



**STATEMENT OF**

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For a Hearing on:

**“The State of Patent Eligibility in America: Part II”**

Before

**United States Senate Committee on the Judiciary**  
**Subcommittee on Intellectual Property**

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Chairman Tillis, Ranking Member Coons, and Members of the Subcommittee,  
Thank you for the opportunity to testify on behalf of the American Civil Liberties Union (ACLU)<sup>1</sup> and for holding this hearing on “The State of Patent Eligibility in America.”

Chairman Tillis and Ranking Member Coons have released a draft of legislation that would rewrite Section 101 of the Patent Act. Section 101 governs what subject matter is eligible to be patented. Courts have long recognized that laws of nature, such as naturally occurring correlations and processes, products of nature, like human genes, and abstract ideas are not patent-eligible. The draft bill would overrule these longstanding precedents and would direct courts to construe Section 101 in favor of patent-eligibility. The effect will be to greatly expand what can be patented, opening the door to a world in which private parties could claim 20-year monopolies on, for example, human genes, associations between genes and diseases, naturally occurring associations or processes, or common abstract practices, like hedging risk, through clever drafting by patent lawyers. By eradicating categories of subject matter ineligible to receive patents, the legislative proposal would no longer disallow patents on what should properly remain in the commons.

The Tillis-Coons framework’s expansion of patent eligibility would also trigger constitutional questions. The framework would permit government-sanctioned monopolies to private parties over fields of knowledge, limiting information sharing and free experimentation, raising serious concerns about whether the patent system would be blocking, rather than promoting, progress. There can be little doubt that government-granted exclusive monopolies over bodies of knowledge, including patents on human genes, human thought processes, or abstract ideas would violate our constitutional rights to speak, and express ourselves, and receive information free from government restraint.

Patents on human genes and their connections with diseases are a prime example of the importance of the current Section 101 exceptions to preventing patents that impede innovation and scientific inquiry. The ACLU brought a lawsuit on behalf of 20 plaintiffs including the Association for Molecular Pathology, geneticists, patients, and others challenging the validity of patents held by Myriad on two genes – BRCA1 and BRCA2 – that are associated with a high risk of cancer.<sup>2</sup> We argued that human genes are products of nature and that genes and other naturally occurring matter and relationships should never be granted to anyone as intellectual property.<sup>3</sup> The Supreme Court unanimously ruled that human genes, when isolated from the genome, are not patent-eligible because they are products of nature.

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<sup>1</sup> For nearly 100 years, the ACLU has been our nation’s guardian of liberty, working in courts, legislatures, and communities to defend and preserve the individual rights and liberties that the Constitution and laws of the United States guarantee everyone in this country. With more than three million members, activists, and supporters, the ACLU is a nationwide organization that fights tirelessly in all 50 states, Puerto Rico, and Washington, D.C., to preserve American democracy and open government.

<sup>2</sup> Brief for Petitioners, *The Assoc. for Molecular Pathology, et. al*, 566 U.S. 66 (2012) (No. 12-398). In addition to arguing that Myriad’s patents were not patent-eligible under Section 101 of the Patent Act, the ACLU also argued that Myriad’s patents violated the First Amendment to the Constitution because they granted one private party a monopoly over an entire area of knowledge, depriving scientists of the opportunity to examine and study the BRCA 1 and BRCA 2 genes. *Id.* at 57.

<sup>3</sup> *Id.* At 23-25.

The *Myriad* decision was not radical. It interpreted and applied 150 years' worth of precedent regarding patentable subject matter.<sup>4</sup> *Myriad* was part of a series of recent unanimous Supreme Court cases from 2012-2014 that affirm and clarify the law of nature, product of nature, and abstract idea exceptions to patent-eligibility under Section 101 of the Patent Act.<sup>5</sup> These cases have created a legal foundation that is promoting innovation and competition across numerous sectors, ensuring that the basic tools of ingenuity are not tied up for the exclusive use of one entity. As just one example of the case law improving the affected markets, the same day the Supreme Court issued its decision in *Myriad*, five laboratories announced they would provide *BRCA* testing to patients, significantly reducing cost and providing more comprehensive testing.<sup>6</sup>

