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# Patents and Innovation Policy

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## Patents and Innovation Policy

Encouraging scientific and technological innovation and U.S. economic competitiveness has been a longstanding interest of Congress and other federal policymakers. Motivated by the widely-held view that scientific and technological advances drive economic growth, Congressional interest has focused on the patent system—perhaps the longest-running element of U.S. innovation policy. Congressional authority over the patent system is grounded in the U.S. Constitution, which states that “The Congress Shall Have the Power.... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Today, Title 35 of the U.S. Code provides the statutory basis for U.S. patent law.

Patent ownership is designed to incentivize innovation by offering a limited-time monopoly over the use of an invention in exchange for the public disclosure of the invention. By granting a temporary monopoly on the invention, patents may generate financial returns that could help offset costs incurred by the inventor during the discovery process. Likewise, by publicly disclosing the technical details of the invention, patents may also contribute to the growth of knowledge in the public domain.

Different views exist, however, regarding how to best structure and administer the patent system to encourage innovation, without unduly harming competition. Some argue, for example, that strong patent rights are essential to spur innovation and generate economic growth. Such arguments contend that recent changes in patent law, which have made it easier to challenge patents, have led to decreased investment in technological research and development, harming U.S. competitiveness and economic growth.

Others contend that, at least in some situations, more flexibility in patent rights is necessary to ensure the wider dissemination and reduced costs of a particular invention, which may result in economic and social benefits to the public. For example, during the global COVID-19 pandemic, advocates have argued for waivers or other flexibilities in patent rights to increase the availability and distribution of technologies such as COVID-19 vaccines. Still, others argue that patents are too often granted for inventions that are not truly innovative, leading to increased costs for products (like pharmaceutical drugs) and potentially blocking future inventions that are truly innovative.

As Congress considers whether the patent system most effectively encourages innovation, a number of issues related to how patents are awarded, implemented, and protected may be of interest, including:

- Patent subject matter eligibility standards determine the types of inventions that can be patented. Changes to the scope and implementation of such standards could either hinder or strengthen the patent system’s ability to protect and encourage innovation—particularly in key emerging technology sectors.
- Patent quality generally refers to whether granted patents actually meet the standards of patentability specified in current statute. When unclear or otherwise invalid patents are granted, they can breed uncertainty in the enforceability of patent rights as well as make it more difficult for others to “invent around” a particular patent, thus making investing in innovation a riskier financial prospect.
- The belief that poor quality patents inhibit innovation has spurred debate over the costs and benefits of making it easier to challenge the validity of patents once they are granted. The 2011 Leahy-Smith America Invents Act (P.L. 112-29) introduced the Patent Trial and Appeal Board (PTAB) and new administrative mechanisms to challenge the validity of issued patents, which has recently been the subject of criticism and reform proposals.
- U.S. technological competitiveness is also believed to (at least partially) rely on the quality and diversity of inventive ideas that fuel innovation, making equity-related aspects of patent policy potentially of interest.

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# Introduction

Congressional interest in innovation policy takes many forms—from federal investments in university research and development (R&D) programs and subsidies for private research initiatives to federal programs and incentives to spur the commercialization of products and services.

The patent system is a cornerstone of congressional efforts to encourage innovation—the creation and implementation of new knowledge or products to improve efficiency and create value. Perhaps the oldest and longest-running element of innovation policy, the patent system is grounded in the U.S. Constitution, which states that “The Congress Shall Have the Power ...To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>1</sup> Because patents confer on their owners a limited-time monopoly on the use of their invention, inventors have the potential to receive financial returns that may help offset the costs of the discovery process or generate net profits. In this way, patent ownership is designed to be an incentive for innovation. As former U.S. President Abraham Lincoln explained in 1859, the patent system adds “the fuel of *interest* to the fire of *genius*, in the discovery and production of new and useful things.”<sup>2</sup>

The widely-held view that scientific and technological advances underpin innovation and drive economic growth has fueled congressional interest in patent policy and reform.<sup>3</sup> Such interest has intensified as the American economy has shifted from primarily relying on investments in “tangible capital” (such as machinery) to investments in “intangible capital” (such as research and development (R&D)) to stimulate economic growth.<sup>4</sup> For example, by the mid-1990s, U.S. companies began spending more on R&D and its commercialization than tangible capital assets.<sup>5</sup>

Though difficult to measure precisely, some have argued that intellectual property (IP) rights have increasingly enabled economic growth by helping to protect these intangible capital assets.<sup>6</sup> By some estimates, intangible assets account for as much as 90% of all assets held by companies listed in the S&P 500—a stock market index tracking 500 large, publicly-traded, U.S. companies.<sup>7</sup> Additionally, a 2021 study released by business consulting firm McKinsey and Company finds a positive correlation across economic sectors between company investments in intangible assets and growth rates.<sup>8</sup> According to the United States Patent and Trademark Office

<sup>1</sup> U.S. Constitution, Article I, Section 8, Clause 8.

<sup>2</sup> Abraham Lincoln, “Second Lecture on Discoveries and Inventions, 1859,” in *Collected Works of Abraham Lincoln*, vol. 3 (Ann Arbor: University of Michigan Digital Library Production Services, 2001), p. 363, at <http://name.umd.umich.edu/lincoln3>; emphasis in the original.

<sup>3</sup> Gregory Tasse, *The Economics of R&D Policy* (Connecticut: Quorum Books, 1997), p. 54. See also *Technology and the Wealth of Nations*, eds. Nathan Rosenberg, Ralph Landau, and David C. Mowery (Stanford: Stanford University Press, 1992); Edwin Mansfield, “Intellectual Property Rights, Technological Change, and Economic Growth,” in *Intellectual Property Rights and Capital Formation in the Next Decade*, eds. Charles E. Walker and Mark A. Bloomfield (New York: University Press of America, 1988).

<sup>4</sup> Andrew A. Toole, Richard D. Miller, and Nicholas Rada, *Intellectual Property and the U.S. Economy: Third Edition*, USPTO, Alexandria, VA, March 2022, p. ii, at <https://www.uspto.gov/ip-policy/economic-research/intellectual-property-and-us-economy>.

<sup>5</sup> Ibid.

<sup>6</sup> Ibid., p. 1.

<sup>7</sup> See, for example, Visual Capitalist, “The Soaring Value of Intangible Assets in the S&P 500,” November 12, 2020, at <https://www.visualcapitalist.com/the-soaring-value-of-intangible-assets-in-the-sp-500/>.

<sup>8</sup> McKinsey and Company, “Getting Tangible About Intangibles: The Future of Growth and Productivity?,” discussion paper, June 16, 2021, at <https://www.mckinsey.com/business-functions/growth-marketing-and-sales/our-insights/>

(USPTO), in 2019 IP-intensive industries accounted for \$7.8 trillion of U.S. GDP<sup>9</sup> and 44% of total U.S. employment, amounting to some 63 million jobs.<sup>10</sup>

Policymakers have long debated, though, how to best structure and administer the patent system to effectively encourage the economic and social benefits of innovation, as different perspectives persist regarding which patent policies best serve these objectives.

Some assert that strong patent rights are essential to incentivize innovation and generate economic growth. Others contend that certain situations require greater flexibility in patent rights to ensure the wider dissemination of a particular invention, which may result in economic and social benefits that outweigh any potential costs associated with weakened patent rights.

This report surveys current issues related to patent and innovation policy, including patent subject-matter eligibility standards; patent quality; patent validity challenges; equity in innovation; past congressional action; current legislative proposals; and selected policy options.

## An Overview of the U.S. Patent System

Congressional authority over patent rights—a form of IP<sup>11</sup>—is set forth in the U.S. Constitution.<sup>12</sup> Under this authority, Congress has enacted patent laws that grant inventors the exclusive right to the make, use, import, sell or offer for sale their inventions for a set period, in exchange for publicly disclosing information related to their inventions.

The United States patent system has existed since 1790. The basic structure of modern U.S. patent law—including the general mechanics of patent administration and specific policies such as those governing what may be patented—however, was outlined in the Patent Act of 1952 (P.L. 82-593). The Patent Act of 1952 is codified in Title 35 of the U.S. Code.

Congress established the United States Patent and Trademark Office (USPTO) to issue patents on behalf of the government.<sup>13</sup> As the entity responsible for administering the U.S. patent system, USPTO:

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getting-tangible-about-intangibles-the-future-of-growth-and-productivity. See also, Neal Solomon, “Correlation of U.S. Patent System and Productivity Growth,” *IPWatchdog*, September 29, 2016, at <https://www.ipwatchdog.com/2016/09/29/correlation-us-patent-system-productivity-growth/id=73254/>.

