, as compared to the E.U., 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 is mounting that the U.S. patent system is closing the door to the inventors creating cutting-edge technological innovation.

⁷⁷ U.S. Patent Application No. US13420589A, Publication No. US20130072795A1 (published Mar. 21, 2013)(Mo Ruoli; Gong Dongliang; Zhao Mingchang; Zhao Danhua, applicants).