The ACLU opposes the draft bill released by Senators Coons, Tillis, and Reps. Johnson, Stivers, and Collins. The changes to Section 101 it proposes will reduce access to information about our own genetic risks and raise the prices of medical care, harming patients and their families. The draft bill released by Chairman Tillis and Ranking Member Coons would rewrite Section 101 of the Patent Act.<sup>7</sup> “[T]he underlying policy of the patent system [is] that ‘the things which are worth to the public the embarrassment of an exclusive patent,’ . . . must outweigh the restrictive effect of the limited patent monopoly.” I.<sup>8</sup> “The basic tools of scientific and technological work”<sup>9</sup> do not meet that test (but they are not the only example). Under the bill, laws of nature, natural phenomena, and abstract ideas will be patent-eligible for the first time. The bill would clearly make human genes, isolated from the rest of the genome, patent-eligible again. It would also create tremendous uncertainty regarding patent-eligibility, potentially broadening patentable subject matter to allow exclusivity claims on naturally occurring correlations, well-known and common processes, or even human thought, if applications are cleverly drafted by patent lawyers.

We are also concerned that patient advocacy organizations and other groups representing communities that will be harmed by the changes to patent law under discussion have not been invited to testify. Dozens of organizations and individuals made submissions to the courts opposing these patents, including the American Medical Association, AARP, geneticist Eric Lander, economist Joseph Stiglitz, and the Southern Baptist Convention. We encourage the Subcommittee to schedule another hearing to invite more diverse perspectives, including our

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<sup>4</sup> See *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 573 U.S. 208, 216 (2014) (“We have interpreted 101 and its predecessors in light of [the patent-eligibility exception for laws of nature, natural phenomena and abstract ideas] for more than 150 year.”).

<sup>5</sup> See *Alice*, 573 U.S. at 208; *Myriad*, 566 U.S. at 66; *Mayo Collaborative Services v. Prometheus Labs.*, 566 U.S. 66 (2012). See also *Bilski v. Kappos*, 561 U.S. 593 (2010) (finding that a claim on a procedure for hedging risk in certain markets was not patent eligible because hedging risk is an abstract idea).

<sup>6</sup> Andrew Pollack, *After Patent Ruling, Availability of Gene Tests Could Broaden*, NY TIMES (Jun. 13, 2013), <https://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html>.

<sup>7</sup> Press Release, Sens. Coons and Tillis and Reps. Collins, Johnson, and Stivers release draft bill text to reform Section 101 of the Patent Act (May 22, 2019), <https://www.coons.senate.gov/newsroom/press-releases/sens-coons-and-tillis-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act>.

<sup>8</sup> See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148 (1989) (“Thus, from the outset, federal patent law has been about the difficult business ‘of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not.’”) (quoting 13 WRITINGS OF THOMAS JEFFERSON 335 (Memorial ed. 1904)).

<sup>9</sup> *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

partners at Breast Cancer Action, FORCE (Facing Our Risk of Cancer Empowered), and the Association for Molecular Pathology. Their input is necessary to guard against any unintended consequences of patent reform legislation.

**Congress should not overturn over a century and a half of court-developed precedent to rewrite Section 101 of the Patent Act allowing patents on natural laws, products of nature, and abstract ideas. The proposal released by Chairman Tillis and Ranking Member Coons will harm researchers, doctors, patients, and their families in the same ways they suffered before *Myriad* was decided. Indeed, these harms will only grow in an era where exclusivity over a piece of DNA or a naturally-occurring correlation will block the development of precision medicine and further innovations in genetic testing, research, and therapies. Additionally, the broad patent-eligibility contemplated by the Tillis-Coons framework for other naturally occurring relationships and abstract ideas will have a chilling effect on scientific inquiry, innovation, and development in other fields that will thwart the very purpose of the patent laws themselves.**

- I. The draft legislation would allow patenting of human genes, other naturally occurring matter and relationships, and abstract ideas and areas of general knowledge, though it has long been understood that they should never be granted to anyone as intellectual property.
  - a. **Genes are the most fundamental building block of life. No one invented genes. History has shown that granting private parties exclusive rights to genes stifles research and innovation by tying up all basic uses of the gene. No private party should have exclusive rights to our genes.**

The Constitution provides for patent-protection (as well as other intellectual property rights) in order to encourage innovation and the advancement of science and other useful arts to the benefit of the public.<sup>10</sup> However, “‘monopolization of [the basic tools of scientific and technological work] through the grant of a patent might tend to impede innovation more than it would tend to promote it,’ thereby thwarting the primary objective of the patent laws.”<sup>11</sup> To address that risk, the Supreme Court has long recognized important exceptions to the patent eligibility statute.<sup>12</sup> Laws of nature, natural phenomena, and abstract ideas are not patentable.<sup>13</sup> Despite this long-standing precedent, the Patent Office issued thousands of patents on human genes to companies, relying on the flawed logic that the first to sequence and isolate the DNA, or remove it from a human cell, could also patent it.<sup>14</sup>

The *Myriad* decision recognized a fundamental truth: genes and other naturally occurring matter and relationships should never be granted to anyone as intellectual property. The decision was also compelled by well-established precedent.<sup>15</sup> In *Diamond v. Chakrabarty*, the Court deemed

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<sup>10</sup> U.S. Const. Art. 1, §8, cl.8.