<sup>9</sup> Andrew A. Toole, Richard D. Miller, and Nicholas Rada, *Intellectual Property and the U.S. Economy: Third Edition*, USPTO, Alexandria, VA, March 2022, p. 3, at <https://www.uspto.gov/ip-policy/economic-research/intellectual-property-and-us-economy>. To identify IP-intensive industries, the study constructed a measure of industry-level IP intensity (for each form of IP protection: utility patents, design patents, trademarks, and copyrights) equal to the number of IP rights obtained during the five-year period ending in 2016 per 1,000 employees.

<sup>10</sup> *Ibid.*, p. iii.

<sup>11</sup> Patents represent one of four main forms of federal legal protection for IP: patents, copyrights, trademarks, and trade secrets. For a comprehensive overview and analysis of IP law see CRS In Focus IF10986, *Intellectual Property Law: A Brief Introduction*, by Kevin J. Hickey.

<sup>12</sup> Article I, Section 8, Clause 8, empowers Congress to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”

<sup>13</sup> The Patent Office was established in 1802 within the Department of State and was overseen by a “Superintendent of Patent.” In 1836, newly enacted patent laws reorganized the office, designating the “Commissioner of Patents” as the head official. The Patent Office was transferred from the Department of State to the Department of Interior in 1849 and later transferred to the Department of Commerce in 1925, where it remains today. In 1975, the Patent Office was renamed as the Patent and Trademark Office, before receiving its current name in 2000—the United States Patent and Trademark Office. For more on the organizational history of USPTO see the “United States Patent and Trademark Office” section of “General Information Concerning Patents,” USPTO, available at <https://www.uspto.gov/patents/>

examines applications and grants patents on inventions when applicants are entitled to them; it publishes and disseminates patent information, records assignments of patents, maintains search files of U.S. and foreign patents, and maintains a search room for public use in examining issued patents and records.<sup>14</sup>

USPTO grants three types of patents: utility patents, which “may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof”; design patents, which “may be granted to anyone who invents a new, original, and ornamental design for an article of manufacture”; and plant patents, which “may be granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant.”<sup>15</sup>

Patent applications are reviewed by USPTO technical experts referred to as patent examiners. The process of applying for and (potentially) receiving a patent is called “patent prosecution.” In order to receive a patent, an applicant must satisfy a number of requirements related to the specificity and scope of information disclosed in the patent application. A patent application must contain a sufficiently detailed and clear description of an invention to enable a person skilled in the field to make and use the claimed invention. A patent’s technical details, which are referred to as its “specification,” must also be detailed enough to support the patent’s “claims.” Patent claims constitute an important aspect of the patent application, as they must clearly define the scope of the exclusive legal rights potentially granted by the patent.

Other patentability requirements relate to the substance of the invention. In general, to be patentable, an invention must be useful, novel, and nonobvious, and claim patentable subject matter. The requirement of usefulness, or utility, is satisfied if the invention is operable and provides some tangible benefit.<sup>16</sup> To be judged novel, the invention must not be fully anticipated by a prior patent, publication, or other state of the art knowledge that is collectively termed the “prior art.”<sup>17</sup> A nonobvious invention must not have been readily within the ordinary skills of a competent artisan at the time the invention was made.<sup>18</sup>

In the process of determining an invention’s patentability, a USPTO examiner considers a range of guidance, including statutory definitions of patentability established by Congress, judicial guidance that may interpret or clarify statutory standards of patentability, as well as guidance issued by USPTO in its *Manual of Patent Examining Procedure* (MPEP) that specifies how examiners should apply such standards when evaluating patent applications.<sup>19</sup>

If the patent examiner judges an application and corresponding invention as having met these requirements, USPTO will issue a patent. A patent confers certain legal rights on its owner for a period beginning when the patent issues and ending twenty years after the date the patent application was filed.<sup>20</sup> A valid patent grants its holder the “right to exclude others from making, using, offering for sale, or selling” the covered invention in the United States, as well as the right

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basics/general-information-patents.

<sup>14</sup> USPTO, “General Information Concerning Patents,” available at <https://www.uspto.gov/patents/basics/general-information-patents>.

<sup>15</sup> Ibid.

<sup>16</sup> 35 U.S.C. §101.

<sup>17</sup> 35 U.S.C. §102.

<sup>18</sup> 35 U.S.C. §103.

<sup>19</sup> USPTO, *Manual of Patent Examining Procedure*, 9<sup>th</sup> ed., Alexandria, VA, June 2020, available at <https://www.uspto.gov/web/offices/pac/mpep/index.html>.

<sup>20</sup> 35 U.S.C. §154(a)(2).

to exclude others from importing the invention into the United States.<sup>21</sup> Persons that violate these exclusive rights are said to “infringe” the patent, and may be sued in court for money damages or other legal remedies.<sup>22</sup> Thus, a patent grants its owner only the “negative” right to prevent others from using the invention without permission, and not the “positive” right to practice (use) the invention, which distinguishes it from other forms of property rights.<sup>23</sup> Once the term of the patent ends, the covered invention enters into the public domain and may generally be used freely by anyone without regard to the expired patent.

Patent rights are not self-enforcing; patentees must enforce their patents. The main way patents are enforced is through civil lawsuits that patentees may file against alleged infringers in federal district court.<sup>24</sup> The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) possesses national jurisdiction over most patent appeals from district courts. The U.S. Supreme Court has discretionary authority to review cases decided by the Federal Circuit.

## Role of Patents in U.S. Innovation Policy

Patent ownership is designed to incentivize innovation by offering a limited-time monopoly over the use of an invention in exchange for public disclosure of information related to the invention (published in the patent application). In this way, the patent system is intended to encourage the long-term economic growth that many perceive as resulting from innovation. This section surveys various explanations of how the patent system encourages inventive activity as well as competing views that assert patent policies may inhibit innovation.

Patent ownership is intended to stimulate the investment necessary to develop an idea and bring it to the marketplace. It is primarily through the commercialization and use of new products and processes that companies and economies realize productivity gains and the scope and quality of goods and services are expanded. Patent licensing, in particular, allows patent holders to secure a return on investment by allowing others to make or use the patented product or process in exchange for some agreed-upon remuneration. For example, patent licensing may allow patent holders to receive a return on investment even if the patent holder lacks the capacity to bring an invention to market (such as in cases when required capital or manufacturing facilities are unavailable), or chooses not to engage in the commercialization process (such as an academic researcher lacking an interest in entrepreneurship).

Another often-cited positive effect relates to the patent system’s encouragement of the disclosure of new products and processes, which might otherwise be kept as trade secrets by their discoverers. Each issued patent must include a description sufficient to enable skilled artisans to practice the patented invention.<sup>25</sup> At the end of the patent’s 20-year term, others may practice the claimed invention without regard to the expired patent. In this manner the patent system ultimately contributes to the growth of knowledge in the public domain.

<sup>21</sup> 35 U.S.C. §154(a)(1).

<sup>22</sup> 35 U.S.C. §28–29.

<sup>23</sup> This means the patent holder has legal recourse only when the right to have the patent *not* infringed is violated by an infringer.

<sup>24</sup> 35 U.S.C. §281. In some circumstances, patent owners may also file complaints with the U.S. International Trade Commission when they allege that articles being imported into the United States infringe their patent, 19 U.S.C. § 1337(a)(1)(B) cited in CRS Report R46525, *Patent Law: A Handbook for Congress*, coordinated by Kevin J. Hickey.

<sup>25</sup> 35 U.S.C. § 112.



Even during the term of a patent, others may be encouraged to “invent around” or, build upon, the disclosure contained in the patent to produce technologies that fall outside the exclusive rights associated with it.<sup>26</sup> In this way, a patent may point the way to new products, markets, economies of production, and even entire industries.

