

## TURNING GOLD TO 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

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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-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

decisions by 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 doctrine. In four decisions issued between 2010 and 2014,

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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.” (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*, INTEL. 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.”).

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 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

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<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-Lead-Final-Dataset.pdf>. For questions about the database, please contact Robert Sachs at [RSachs@fenwick.com](mailto:RSachs@fenwick.com).

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.

### 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

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<sup>11</sup> See *infra* note 81 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”).

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

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 *Charkrabarty* 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>

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

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<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).

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

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