<sup>11</sup> *Alice*, 573 U.S. at 216 (quoting *Mayo*, 566 U.S. at 71).

<sup>12</sup> *Myriad*, 569 U.S. at 589.

<sup>13</sup> *Id.*

<sup>14</sup> See Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

<sup>15</sup> See *Myriad*, 569 U.S. at 590-92.

naturally-occurring bacterium to which scientists had added four plasmids, which made the bacterium capable of breaking down crude oil, to be patent-eligible.<sup>16</sup> The bacterium was new and had different characteristics from the bacterium in its naturally occurring state, and, therefore, was not a product of nature, but one of human invention.<sup>17</sup> Conversely, in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, the Court held that a mixture of naturally-occurring bacterium that aided in fixing nitrogen in soil was not patent-eligible, where the properties of each in the mixture was well known and mixing them did not alter them significantly.<sup>18</sup> Drawing from these precedents in *Myriad*, the Court unanimously concluded that the location and order of the nucleotides that make up BRCA1 and BRCA2 existed in nature and the process of isolating them from the genome did not significantly alter the genes from their natural state. Myriad did not invent the genes or add anything to them.<sup>19</sup> Moreover, the process of isolating them from the genome did not create a nonnaturally occurring molecule.<sup>20</sup> For those reasons, genes are products of nature and cannot be patented, even when isolated from the body by processes of human invention.

Many diverse groups and experts that called for the invalidation of these patents applauded the decision. They included geneticists Drs. Eric Lander and John Sulston, economist Joseph Stiglitz, the American Medical Association, AARP, Southern Baptist Convention and the U.S. Government itself. Indeed, the U.S. government argued before the Court that it should never have issued the patents granted on human genes in the first place.<sup>21</sup> Dr. Francis Collins, Director of the National Institutes of Health, hailed the ruling, saying in a statement that “[t]he decision represent[ed] a victory for all those eagerly awaiting more individualized, gene-based approaches to medical care.”<sup>22</sup>

The draft legislation would overrule this important case and, through its new definition of the statutory term “useful” would explicitly adopt one of the arguments made by Myriad in favor of their patents. Genes, isolated from the genome by human intervention, would be patentable, bringing us back to a time where companies could block access to information about one’s own body and appropriate care. Patentholders would control the cost of testing, the type of testing offered, and whether testing was even available; there is no obligation placed on patentholders to actually “use” what they have patented. Moreover, patent claims on genes and correlations between genes and diseases grant exclusive access to entire fields of knowledge to one entity thereby depriving scientists and other researchers the ability to examine and study genes. For that reason, gene patents also violate the First Amendment.<sup>23</sup> The draft legislation, therefore, also raises serious constitutional concerns.<sup>24</sup>

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<sup>16</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>17</sup> *Id.* 309-10.

<sup>18</sup> *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 334 U.S. 127 (1948).

<sup>19</sup> *Myriad*, 569 U.S. at 593-94.

<sup>20</sup> *Id.* At 594.

<sup>21</sup> Brief for the United States, as Amici Curiae Supporting Neither Party, 566 U.S. 66 (2012) (No. 12-398).

<sup>22</sup> Press Release, Statement by NIH Dr. Francis Collins on U.S. Supreme Court Ruling on Gene Patenting (Jun. 13, 2013) <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-director-francis-collins-us-supreme-court-ruling-gene-patenting>.

<sup>23</sup> Brief for Petitioners, The Assoc. for Molecular Pathology, et. al, at 56-57, 569 U.S. 66 (2012) (No. 12-398).