Some commentators argue, however, that this potential benefit has been greatly diminished by the increasing opacity with which inventions are commonly described in patent applications. They argue that this strategy may make it impossible to recreate an invention based on the associated patent application. If a patentee successfully avoids disclosing critical information that could lead to competitive innovation, it negates the original intent of the patent system.<sup>27</sup>

Though the belief that patents stimulate innovation is widely held and is the prevalent view motivating current policy discussions, others raise questions about the role and efficacy of patents in stimulating innovation.<sup>28</sup> Some argue that the U.S. patent system currently places a drag on innovation and that the rate of innovation and technological progress might be greater without the current patent regime.<sup>29</sup> Seeking to validate this perspective, one study examined the net effect patents have on stimulating firm investments in innovation by comparing patent-related profits to R&D spending rates.<sup>30</sup> In general, they found that the costs of patent litigation and the necessary R&D investments underlying patented inventions outweighed profits attributed to patents. The study, however, found two key industry-level variations in this trend. For firms in the chemical and pharmaceutical industries, patent profits largely eclipsed patent litigation and R&D costs.<sup>31</sup>

In 2016, Jason Furman, then Chairman of the White House Council of Economic Advisers, noted that “a balance needs to be struck between the dynamic incentives conferred by intellectual property [protections] and the static costs of the monopoly power.... Moreover, it is increasingly understood that overly stringent intellectual property practices can impede innovation itself—including by reducing the follow-on innovation that so often can be important, especially in areas like technology.”<sup>32</sup>

Other scholars have gone further. In a 2013 journal article, the authors argue that the patent regime should be completely dismantled and that patents do not significantly increase innovation and productivity and, in fact, may generally impede innovation by limiting market and intra-firm competition in a way that helps large, incumbent firms and harms small, new, creative

<sup>26</sup> Rebecca S. Eisenberg, “Patents and the Progress of Science: Exclusive Rights and Experimental Use,” *University of Chicago Law Review*, vol. 46, issue 3, pp. 1017-1170 (1989).

<sup>27</sup> Michele Boldrin and David Levine, “The Case Against Patents,” *Journal of Economic Perspectives*, vol. 27, no. 1 (2013), pp. 3-22.

<sup>28</sup> Zia Qureshi, “Boosting Productivity and Reducing Inequality: An Interconnected Policy Agenda,” in *Productive Equity: the Twin Challenges of Reviving Productivity and Reducing Inequality* (Brookings Institution and Chumir Foundation, 2019), p. 204; Petra Moser, “Patents and Innovation: Evidence from Economic History,” *Journal of Economic Perspectives*, vol. 27, no. 1 (2013), pp. 23-44; Heidi Williams, *How Do Patents Affect Research Investments*, National Bureau of Economic Research, Working Paper 23088, Cambridge, MA, 2017, at <https://www.nber.org/papers/w23088>.

<sup>29</sup> James Bessen and Michael Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (Princeton: Princeton University Press, 2008). The study evaluated a sample of public firms between 1995 and 1999.

<sup>30</sup> The study uses R&D spending as a measure of firm investment in innovation. *Ibid.*, p. 145.

<sup>31</sup> *Ibid.*

<sup>32</sup> Jason Furman, “Beyond Antitrust: The Role of Competition Policy in Promoting Inclusive Growth,” Remarks by the Chairman of the White House Council of Economic Advisers at the Searle Conference on Antitrust Economics and Competition Policy, Chicago, IL, September 16, 2016, at [https://obamawhitehouse.archives.gov/sites/default/files/page/files/20160916\\_searle\\_conference\\_competition\\_furman\\_cea.pdf](https://obamawhitehouse.archives.gov/sites/default/files/page/files/20160916_searle_conference_competition_furman_cea.pdf).



businesses.<sup>33</sup> Further, they argue that competition plays a more significant role than patent protections in stimulating innovation, citing as evidence historical examples where competitive business environments enabled the initial bursts of innovation that led to new industries.<sup>34</sup>

## Current Issues and Concerns

There are a number of policies that govern how patents are awarded, implemented, and protected that impact the patent system's ability to effectively incentivize innovation. The following section provides an overview of selected issues in patent policy that have been the subject of recent discussions and which have particular relevance to innovation policy.

### Patent Subject Matter Eligibility Standards

The types of inventions that can be patented may affect the patent system's ability to serve as an effective incentive for innovation. For example, if the standards of subject matter eligibility are set too broadly, inventors might be able to patent general concepts or principles that are so fundamental to technological progress that patent rights might block future innovation. By contrast, if eligibility standards are set too narrowly, important areas of technological development might be deemed ineligible, thus removing the incentive to invest in developing and commercializing particular technologies or fields.

In addition, an inconsistent application of eligibility standards might introduce enough uncertainty to the patent process that investors may view the potential financial rewards of securing patent rights as too risky to justify their investments. Such inconsistencies could have negative effects on innovation. As Kathi Vidal, Under Secretary of Commerce for Intellectual Property and Director of the USPTO, asserted in 2022, "innovation cannot thrive in uncertainty."<sup>35</sup>

Section 101 of the Patent Act provides the statutory basis for patent eligible subject matter. It outlines broad categories of innovation which are patentable, including any new and useful process, machine, manufacture, or composition of matter. In addition to the statute, subject matter eligibility criteria have been shaped by over a century of Supreme Court decisions, which have identified certain categories as not patent eligible, including abstract ideas, natural laws, and natural phenomena.<sup>36</sup>

The breadth of these judicially created exceptions has expanded in recent years with several prominent U.S. Supreme Court rulings from 2012 to 2014, including *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, and *Alice Corp. Pty. v. CLS Bank Int'l*.<sup>37</sup> These cases established a new two-step test, known as the

<sup>33</sup> Michele Boldrin and David Levine, "The Case Against Patents," *Journal of Economic Perspectives*, vol. 27, no. 1 (2013), pp. 3-22.

<sup>34</sup> Ibid. Boldrin and Levine cite innovations related to chemicals, cars, radio, television, personal computers, and investment banking as examples of the relatively importance of competition compared to patent protections.

<sup>35</sup> USPTO, "Following a Series of Supreme Court Decisions, New USPTO Report on Patent Subject Matter Eligibility Finds Diversity of Views Regarding the Current State of Jurisprudence in the U.S.," press release, June 28, 2022, at <https://content.govdelivery.com/accounts/USPTO/bulletins/31df580>.

<sup>36</sup> United States Patent and Trademark Office, *Patent Eligible Subject Matter: Public Views on the Current Jurisprudence in the United States*, Report to Congress, June 2022, p. 3, at <http://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf>.

<sup>37</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012); *Ass'n for Molecular Pathology v.*

*Alice/Mayo* framework, to determine patentable subject matter.<sup>38</sup> In response to a letter from a bipartisan group of lawmakers,<sup>39</sup> USPTO published a July 2021 notice in the Federal Register inviting public comment on the impacts of recent subject matter eligibility jurisprudence on investment and innovation.<sup>40</sup>

In June 2022, USPTO submitted a report to Congress which reviewed the comments received on the topic of patent subject matter eligibility by a wide range of stakeholders, including legal associations, industry organizations, advocacy groups, nonprofit entities, businesses, law firms, practitioners, academics, and inventors.<sup>41</sup> Stakeholder feedback varied widely on the degree to which changes in the interpretation and application of subject matter eligibility standards either encouraged or impeded innovation. This variability underscores an important aspect of patent and innovation policy: changes to patent policy often impact innovative capacity in different ways depending on a number of factors, including the economic sector, industry, firm size in question, among others.

A number of groups reported that recent interpretations of subject matter eligibility standards are having positive impacts on innovation. For example, several civil liberties and nonprofit organizations argued in favor of current legal exclusions on the patentability of basic tools and concepts, which they claimed helped foster invention and innovation in the public interest. One group cited the example of freely-available genomic information that assisted researchers in the recent fight against COVID-19. Additionally, the 2022 USPTO report cited an investor who credited the inability to patent overly general ideas, particularly by “non-practicing entities” (NPEs)<sup>42</sup> with encouraging innovation by freeing up resources for firms to invest in development and commercialization that would otherwise be directed toward legal fees required to defend against infringement suits.<sup>43</sup>

Other respondents, however, reported negative impacts on innovation as a result of the expansion of judicially created exclusions, especially the life sciences and warned of the potential negative

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Myriad Genetics, Inc., 569 U.S. 576, 590-94 (2013); *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014).

<sup>38</sup> Step one addresses whether the patent claims are “directed to” a law of nature, natural phenomenon, or abstract idea. If the answer is no, the invention is patentable. If the answer is yes, however, the second step is applied. Step two asks whether the patent claims have an “inventive concept,” meaning that the patent claim amounts to something “significantly more” than a patent on an ineligible concept. For an overview of the case and its legal implications for the patent process, especially the two-step test determining subject matter eligibility referred to as the *Alice/Mayo* framework, see CRS Report R45918, *Patent-Eligible Subject Matter Reform in the 116th Congress*, by Kevin J. Hickey.

<sup>39</sup> Letter from Senators Thom Tillis, Christopher A. Coons, Mazie Hirono, and Tom Cotton, United States Senate, to Drew Hirshfeld, Commissioner for Patents, March 5, 2021, at <https://www.tillis.senate.gov/services/files/04D9DCF2-B699-41AC-BE62-9DCA9460EDDA>.

<sup>40</sup> Patent and Trademark Office, “Patent Eligibility Jurisprudence Study,” 86 *Federal Register* 36257, 2021.

<sup>41</sup> Public comments associated with Docket ID PTO-P-2021-0032 are available at <https://www.regulations.gov/docket/PTO-P-2021-0032>; also see U.S. Patent and Trademark Office, *Patent Eligible Subject Matter: Public Views on the Current Jurisprudence in the United States*, June 2022, appendix C, at <https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf>.

<sup>42</sup> NPEs are also referred to as “patent assertion entities” (PAEs) or, more colloquially, as “patent trolls.” These groups seek to profit from buying and asserting patent rights against other firms rather than commercializing or developing patentable inventions. For more information on NPEs and PAEs see CRS Report R46525, *Patent Law: A Handbook for Congress*, coordinated by Kevin J. Hickey.

<sup>43</sup> United States Patent and Trademark Office, *Patent Eligible Subject Matter: Public Views on the Current Jurisprudence in the United States*, Report to Congress, June 2022, p. 21, at <http://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf>.

implications for the United States' position as a global leader in innovation.<sup>44</sup> For example, one representative of the biotechnology industry stated that current interpretations of subject matter eligibility standards had jeopardized the industry's ability to develop and deliver "precision medicine, pharmaceutical treatments, and diagnostics" to patients.<sup>45</sup>

A third group of commenters argued that it was impossible to determine the relationship between patent eligibility standards and innovation. For example, a number of academics argued that determining whether limits on patent eligibility would increase or decrease innovation would require relying on a counterfactual scenario in which the evolution of innovation could be measured absent any change in eligibility standards.<sup>46</sup>

### *Implications for Investments in Innovation*

Changes to how patent eligibility standards are interpreted can also impact the ability of inventors to attract the capital investments on which their innovations rely. As discussed in a previous section, the patent system aims to incentivize individuals and businesses to engage in inventive activity and to commercialize such inventions. Any perceived risk to the reliability with which patent rights might secure financial returns on investment, however, might discourage such investments in the first place.

One USPTO study demonstrated that limiting the scope of what is considered patent-eligible subject matter may increase uncertainty for innovators using the patent system. This could serve as an impediment to innovation given that economic research has shown that greater levels of uncertainty may reduce investments.<sup>47</sup> Additionally, the study concluded:

Higher levels of uncertainty may also negatively impact previously issued patents by lowering their expected value, reducing patent purchases and licensing transactions, and limiting opportunities to obtain entrepreneurial financing.<sup>48</sup>

Many argue that the uncertainty and unpredictability in how subject matter eligibility standards have been interpreted especially affect startups and small and medium-sized enterprises (SMEs). Without reliable patent rights, such entities are, according to the USPTO, increasingly unable to attract the outside investments on which they rely more than larger firms.<sup>49</sup>

### *Implications for Emerging Technology*

Innovation in emerging technology areas may face unique challenges due to the restricted scope of what counts as patentable subject matter as well as the variability in how such standards are interpreted during the patent examination process. For example, an emerging area of policy

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<sup>44</sup> Ibid., p. 22.

<sup>45</sup> Quoted in *ibid.*, p. 22.

<sup>46</sup> Ibid., p. 21.

<sup>47</sup> Andrew Abel et al., "Options, the Value of Capital, and Investment," *Quarterly Journal of Economics*, vol. 111, issue 3, pp. 753-777 (1996); Edward Sherry and D. Teece, "Royalties, Evolving Patent Rights, and the Value of Innovation," *Research Policy*, vol. 33, issue 2, pp. 179-191 (2004); Joshua Gans et al., "The Impact of Uncertain Intellectual Property Rights on the Market for Ideas: Evidence from Patent Grant Delays," *Management Science*, vol. 54, issue 5, pp. 998-1014 (2008).

<sup>48</sup> Andrew A. Toole and Nicholas A. Pairorero, *Adjusting to Alice: USPTO Patent Examination Outcomes After Alice Corp. v. CLS Bank International* (2020), p. 2, at [https://www.uspto.gov/sites/default/files/documents/OCE-DH\\_AdjustingtoAlice.pdf](https://www.uspto.gov/sites/default/files/documents/OCE-DH_AdjustingtoAlice.pdf).

<sup>49</sup> United States Patent and Trademark Office, *Patent Eligible Subject Matter: Public Views on the Current Jurisprudence in the United States*, Report to Congress, June 2022, p. 41.

concern relates to patent-eligible subject matter standards as they apply to innovations in artificial intelligence (AI). Though the number of patent applications pertaining to AI-related subject matter have been increasing, stakeholders have reported concern that AI-inventions are at risk of patent ineligibility under the current framework because “they may be characterized as methods of organizing human activity, mental processes, or mathematical concepts.”<sup>50</sup>

## Patent Quality

In addition to subject matter eligibility standards, the quality of patents issued by USPTO is also widely considered a major factor in the patent system’s ability to stimulate or hinder innovation.<sup>51</sup> Patent quality generally refers to whether granted patents actually meet the standards of patentability specified in current statute. These include requirements that the invention claimed in a patent be novel,<sup>52</sup> non-obvious,<sup>53</sup> and clearly described.<sup>54</sup>

Perhaps the most frequently articulated justification for why patent quality matters for innovation relates to the patent system’s ability to confer rights to inventions with predictability and certainty. When unclear or otherwise invalid patents are granted, they can breed uncertainty in the enforceability of patent rights as well as make it more difficult for others to “invent around” a particular patent, thus making investing in innovation a riskier financial prospect. On the other hand, patent quality can also suffer if valid patents are wrongly rejected by examiners, potentially inhibiting the patent system’s ability to incentivize innovation.

Some argue that low patent quality is the result of the USPTO patent examination and administration processes.<sup>55</sup> One critique focuses on the effects of USPTO’s budget and its dependence on revenue collected by patent fees. Since 1991, USPTO has been almost solely funded by user fees associated with the application and maintenance of patents.<sup>56</sup> One study linked this budgetary structure to a rise in the issuance of low quality patents. Because the costs the agency incurs to examine patent applications outweigh the revenue generated by examination fees (which are paid when a patent application is filed), USPTO is heavily dependent on revenue from issuance and maintenance fees (which are paid only after a patent is granted) to fund its operations. The authors of the study stated that, as a result, USPTO might have a “possible incentive to grant rather than deny patents.”<sup>57</sup>

Other critiques of patent examination practices focus on the insufficiency of time examiners have to devote to patent application review.<sup>58</sup> Research has demonstrated that patent examiners spend

<sup>50</sup> Ibid, p. 1; see also USPTO, *Public Views on Artificial Intelligence and Intellectual Property Policy*, 2020, at [https://www.uspto.gov/sites/default/files/documents/USPTO\\_AI-Report\\_2020-10-07.pdf](https://www.uspto.gov/sites/default/files/documents/USPTO_AI-Report_2020-10-07.pdf).

<sup>51</sup> Patent quality should not be confused with patent value. The following discussion considers patent quality on the basis of a granted patent’s fulfillment of statutory patentability requirements. Though sometimes correlated with patent quality, patent value can be understood as relating to a patent’s potential market as well as the patent’s scope relative to the potential market, in addition to other factors.

<sup>52</sup> 35 U.S.C. §102.

<sup>53</sup> 35 U.S.C. §103.

<sup>54</sup> 35 U.S.C. §112.

<sup>55</sup> Halimah DeLaine Prado, “Reforming the Patent System to Support American Innovation,” *The Keyword*, Google, April 28, 2022 at <https://blog.google/outreach-initiatives/public-policy/reforming-the-patent-system-to-support-american-innovation/>.

<sup>56</sup> Michael D. Frakes and Melissa F. Wasserman, “Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO’s Granting Patterns,” *Vanderbilt Law Review*, vol. 66, no. 1 (2013), pp. 67-146.

<sup>57</sup> Ibid., p. 80.