<sup>24</sup> *See*, *Intellectual Ventures, LLC v. Symantec*, 838 F. 3d 1307, 1322 (Fed. Cir. 2016) (Mayer, J. concurring) (arguing that “patents restricting constricting essential channels of online communication run afoul of the First Amendment); *In re Bilski*, 454 F. 3d 943, 1004 (Fed. Cir. 2008) (Mayer, J. concurring) (noting that patents on

**b. Other products of nature, including naturally occurring relationships, abstract ideas and areas of general knowledge should not be patent-eligible.**

*Myriad* was part of a series of recent unanimous Supreme Court cases from 2012-2014 that affirm and clarify the law of nature, product of nature, and abstract idea exceptions to patent-eligibility under Section 101 of the Patent Act. In addition to *Myriad*, in *Mayo Collaborative Services v. Prometheus Laboratories*, the Court unanimously held that a naturally occurring relationship between certain metabolite levels in the blood and the likelihood of whether a drug dosage is effective was not patent-eligible.<sup>25</sup> The biological relationship between the metabolite level and the appropriate drug dosage was a natural law, not one invented by the patentee. And, in *Alice Corp v. CLS Bank*, the Court, again unanimously, rejected a patent on a computer system that did little more than employ the well-known concept of using a third party to mitigate risks of financial settlement because the patent was directed at obtaining exclusivity over that abstract idea itself.<sup>26</sup> The ACLU opposed the patents in these cases for the very reasons found by the Court.<sup>27</sup> Patent claims on laws of nature, natural phenomena, and abstract ideas impede innovation and progress by reserving the building blocks of new invention to the exclusive use of one private entity.

The holdings in these cases were compelled by the same long-standing precedent at issue in *Myriad* and they address related concerns about preempting free inquiry and use of the store of knowledge that is available to all.<sup>28</sup> As with gene patents, patents that claim natural phenomena and abstract ideas or areas of general knowledge, rather than a new and useful *application* of those phenomena or ideas, will prevent others from using those phenomena or ideas in their own inventive processes.<sup>29</sup> “A principle in the abstract is a fundamental truth: an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.”<sup>30</sup> If it were otherwise, as the draft legislation would have it, patents could be granted to well-known practices like hedging risk,<sup>31</sup> mathematical formulas, such as  $E = mc^2$ ,<sup>32</sup> or human thoughts in relation to naturally occurring relationships so long as the claims were drafted to meet technical patent requirements.<sup>33</sup>

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methods of conducting business raise “significant First Amendment concerns by imposing broad restrictions on speech and the free flow of ideas.”)

<sup>25</sup> *Mayo Collaborative Services v. Prometheus Labs.*, 566 U.S. 66 (2012).

<sup>26</sup> *Alice Corp.*, 573 U.S. at 217.

<sup>27</sup> Brief for Petitioners, *The Assoc. for Molecular Pathology, et. al*, 566 U.S. 66 (2012) (No. 12-398); Brief for the Am. Civil Liberties Union, as Amicus Curiae Supporting Petitioners, 573 U.S. 208 (2014) (No. 13-298); Brief for the Am. Civil Liberties Union, as Amicus Curiae Supporting Petitioners, at 8, 566 U.S. 66 (2012) (No. 10-1150).

<sup>28</sup> *See Alice*, 573 U.S. at 217; *Mayo*, 566 U.S. at 80 (“A more detailed consideration of the controlling precedents reinforces our conclusion.”).

<sup>29</sup> *See* Brief for the Am. Civil Liberties Union, as Amicus Curiae Supporting Petitioners, at 8, 566 U.S. 66 (2012).

<sup>30</sup> *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (quoting *Le Roy v. Tatham*, 14 How. 156, 55 U.S. 175 (1852)).

<sup>31</sup> *Bilski v. Kappos*, 561 U.S. 593 (2010) (finding that a claim on a procedure for hedging risk in certain markets was not patent eligible because hedging risk is an abstract idea).

<sup>32</sup> *Mayo*, 566 U.S. at 70 (“Einstein could not patent his celebrated law that  $E = mc^2$ .”).

<sup>33</sup> *See Id.* at 82; *Assoc. for Molecular Pathology v. U.S. PTO*, 702 F. Supp. 2d 181, 185 (SDNY 2010) (noting that some have called the argument that isolated DNA is patentable a “lawyer’s trick” to circumvent the rule against patenting DNA and finding that isolated DNA is not patent eligible) *aff’d in part, reversed in part*, 689 F.3d 1303 (Fed. Cir. 2012). *See also* Brief for the Am. Civil Liberties Union, as Amicus Curiae Supporting Petitioners, at 8, 566 U.S. 66 (2012) (“Whatever patent law allows in these circumstances, the First Amendment does not permit the

- c. The draft legislation would greatly expand patent-eligibility, radically changing the way the eligibility of patents can be challenged, and opening the door for clever patent lawyers to claim what should properly remain in the public commons for all to study and use.**

Section 101 of the Patent Act currently states, in its entirety:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”<sup>34</sup>

The draft legislation would expand this provision by eliminating the law of nature, natural phenomena, and abstract idea exceptions and a century and a half of court precedent interpreting those concepts.<sup>35</sup> It would also eliminate the requirement that an invention be “new” and define the term “useful” to mean “any invention or discovery that provides specific and practical utility in any field of technology through human intervention.”