<sup>58</sup> Patent application review includes a number of time-consuming procedures, including: “reading the application,

an average of 19 hours reviewing each patent application, which may not be adequate given that the initial burden of proving unpatentability rests on USPTO.<sup>59</sup> To reject a patent application, a patent examiner must explicitly state the reasons why it does not meet the patentability requirements. As a result, having insufficient time to fully vet an application might lead to examiners granting low quality patents due to time and, in effect, funding constraints.<sup>60</sup>

## Challenging the Validity of Issued Patents

Given the common opinion that poor quality patents impede innovation, congressional interest has also focused on the issue of what to do about such patents once they are granted. In 2011, Congress passed H.R. 1249, the Leahy-Smith America Invents Act (AIA, P.L. 112-29), considered one of the most substantial reforms to patent policy since the 1952 Patent Act.<sup>61</sup> The AIA introduced a number of reforms including new mechanisms by which to challenge the validity of issued patents.

Accused infringers have long been able to challenge patent validity if sued in court,<sup>62</sup> but the AIA introduced a new administrative means to challenge patents with the creation of the Patent Trial and Appeal Board (PTAB). Formed within USPTO, the PTAB reviews patent application rejections made by examiners (referred to as ex parte appeals) and decides patentability challenges raised by third parties about issued patents (referred to as AIA trials).<sup>63</sup> Third parties may challenge the validity of claims in issued patents before PTAB through two main types of proceedings: inter partes review (IPR) and post grant review (PGR).<sup>64</sup> Lawmakers intended the proceedings to provide an important avenue to address invalid patents “on the back end.”<sup>65</sup> Using IPR or PGR to challenge patents is often more advantageous than judicial proceedings for challengers as the PTAB process is typically faster, less expensive, and requires a lower burden of proof for invalidating patents.

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searching for prior art, comparing the prior art with the application, and (in the case of a rejection) writing a rejection, responding to the patent applicant’s arguments, and conducting an interview with the applicant’s attorney.” The process is elaborated in Michael D. Frakes and Melissa F. Wasserman, *Decreasing the Patent Offices Incentives to Grant Invalid Patents*, The Hamilton Project, Brookings, Policy Proposal 2017-17, December 2017, p. 11, at [https://www.hamiltonproject.org/papers/decreasing\\_the\\_patent\\_offices\\_incentives\\_to\\_grant\\_invalid\\_patents](https://www.hamiltonproject.org/papers/decreasing_the_patent_offices_incentives_to_grant_invalid_patents).

<sup>59</sup> Michael D. Frakes and Melissa F. Wasserman, “The Failed Promise of User Fees: Empirical Evidence from the U.S. Patent and Trademark Office,” *Journal of Empirical Legal Studies*, vol. 11, no. 4 (2014), pp. 602-636.

<sup>60</sup> Michael D. Frakes and Melissa F. Wasserman, “Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data,” *Review of Economics and Statistics*, vol. 99, no. 3 (2017), pp. 550-563; R. Polk Wagner, “Understanding Patent-Quality Mechanisms,” *Faculty Scholarship at Penn Law*, vol. 157 (2009), pp. 2135-2173 at [https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=2195&context=faculty\\_scholarship](https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=2195&context=faculty_scholarship); Gideon Parchomovsky and R. Polk Wagner, “Patent Portfolios,” *University of Pennsylvania Law Review*, vol. 154, issue 1, p. 77 (2005).

<sup>61</sup> John Villasenor, *The Comprehensive Patent Reform of 2011: Navigating the Leahy-Smith America Invents Act*, Brookings, Policy Brief #184, September 8, 2011, at <https://www.brookings.edu/research/the-comprehensive-patent-reform-of-2011-navigating-the-leahy-smith-america-invents-act/>; Nathan Hurst, “How the America Invents Act Will Change Patenting Forever,” *Wired*, March 15, 2013, Design, available at <https://www.wired.com/2013/03/america-invents-act/>.

<sup>62</sup> 35 U.S.C. §282(b).

<sup>63</sup> USPTO, “About PTAB,” at <https://www.uspto.gov/patents/ptab/about-ptab>.

<sup>64</sup> USPTO, “What Are AIA Proceedings?” at <https://www.uspto.gov/patents/patent-trial-and-appeal-board/about-ptab/what-are-aia-proceedings>.

<sup>65</sup> Senator Patrick Leahy and Senator Thom Tillis, “Ensuring That the Patent Trial and Appeal Board Is a Truly Fair and Impartial Forum,” *The Hill*, April 12, 2022, Opinion, at <https://thehill.com/blogs/congress-blog/3265982-ensuring-that-the-patent-trial-and-appeal-board-is-a-truly-fair-and-impartial-forum/>.



Critics, however, have criticized the PTAB's ability to invalidate patents, labeling it a "patent death squad."<sup>66</sup> Others have argued that the increased ability to challenge the validity of patents that USPTO has already deemed valid, undercuts the value and reliability of the patent system as a whole. For example, the Alliance of U.S. Startups and Inventors for Jobs (USIJ) has argued that the Patent Trial and Appeal Board and Inter Partes Review processes have introduced a degree of uncertainty that has stifled innovation.<sup>67</sup> Strong intellectual property protections, or the ability for an inventor to guarantee rights to a patent that has been issued, they argue, helps attract investments from venture capitalists who rely on patent protections to minimize risks to their investments. Groups like the USIJ report that the weakening of property rights by such reforms has led to a decrease in capital availability in patent-intensive industries and early-stage startups, which often entail the riskiest investments.<sup>68</sup>

## Equity in Innovation

Scholars, policymakers, and administrators have increasingly expressed concerns over who participates in America's innovation ecosystem, and who is and is not able to access the benefits it affords. For example, the Biden administration's Office of Management and Budget and the Office of Science and Technology Policy have emphasized the importance of "innovation for equity" in the "Multi-Agency Research and Development Priorities for the FY 2023 Budget" memoranda that is issued to the heads of executive departments and agencies each year outlining the priorities for federal R&D, including to "advance equity for all."<sup>69</sup>

This section of the report focuses on aspects of U.S. patent policy that are related to equity. For example, some have advocated for reforms to patent policy that might encourage particular inventions, such as pharmaceuticals, to be distributed more equitably during public health emergencies like the recent COVID-19 pandemic.<sup>70</sup>

Others have called for federal initiatives that focus on improving regional innovative capacity and the equitable distribution of patenting activity throughout the United States.<sup>71</sup> Analyzing the "geography of U.S. patenting," the *2022 Science and Engineering Indicators* report, published by the National Science Board, found that areas of high patenting intensity in the United States are primarily concentrated along the coasts, in Texas, and in parts of the Great Lakes and Rocky

<sup>66</sup> Peter J. Pitts, "'Patent Death Squads' vs. Innovation," *Wall Street Journal*, June 10, 2015, Opinion; Susan Decker, "Apple Likes the Patent 'Death Squad.' Allergan Pays to Avoid It," *Bloomberg*, September 2, 2017, Technology; Gene Quinn, "A Kinder, Gentler 'Death Squad' Ten Years in, Despite Some Reforms, the USPTO Is Still Killing U.S. Patents," *IP Watchdog*, September 19, 2021, Government.

<sup>67</sup> Alliance of U.S. Startups and Inventors for Jobs, "Why Patents Matter," at <https://www.usij.org/why-patents-matter>.

<sup>68</sup> USIJ, "For Principles for a Stronger Patent System," at <https://www.usij.org/4-principles-for-a-stronger-patent-system>.