The bill would direct nearly all questions regarding what can be patented to other provisions in the statute, namely sections 102 (requiring inventions be novel), 103 (requiring that they not be obvious), and 112 (specification requirement). In *Mayo*, the Supreme Court dismissed this approach, specifically noting that “to shift the patent-eligibility inquiry entirely to these later sections risks creating significant legal uncertainty, while assuming those sections can do work that they are not equipped to do.”<sup>36</sup> These other provisions cannot be effectively used to challenge categories of improperly granted patents. Because Section 101 prohibited patents on natural phenomena, the Court’s decision in *Myriad* created precedent invalidating all patents on isolated DNA. If Section 101 had not contained these exceptions, patents on isolated DNA could only have been challenged on a case-by-case basis, examining the specific circumstances of the identification of the genes at issue.

The bill is not saved by its tightening of Section 112’s specification requirements, either.<sup>37</sup> Even with language narrowing the breadth of individual patents, our concerns remain because the overall effect will be to shift the structure of the statute to eliminate the principle that it is in the public interest that certain building blocks of human innovation should not be reserved to anyone’s exclusive use.

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government to control thoughts, whether it does so directly through regulation or by delegating that authority to a private party through a patent.”).

<sup>34</sup> 35 U.S.C. § 101.

<sup>35</sup> Press Release, Sens. Coons and Tillis and Reps. Collins, Johnson, and Stivers release draft bill text to reform Section 101 of the Patent Act (May 22, 2019), <https://www.coons.senate.gov/newsroom/press-releases/sens-coons-and-tillis-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act>.

<sup>36</sup> *Mayo*, 566 U.S. at 90.

<sup>37</sup> Section 112(f) would be amended to read “An element in a claim expressed as a specified function without the recital of structure, material, or acts in support thereof shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” Press Release, Sens. Coons and Tillis and Reps. Collins, Johnson, and Stivers release draft bill text to reform Section 101 of the Patent Act (May 22, 2019), <https://www.coons.senate.gov/newsroom/press-releases/sens-coons-and-tillis-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act>.

II. By granting patents to laws of nature, natural phenomena and abstract ideas, the draft bill would harm innovation in contravention of the purpose of the patent laws.

The Supreme Court, through its Section 101 jurisprudence, recognizes that patents on abstract ideas and natural phenomena, like those at issue in *Mayo* and *Alice*, violate the central constitutional and economic rationale of the patent laws.<sup>38</sup> Patents exist to spur innovation, creativity and capital investment in the public interest. They do so by granting a 20-year monopoly over the fruit of the inventive process.<sup>39</sup> Follow-on innovation results from others' access to information about the patented matter, allowing them to innovate around the patent, or improve upon the patented invention once it becomes part of the body of public knowledge when the patent expires. By contrast, patents that cover abstract ideas and natural phenomena *preclude* future innovation during their term because they deny future innovators the essential tools with which to innovate.<sup>40</sup>

Prior to the Supreme Court's *Myriad* decision, the Secretary of Health and Human Services' Advisory Committee on Genetics, Health and Society (SACGHS) issued a report finding that patents covering genetic material are unnecessary to protect scientific innovation, and harm patient welfare by limiting access to and reducing the quality of potentially lifesaving genetic testing.<sup>41</sup> The report found that the patent monopoly *does not* play a major role in driving genetic research. And, perhaps most importantly for the Subcommittee's interests, the report found evidence that gene patents serve the opposite ends of the patent system: gene patents impeded innovation.

Other studies from that period bolster those findings and provide additional evidence of the chilling effect that gene patents have on scientific inquiry.<sup>42</sup> For instance, in 2010, Heidi Williams with the National Bureau of Economic Research published an empirical study showing that during the period certain genes were covered by patents, there was a reduction in scientific research and product development on the order of a *third*.<sup>43</sup> In 2011, Berthels et al. showed a similar chilling effect for spinocerebellar ataxia, one of the conditions covered by the SACGHS study.<sup>44</sup>

The facts of *Myriad* are instructive as well. Myriad Genetics (Myriad) claimed patents over two human genes – *BRCA1* and *BRCA2*.<sup>45</sup> These patents granted Myriad a monopoly over the

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<sup>38</sup> *Alice*, 573 U.S. at 216 (quoting *Mayo*, 566 U.S. at 84 (“We have ‘repeatedly emphasized this ... concern that patent law not inhibit further discovery by improperly tying up the future use of’ these building blocks of human ingenuity.”)).

<sup>39</sup> ACLU Comment, Request for Comments and Notice of Public Hearing on Genetic Diagnostic Testing, USPTO, Docket No. PRO-P-2012-0003, at 3 (Mar. 26, 2012).

<sup>40</sup> *Id.*

<sup>41</sup> SACGHS, *Gene Patents and Licensing Practices and their Impact on Patient Access to Genetic Tests* (2010).

<sup>42</sup> See ACLU Comment, Request for Comments and Notice of Public Hearing on Genetic Diagnostic Testing, USPTO, Docket No. PRO-P-2012-0003, at 6-7 (Jul. 8, 2014). See also Mildred K. Cho, et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3-8 (Feb. 2003) (finding that clinical geneticists feel their research is hindered by patents).

<sup>43</sup> Heidi L. Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome* 26 (Nat'l Bureaus of Econ. Research Working paper 16,213, 2010).

<sup>44</sup> Nele Berthels, et al., *Impact of Gene Patents on Diagnostic Testing: A New Patent Landscaping Method Applied to Spinocerebellar Ataxia*, 2011 Eur. J. Hum. Genetics 1.

<sup>45</sup> *Myriad*, 569 U.S. at 583.



genes.<sup>46</sup> Myriad had exclusive rights to clinical testing of the *BRCA1* and *BRCA2* genes.<sup>47</sup> Myriad used those rights to shut down genetic testing performed by other laboratories, even when those laboratories used different testing methods.<sup>48</sup> Myriad also prevented other laboratories from providing more comprehensive testing of the genes, though its standard test for years did not include mutations that were known to be correlated to high risk for breast and ovarian cancer—resulting in patients receiving false negative results.<sup>49</sup> And because it had no competition, the price of its test rose dramatically over time, even as the cost of genetic testing was dropping.<sup>50</sup> The patents authorized Myriad to block all manner of scientific inquiry into the genes, chilling research at academic medical centers throughout the country.

History teaches that gene patents impede innovation, raise prices, and harm patients. In an era where scientists, medical professionals, and laboratories offer whole genome sequencing to patients and where precision medicine promises tailored therapies, permitting exclusivity over genes or naturally-occurring correlations between genes and diseases will only impede the progress of medicine and healthcare. The draft legislation would bring us back to this time of chilled scientific inquiry, increased healthcare and diagnostic costs, and lack of competition. The bill would authorize patenting of human genes and naturally-occurring associations between genes and diseases again. Indeed, it would explicitly adopt one of the arguments rejected by the Court regarding the patentability of genes isolated from the genome.<sup>51</sup> Allowing these patents will prevent the discovery of novel treatments for diseases including cancer, muscular dystrophy, Alzheimer’s disease, heart disease, and other rare and common diseases. It will also create barriers to patients’ access to potentially lifesaving genomic tests, eliminate access to confirmatory testing and dramatically increase the cost of tests that have benefited from innovation that led to reduced costs of DNA sequencing technology. Further, it will stymie competition for developing and improving diagnostic and clinical tests, and increase the cost and hinder advancement of targeted therapeutics involving genomic markers. That means higher costs for patients, payers, and the healthcare system overall. All of the harms the *Myriad* case addressed would happen again.

To cite a recent example of innovation that could have been affected by a gene patent, the Food and Drug Administration (FDA) recently approved a new gene therapy to treat a rare disease

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<sup>46</sup> Brief for Am. Med. Ass’n., Am. Soc’y of Human Genetics, Am. Coll. Of Obstetricians and Gynecologists et al. as Amici Curiae Supporting Petitioners, at 8 566 U.S. 66 (2012) (No. 12-398).

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> See Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 J. OF THE AM. MED. ASS’N 1379, 1386 (2006).

<sup>50</sup> Brief for Am. Med. Ass’n, *supra* note 8 at 11-15.