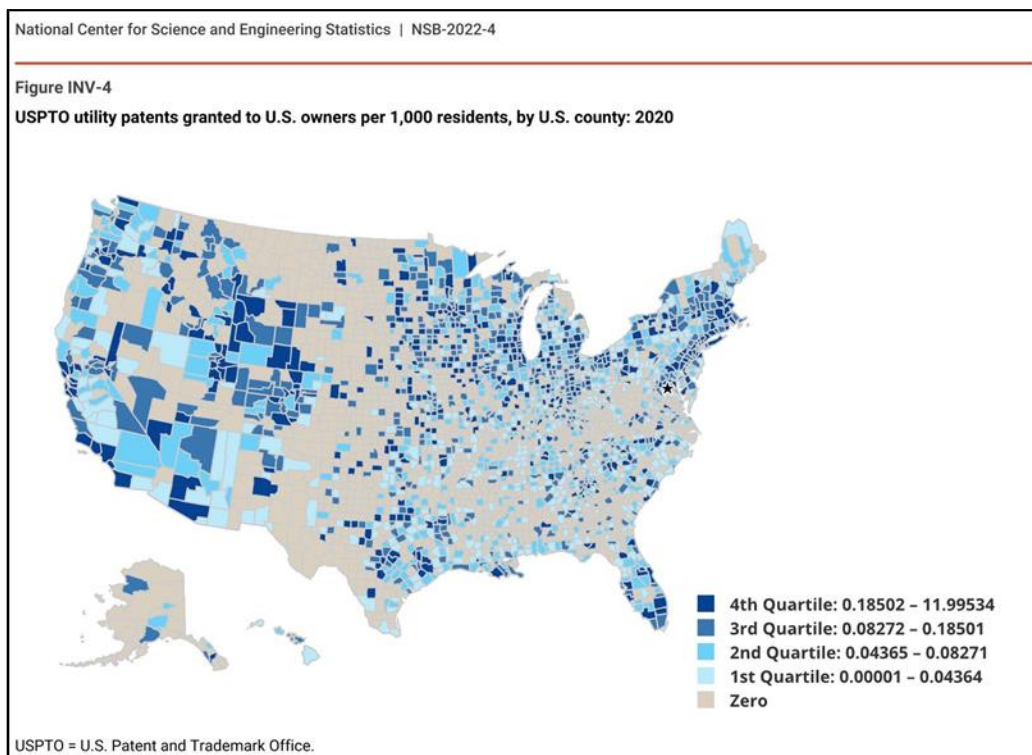
<sup>69</sup> "Multi-Agency Research and Development Priorities for the FY 2023 Budget," Memorandum for the Heads of Executive Departments and Agencies, From Shalanda D. Young, Acting Director, Office of Management and Budget; Eric S. Lander, Director, Office of Science and Technology Policy (M-21-32: August 27, 20221), p. 4; "Multi-Agency Research and Development Priorities for the FY 2024 Budget," Memorandum for the Heads of Executive Departments and Agencies, From Shalanda D. Young, Director, Office of Management and Budget; Alondra Nelson, Deputy Assistant to the President Performing the Duties of the Director, Office of Science and Technology Policy (M-22-15: July 22, 2022), p. 7.

<sup>70</sup> Shobita Parthasarathy, "Innovation as a Force for Equity," *Issues in Science and Technology*, vol. XXXVIII, no. 2 (Winter 2022).

<sup>71</sup> Jonathan Gruber and Simon Johnson, *Jump-Starting America: How Breakthrough Science Can Revive Economic Growth and the American Dream* (New York: Public Affairs, 2019).

Mountains regions (see **Figure 1**).<sup>72</sup> The report also found that, in 2020, 41.6% of U.S. counties had zero patents granted to owners residing in that county.<sup>73</sup>

**Figure 1. USPTO Utility Patents Granted to U.S. Owners Per 1,000 Residents, by U.S. County: 2020**



**Source:** Figure INV-4 National Center for Science and Engineering Statistics; Science-Metrix; PatentsView, USPTO, accessed June 2021; Population data from the U.S. Census Bureau accessed June 2021 at <https://www.census.gov/newsroom/press-releases/2021/2020-vintage-population-estimates.html> cited in National Science Board, National Science Foundation, *Invention, Knowledge Transfer, and Innovation. Science and Engineering Indicators 2022*, NSB-2022-4. 2022, at <https://ncses.nsf.gov/pubs/nsb20224/>.

Likewise, others have argued that who innovates also impacts the nation’s innovative capacity and potential economic impacts stemming from such innovations.<sup>74</sup> Some studies suggest that the marginalization of certain groups within society, in terms of who can access the “innovation ecosystem” (including advanced training and education, R&D funding, and venture capital) has a dampening effect on innovation.<sup>75</sup> When significant numbers of potential innovators do not

<sup>72</sup> National Science Board, National Science Foundation, *Invention, Knowledge Transfer, and Innovation. Science and Engineering Indicators 2022*, NSB-2022-4, Alexandria, VA, p. 19 at <https://ncses.nsf.gov/pubs/nsb20224/>.

<sup>73</sup> *Ibid.*, p. 20.

<sup>74</sup> Alexander Kersten and Gabrielle Athanasia, *Untapped Innovation? The Racial and Gender Divides That Hinder the U.S. Knowledge Economy*, Center for Strategic and International Studies, CSIS Briefs, May 2022, at [https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/220525\\_Kersten\\_Untapped\\_Innovation.pdf?xSNyYfIYj1TUIHfA\\_TJ7mdbu2TLxijpb](https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/220525_Kersten_Untapped_Innovation.pdf?xSNyYfIYj1TUIHfA_TJ7mdbu2TLxijpb).

<sup>75</sup> Lisa D. Cook, *Policies to Broaden Participation in the Innovation Process*, The Hamilton Project, Brookings, Policy Proposal 2020-11, August 2020.



participate in the innovation process, they assert, their unique perspectives and ideas on problems confronting society and potential solutions are lost.<sup>76</sup>

For example, a 2010 study found that during the period from 1970 to 2006, Black inventors in the United States were granted 6 patents per million people, compared to the overall rate (including all inventors) of 235 patents per million people.<sup>77</sup> Another paper cited a 2016 study, which found Black Americans “apply for patents at nearly half the rate of whites.”<sup>78</sup>

Additionally, one recent study published in *Nature* found that women are 58% less likely to receive credit for their work on patentable inventions than men.<sup>79</sup> Though the study’s authors recognize that numbers alone do not explain why women receive less credit, they argue that their analysis of related qualitative data reveals a more detailed explanation of potential causes. When interviewed, both men and women reported feeling that their work was underestimated but the study found that women more frequently reported such experiences.<sup>80</sup>

Some economists argue that the stakes of ignoring equity within the patent system are particularly high for the U.S. economy. For example, in a recent interview one economist asserted that attempts to promote innovation by narrowly focusing on ensuring strong property rights ignores other important factors that impact preconditions for innovation, such as societal inequities and even threats to physical safety, which may be experienced more acutely by various demographic groups within society. Additionally, she argued that these impacts limit the economic effects of innovative activity.<sup>81</sup>

## Considerations for Congress

Congress has demonstrated continued interest in technology and innovation policy in response to concerns about U.S. leadership in critical and emerging technology sectors as well as scientific research and development.<sup>82</sup> Given the perceived importance of patents in encouraging innovation, Congress may consider whether changes to the patent system are necessary in order to improve America’s innovative capacity.

<sup>76</sup> Holly Fechner and Matthew S. Shpanka, “Closing Diversity Gaps in Innovation: Gender, Race, and Income Disparities in Patenting and Commercialization of Inventions,” *Technology and Innovation*, vol. 19 (2018), pp. 727-734.

<sup>77</sup> *Ibid.*

<sup>78</sup> Shontavia Jackson Johnson, “The Colorblind Patent System and Black Inventors,” *Landslide*, The American Bar Association, vol. 2, no. 4 (2019).

<sup>79</sup> Matthew B. Ross et al., “Women Are Credited Less in Science Than Men,” *Nature*, vol. 608 (June 22, 2022), pp. 135-145.

<sup>80</sup> *Ibid.*

<sup>81</sup> Hyun-Sung Khang, “The Accidental Economist: Michigan State University’s Lisa D. Cook Shows How Racism and Sexism Hurt Us All,” *Finance & Development* (Publication of the International Monetary Fund), December 2020, pp. 48-51.

<sup>82</sup> National Science Board, *Vision 2030*, May 2020, at <https://www.nsf.gov/nsb/publications/2020/nsb202015.pdf>; The National Counterintelligence and Security Center, *Protecting Critical and Emerging U.S. Technologies from Foreign Threats*, October 2021, at [https://www.dni.gov/files/NCSC/documents/SafeguardingOurFuture/FINAL\\_NCSC\\_Emerging%20Technologies\\_Factsheet\\_10\\_22\\_2021.pdf](https://www.dni.gov/files/NCSC/documents/SafeguardingOurFuture/FINAL_NCSC_Emerging%20Technologies_Factsheet_10_22_2021.pdf).

## Patent Eligibility Standards

A range of policy options currently exist regarding the scope, clarification, and consistent implementation of patent subject matter eligibility standards to protect and encourage innovation, especially in particular emerging technology sectors. Options include statutory changes that might clarify judicial standards as well as altering aspects of patent administration, such as the examination process.

### *Changing Statutory Standards*

Given potential uncertainty over subject matter patent-eligibility, Congress may consider changing the statutory standards governing which inventions are patentable.

An example of this approach is found in Section 7 of H.R. 5874, the “Restoring America’s Leadership in Innovation Act of 2021, which would amend Section 101 of Title 35 of the U.S. Code to abrogate the previously cited Supreme Court decisions relating to patentable subject matter. The bill would institute an eligibility exception only for any invention that “exists in nature independently of and prior to any human activity, or exists solely in the human mind.”<sup>83</sup> As a result, H.R. 5874 seeks to “ensure that life sciences discoveries, computer software, and similar inventions and discoveries are patentable, and that those patents are enforceable.”<sup>84</sup>

Congress may also wish to consider legislation that would build on the intent of judicial standards relating to patentability, while also specifying statutory exceptions related to certain technologies. Given the potential economic impacts of innovations in critical and emerging technology areas (artificial intelligence, quantum computing, biotechnology, etc.), Congress may wish to create specific statutory exceptions to patent eligibility standards to ensure that innovations in these fields are eligible for patents.

Creating such specific exceptions could serve as a mechanism by which to tailor patent policy in a way that simultaneously addresses the concerns of multiple stakeholders: those who favor eligibility standards that exclude abstract ideas because they operate in industries where overly vague patents routinely serve as the basis for what some see as abusive litigation practices and those who oppose such exclusions because they are seen as a threat to the viability of patents in emerging fields that rely on comparatively abstract concepts.<sup>85</sup>

S. 4734, the Patent Eligibility Restoration Act of 2022, for example, would replace current judicial exceptions to patent eligibility with a list of more limited statutory exceptions.<sup>86</sup> Proponents of the bill argue that it would provide much needed clarity to patent eligibility exceptions and could expand eligibility for patents related to software or the life sciences.<sup>87</sup> Some of the bill’s critics, however, argue that it doesn’t provide enough clarity and that innovations in areas like medical diagnostics, many of which have been deemed ineligible to be patented under current standards, would still face uncertainty. They argue that the bill could include more specific language addressing medical diagnostics and processes, to ensure that future developments in the field would be patent eligible.<sup>88</sup>

<sup>83</sup> H.R. 5874 §7.

<sup>84</sup> Ibid.

<sup>85</sup> S. 4734.

<sup>86</sup> S. 4732 §2.

<sup>87</sup> Samantha Handler and Riddhi Setty, “New Patent Eligibility Bill Takes Aim at High Court Inaction,” *Bloomberg Government*, August 3, 2022.

<sup>88</sup> Ryan Davis, “New Patent Bill Could Boost Diagnostics, but Needs Work,” *Law360*, August 12, 2022.

## Changes to the Patent Examination Process

Congress may wish to consider reforms to patent administration. Such an approach might include directing USPTO to issue technology-specific guidance to patent examiners that would influence how subject matter eligibility standards are applied during the prosecution process. This could avoid inconsistency or undue effects on emerging technology areas—especially if the policy goal is to incentivize innovation in these fields.

For example, the Supreme Court’s 2014 decision in *Alice Corp. Pty. v. CLS Bank Int’l* rejected a patent claim on a method of mitigating settlement risk in financial transactions using a computer because the claim pertained to an abstract idea. Subsequently, USPTO reported that the allowance rate for patent applications containing AI applications or, the number of applications judged by USPTO examiners to meet the standards of patentability and other specified requirements, decreased based on subject matter ineligibility compared to non-AI related applications.<sup>89</sup> USPTO responded to such concerns by giving additional guidance to patent examiners that clarified how to apply the Supreme Court’s two-step subject matter eligibility test, known as the *Alice/Mayo* framework, which led to an increase in the allowance rate for applications containing AI.<sup>90</sup>

In a July 2022 *Director’s Blog* post, USPTO Director Kathi Vidal commented on past agency efforts to improve subject matter eligibility guidance and signaled the agency’s interest in potentially making additional changes.<sup>91</sup> As part of this effort, USPTO has requested public feedback and comments on subject matter eligibility guidance for examiners by September 15, 2022.<sup>92</sup> Based on USPTO’s findings and any potential actions, Congress may wish to continue oversight on this issue, consider additional actions, or review USPTO’s findings and assess the alternatives for technology-specific guidance for examiners to assist in the evaluation of whether related inventions qualify as subject matter eligible to ensure that innovation in emerging technology areas is not hindered.

## Patent Quality

To encourage the issuance of high quality patents, upon which the patent system’s ability to stimulate innovation depends, Congress may wish to consider a range of policy options to improve patent quality.

### Reforming the Patent Examination Process

S. 4704, the Patent Examination and Quality Improvement Act of 2022, introduced during the 117<sup>th</sup> Congress, expresses the “the sense of Congress that Congress must do more to enable the Office to improve—(1) the quality of patents issued by the Office; and (2) the patent examination process at the Office.” The act would require the U.S. Government Accountability Office (GAO) to submit a report to the House and Senate Judiciary committees on the patent examination process and the overall quality of patents issued by USPTO<sup>93</sup> that includes:

<sup>89</sup> *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014); United States Patent and Trademark Office, *Patent Eligible Subject Matter: Public Views on the Current Jurisprudence in the United States*, Report to Congress, June 2022, pp. 12-13.

<sup>90</sup> *Ibid.*, p. 13.

<sup>91</sup> Kathi Vidal, “Providing Clear Guidance on Patent Subject Matter Eligibility,” *Director’s Blog: the Latest From USPTO Leadership*, USPTO, July 25, 2022 at <https://www.uspto.gov/blog/director/entry/providing-clear-guidance-on-patent>.

<sup>92</sup> *Ibid.*

<sup>93</sup> S. 4704.

- Recommendations to improve patent quality and the examination process, specifically emphasizing how to avoid multiple claims and defining what constitutes a clear and thorough search by a patent examiner;
- An evaluation of whether USPTO needs to establish clear standards regarding what constitutes patent quality as well as establish patent quality metrics;
- An evaluation of whether USPTO needs to provide examiners with additional time to examine patent applications; and
- Recommendations to improve the training of patent examiners, including fields affected by emerging and complex technologies and data science, to ensure they are fully equipped to understand the applications of those technologies.<sup>94</sup>

The study's proposed scope would overlap with a 2016 GAO report that also reviewed issues related to patent quality. The 2016 report, *Intellectual Property: Patent Office Should Define Quality, Reassess Incentives, and Improve Clarity*, issued several recommendations, including those related to improving patent quality definitions and standards as well as increasing patent examination times—all of which the GAO website currently lists as “implemented” by the agency.<sup>95</sup> Given the persistence of concerns over patent quality, Congress may wish to consider additional GAO assessment of USPTO efforts to improve patent quality.

Reforms to USPTO's fee structure may offer a means to potentially improve the quality of issued patents. Some argue that USPTO's fee schedule should better align examination fees with examination costs, so that revenue is primarily generated through pre-allowance fees (collected before a patent is granted) rather than post-allowance fees (collected after a patent is granted).<sup>96</sup> Congress may wish to consider whether increases in examination fees might discourage under-resourced inventors and small and medium-sized enterprises (SMEs) from filing patents. Others argue that fee reductions meant to encourage SMEs to file patents have had the unintended consequence of biasing USPTO toward granting patents to larger firms, since their higher fee rates have the potential to generate higher revenues for the agency.<sup>97</sup>

The time USPTO examiners allocate to reviewing each patent application is another issue that may be of interest to Congress. Advocates for increasing examination time argue this may encourage a more consistent review process regardless of the specific examiner chosen to review an application.<sup>98</sup> Alternatively, increasing examination time without increasing USPTO resources to hire additional examiners might diminish the agency's capacity to review the patent applications received.

<sup>94</sup> Thom Tillis, “Tillis and Leahy Introduce Bipartisan Legislation to Improve Patent Quality,” press release, August 2, 2022, <https://www.tillis.senate.gov/2022/8/tillis-and-leahy-introduce-bipartisan-legislation-to-improve-patent-quality>.

<sup>95</sup> U.S. Government Accountability Office, *Intellectual Property: Patent Office Should Define Quality, Reassess Incentives, and Improve Clarity*, GAO-16-490, June 2016, at <https://www.gao.gov/assets/gao-16-490.pdf>.

<sup>96</sup> Michael D. Frakes and Melissa F. Wasserman, “Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO's Granting Patterns,” *Vanderbilt Law Review*, vol. 66, no. 1 (2013), p. 122.

<sup>97</sup> *Ibid.*, 124-125.

<sup>98</sup> Michael D. Frakes and Melissa F. Wasserman, *Decreasing the Patent Offices Incentives to Grant Invalid Patents*, The Hamilton Project, Brookings, Policy Proposal 2017-17, December 2017, p. 15, at [https://www.hamiltonproject.org/papers/decreasing\\_the\\_patent\\_offices\\_incentives\\_to\\_grant\\_invalid\\_patents](https://www.hamiltonproject.org/papers/decreasing_the_patent_offices_incentives_to_grant_invalid_patents).