<sup>51</sup> The draft bill would define the term useful to mean “any invention or discovery that provides specific and practical utility in any field of technology through human intervention.” Press Release, Sens. Coons and Tillis and Reps. Collins, Johnson, and Stivers release draft bill text to reform Section 101 of the Patent Act (May 22, 2019), <https://www.coons.senate.gov/newsroom/press-releases/sens-coons-and-tillis-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act>. Myriad argued that its patents on *BRCA1* and *BRCA2* were valid because human intervention was necessary to isolate the genes from the rest of the genome. *Myriad*, 569 U.S. at 593.

found in infants.<sup>52</sup> At \$2.1 million dollars, it is the most expensive drug ever approved. The drug is called Zolgensma and it treats spinal muscular atrophy. At \$2.1 million dollars, the price is likely out of reach for many families, even if they have health insurance to help cover the cost. Nonetheless, the treatment gives families hope. Children currently being treated for SMA must undergo spinal injections for their whole lives, and the cost of that treatment is \$750,000 a year for the first year and \$375,000 per year after that. Now, we have a one-time gene therapy, that, over time, may cost less than the treatment currently offered. That \$2.1 million price tag could have been higher if the gene to which the therapy is targeted was patented. Royalties to the patent-holder could be owed or monopoly prices could be charged. If a company owned a patent on the gene, it could have prevented the research that led to the discovery of the treatment in the first place.

Reforming Section 101 is often presented as necessary to address uncertainty regarding patent-eligibility created by *Mayo*, *Myriad*, and *Alice*, and allegations that innovation has been chilled by these precedents.<sup>53</sup> Troublingly, there appears to be little, if any, reliable, peer-reviewed and independent evidence that reform to Section 101 is necessary to address any lack of innovation, research and development.<sup>54</sup> If anything, and as pointed out above, research has indicated that patents harm innovation and scientific inquiry in the gene patent context and forbidding such patents has benefited innovation.<sup>55</sup> There are also studies indicating that patents do little, if anything, to encourage innovation in other industries.<sup>56</sup> To our knowledge, there have been no studies establishing the utility and public benefit of patents granted on laws of nature, products of nature, and abstract ideas.

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<sup>52</sup> Chirstopher Rowland, *The FDA Approved a Gene Therapy That is The Most Expensive Drug in the World*, WASH. POST (May 24, 2019), [https://www.washingtonpost.com/business/economy/the-fda-approves-a-gene-therapy-that-is-the-most-expensive-drug-in-the-world/2019/05/24/57c66500-7e4a-11e9-8ede-f4abf521ef17\\_story.html](https://www.washingtonpost.com/business/economy/the-fda-approves-a-gene-therapy-that-is-the-most-expensive-drug-in-the-world/2019/05/24/57c66500-7e4a-11e9-8ede-f4abf521ef17_story.html).

<sup>53</sup> See, e.g., Sen. Chris Coons, *A Few Thoughts on the Supreme Court's Section 101 Jurisprudence*, IP WATCHDOG (Feb. 8, 2017), <https://www.ipwatchdog.com/2017/02/08/thoughts-supreme-courts-section-101-jurisprudence/id=78166/> (“Over the last eight years, however, a series of Supreme Court decisions on Section 101 have substantially moved the line on what is patent-eligible. These rulings have created uncertainty about the validity of previously issued patents, many of which companies have already relied upon to justify significant research and development investments.”); Am. Intellectual Property Law Assoc., *AIPLA/IPO/ABA-IPL Joint Principles Paper on Section 101*, <https://www.aipla.org/policy-advocacy/legislative/aipla-ipo-aba---ipl-joint-principles-paper-on-section-101> (last visited May 29, 2019).

<sup>54</sup> See Heidi L. Williams, *How to patents affect research investments?*, ANNUAL REV. OF ECON. Vol.: 9; 441 (Aug. 2017) (“Today, I would argue that given the limitations of the existing literature we still have essentially no credible empirical evidence on the seemingly simple question of whether stronger patent rights – either longer patent terms or broader patent rights – encourage research investments into development new technologies.”). See also Matthew Schuer, Vice President for Law and Policy at the Computer & Communications Industry Assoc., Testimony at Fed. Trade Comm’n Hearing “Competition and Consumer Protection in the 21<sup>st</sup> Century” (Oct. 23, 2018) (arguing that “[t]here is independent research that shows that patent valuations and secondary markets have remained largely unchanged after *Alice*” and that the evidence that Section 101 reform is necessary is largely overstated).

<sup>55</sup> See Brief for Petitioners, *The Assoc. for Molecular Pathology, et. al.*, at 43-44, 566 U.S. 66 (2012) (No. 12-398) (citing evidence that “[t]he effect of patents has been to prevent and deter research”); ACLU Comment, Request for Comments and Notice of Public Hearing on Genetic Diagnostic Testing, USPTO, Docket No. PRO-P-2012-0003, at 3 (Mar. 26, 2012) (collecting studies).