## The Patent Trial and Appeal Board (PTAB)

A number of policy options have been proposed during the 117<sup>th</sup> Congress related to addressing concerns expressed about the role and efficacy of the PTAB, ranging from targeted reform to repeal.

### *Reforming or Eliminating PTAB*

Some members of Congress have proposed preserving the main functions of the PTAB, including IPR and IGR, but amending the AIA to improve their functioning, in light of previously discussed criticisms. For example, Senator Leahy, one of the original sponsors of the AIA, issued a statement in June 2022 touting the successes of PTAB proceedings but also acknowledging needed reforms.<sup>99</sup> One set of possible reforms was introduced in S. 4417, the Patent Trial and Appeal Board Reform Act of 2022, and included policies designed to cut down on the prevalence of serial petitions filed against patent owners, which may increase the costs required to defend their patent rights; prohibit USPTO from declining proceedings based on ongoing civil actions; and increase the transparency with which the USPTO director may engage with PTAB decisions.<sup>100</sup>

Others have proposed eliminating the IPR and PGR procedures created by the AIA. Critics of these proceedings have called for their abolishment. For example, H.R. 5874, Restoring America's Leadership in Innovation Act of 2021, introduced by Representative Thomas Massie, would repeal Sections 6 and 7 of the AIA which established IPR, PGR, and the PTAB.<sup>101</sup>

## Equitable Innovation

Congress could consider changes to U.S. patent policy to achieve a more equitable innovation ecosystem and, in doing so, whether such changes might potentially improve innovation and economic growth. Such changes could include policies that promote greater inclusiveness with respect to who participates in the innovation process and who benefits from innovation.

### *Inclusive Innovation: Collecting Biographical Data from Inventors*

The ability to develop potential policy solutions aimed at increasing the diversity of those participating in the innovation ecosystem may be restricted, in part, by the absence of data. Currently, USPTO does not request or track demographic information from patent applicants.<sup>102</sup> Such data may be helpful to policymakers in assessing the existence or scope of potential inequities embedded in the patent system and potentially offer insights into possible solutions.<sup>103</sup>

<sup>99</sup> Patrick Leahy, "Statement of Senator Patrick Leahy Hearing on 'The Patent Trial and Appeal Board: Examining Proposals to Address Predictability, Certainty, and Fairness,'" press release, June 22, 2022, at <https://www.leahy.senate.gov/press/statement-of-senator-patrick-leahy-hearing-on-the-patent-trial-and-appeal-board-examining-proposals-to-address-predictability-certainty-and-fairness>.

<sup>100</sup> S. 4417.

<sup>101</sup> H.R. 5874.

<sup>102</sup> Shontavia Jackson Johnson, "The Colorblind Patent System and Black Inventors," *Landslide*, vol. II, no. 4 (National Bar Association, 2019).

<sup>103</sup> Michelle K. Lee and Andrei Iancu, "To Get More Women and Minority Inventors, We Need Data," *International Business Times*, May 29, 2022, at <https://www.ibtimes.com/get-more-women-minority-inventors-we-need-data-3524667?amp=1>.

For example, two bills introduced in the 117<sup>th</sup> Congress, S. 632 and H.R. 1723, both known as the Inventor Diversity for Economic Advancement Act of 2021 or the IDEA Act, would require USPTO to request demographic information (defined as including gender, race, and military or veteran status) from the inventor on each patent application submitted to the agency. Both bills stipulate, however, that inventors would not be required to provide demographic information. The bills also include provisions that would direct USPTO to publicly report collected demographic data. The data collected may help clarify who participates in the innovation process, as measured by patents awarded, and potentially inform changes to patent policy that may encourage a more inclusive innovation ecosystem. Provisions from both bills were included in S. 1260, the United States Innovation and Competition Act of 2021, as engrossed in the Senate,<sup>104</sup> and H.R. 4521, the America COMPETES Act of 2022, as engrossed in the House.<sup>105</sup> Ultimately, however, provisions related to demographic data collection of inventors were not included in the enacted legislation, P.L. 117-167.<sup>106</sup>

Critics of S. 632 and H.R. 1723 have expressed concern that cases may arise where demographic information might be reported to USPTO without the consent of individual inventors.<sup>107</sup> Such cases might arise when a company CEO files a patent application that lists employees as co-inventors and discloses their demographic information without their permission. Congress may wish to weigh any potential benefits yielded by demographic data collection against any potential harms associated with privacy violations.

### ***Innovation for Equity***

Changes to patent administration policy might be used to incentivize specific categories of innovation, such as technologies that might mitigate poverty or uneven access to public health services.<sup>108</sup> For example, Congress might wish to consider whether USPTO could encourage patent applications in specific topic areas by offering reduced fees for particular applications, expediting application review, or other means.

In this regard, H.R. 5796, the Patents for Humanity Act of 2021 and S. 4210, the Patents for Humanity Act of 2022 introduced in the 117<sup>th</sup> Congress, would direct USPTO to hold a competition at least every two years that would recognize patent applications seeking to address humanitarian issues.<sup>109</sup> USPTO would award such applications certificates that would be used to accelerate certain agency proceedings.

## **Drug Affordability and IP Enforcement in International Trade**

Finally, though not the focus of this report, a number of bills under consideration by the 117<sup>th</sup> Congress include provisions that would affect aspects of patent policy and intellectual property rights related to two major concerns: prescription drug availability and affordability,<sup>110</sup> and the protection and enforcement of intellectual property rights, specifically within the context of

<sup>104</sup> S. 1260 §6204.

<sup>105</sup> H.R. 4521 §80102.

<sup>106</sup> P.L. 117-167.

<sup>107</sup> Megan Mineiro, “Senate Judiciary Committee Markup: Panel Advances Bipartisan Bill to Collect Gender and Other Demographic Data,” *CQ Committee Coverage*, April 29, 2021.

<sup>108</sup> *Ibid.*, xxxix.

<sup>109</sup> H.R. 5796 and S. 4210.

<sup>110</sup> For example, see H.R. 1976, H.R. 3035, H.R. 3788, H.R. 5260, H.R. 7430, S. 1435, S. 1683, and S. 1898.



international trade.<sup>111</sup> When evaluating potential changes to patent law and associated regulations to alter pharmaceutical pricing regimes or IP enforcement mechanisms in the global marketplace, Congress may wish to consider a number of overlapping policy and regulatory issues (see, for example, CRS Report R46679, *Drug Prices: The Role of Patents and Regulatory Exclusivities*, coordinated by Erin H. Ward; CRS Report R46741, *Drug Pricing and Intellectual Property: The Legislative Landscape for the 117th Congress*, by Kevin J. Hickey, Kevin T. Richards, and Erin H. Ward; and CRS In Focus IF10033, *Intellectual Property Rights (IPR) and International Trade*, by Shayerah I. Akhtar and Liana Wong).<sup>112</sup>

## Concluding Observations

If Congress chooses to enact patent reforms, it might consider the potential consequences, both intended and unintended, that such policies might have on the U.S. innovation ecosystem. For example, changes to patent subject matter eligibility standards might have an outsized effect on the patentability of emerging technologies. Additionally, changes to patent administration, especially administrative mechanisms used to challenge patent validity, might either strengthen or reduce the quality of patents issued by the USPTO. Any such changes to patent policy, for example, could impact the perceived certainty and enforceability of patent rights, which may increase the financial risk associated with investing in innovation. Additionally, the extent to which targeted reforms of the patent system might impact who participates in the U.S. innovation ecosystem as well as the quality of the inventions it produces.

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<sup>111</sup> For example, see H.R. 2471, S. 1060, S. 1169, S. 1245, S. 1924, S. 3799, S. 39, and S. 687.

<sup>112</sup> Additional related CRS resources include: CRS Report R46679, *Drug Prices: The Role of Patents and Regulatory Exclusivities*, coordinated by Erin H. Ward; CRS In Focus IF11561, *Pharmaceutical Patenting Practices: A Legal Overview*, coordinated by Kevin J. Hickey; CRS In Focus IF11214, *Drug Pricing and the Law: Pharmaceutical Patent Disputes*, by Kevin J. Hickey; CRS Report RL34292, *Intellectual Property Rights and International Trade*, by Shayerah I. Akhtar, Ian F. Fergusson, and Liana Wong; CRS In Focus IF11858, *Potential WTO TRIPS Waiver and COVID-19*, by Shayerah I. Akhtar and Ian F. Fergusson; and CRS Report R46532, *Intellectual Property Violations and China: Legal Remedies*, coordinated by Kevin J. Hickey.



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