<sup>56</sup> See Michele Boldrin & David K. Levine, *The Case Against Patents*, 27 J. OF ECON. PERSPECTIVES 3 (2013) (finding “there is no empirical evidence that [patents] serve to increase innovation and productivity, unless productivity is identified with the number of patents awarded”); Dr. Andrew W. Torrance & Dr. Bill Tomlinson, *Patents and the Regress of Useful Arts*, COLUM. SCI. & TECH. LE. REV. 10 (2009) (finding that the patent system may not incentivize invention).

The benefits of rewriting 150 years of precedent interpreting patent-eligibility are, therefore, entirely unproven. The harms, however, are clear and well established. Rewriting Section 101 as the draft legislation proposes will raise the price of healthcare in many ways. Scientists, researchers, and small companies could be forced to pay royalties to patent-holders on patented naturally occurring correlations, human genes isolated from the body, and abstract concepts, if they are allowed to engage in research at all. Patent-holders will be able to exclude others from whole fields of knowledge and will charge monopoly prices to the public. Patients will lack access to confirmatory testing. Market-participants will be unable to improve upon inventions or testing accuracy during the patent-period. Each of these effects is contrary to the purpose of the patent law. Current Supreme Court precedent provides the solution. Laws of nature, natural phenomena, and abstract ideas are not patent-eligible and they should not be made so legislatively.

### III. The Constitution limits Congress's power to award patents.

Article I, Section 8, Clause 8 and the First Amendment limit the intellectual property laws.<sup>57</sup> In the copyright context, the potential conflict is more obvious and doctrines have developed under the statute that serve First Amendment values and promote progress.<sup>58</sup> The judicial exceptions to Section 101 of the Patent Act have not previously been described as compelled by the First Amendment. Nonetheless, the ability to gather information and think without constraint is central to human autonomy and a cornerstone of First Amendment doctrine. Patents claiming exclusive rights to abstract ideas, laws of nature, and natural phenomena conflict with that doctrine directly.<sup>59</sup>

Consider the patent claims at issue in *Alice*.<sup>60</sup> They directly claimed abstract knowledge, thought, and speech – specifically, the economic practice of using a third party to guarantee financial transactions. The process could have been carried out with a paper, pencil, and rotary phone. The only difference was that the process occurred on a computer, using software. One could imagine the concepts of lending or the attorney-client relationship being described as methods in patents similar to *Alice*'s patents.<sup>61</sup> If all that was necessary to convert these concepts to a patent-eligible invention was the addition of any generic computer and software, nearly any idea capable of being expressed in code could be patent-eligible.

Patents claiming such broad, abstract concepts create barriers to human thought and innovation because they reserve entire concepts and common practices to the exclusive use of one party, in violation of the First Amendment. “The unhindered potential to consider ideas, intellectual

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<sup>57</sup> Brief for Petitioners, *The Assoc. for Molecular Pathology, et. al*, 566 U.S. 66 (2012) (No. 12-398); Brief for the Am. Civil Liberties Union, as Amicus Curiae Supporting Petitioners, 573 U.S. 208 (2014) (No. 13-298); Brief for the Am. Civil Liberties Union, as Amicus Curiae Supporting Petitioners, at 8, 566 U.S. 66 (2012) (No. 10-1150).

<sup>58</sup> See, *Eldred v. Ashcroft*, 537 U.S. 186, 219 (2003); *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 538, 556 (1985).

<sup>59</sup> See *Whitney v. California*, 274 U.S. 357, 375 (1927) (Brandeis, J., concurring) (stating that the First Amendment protects the “freedom to think as you will and to speak as you think”); Laurence Tribe, *American Constitutional Law* § 12-1 (2d ed. 1988); Thomas Emerson, *The System of Freedom of Expression* 6 (1970).

<sup>60</sup> *Alice Corp.*, 573 U.S. at 217.

<sup>61</sup> Brief for the Am. Civil Liberties Union, as Amicus Curiae Supporting Petitioners, at 18, 573 U.S. 208 (2014) (No. 13-298).

concepts, and abstract knowledge is necessary for freedom of thought and speech.”<sup>62</sup> There can be little doubt that government-granted exclusive monopolies over entire bodies of knowledge, including patents on human genes, human thought processes, or abstract ideas would violate our constitutional rights to speak, express ourselves, and receive information free from government restraint.

IV. Consultation with Patient Advocates and Other Affected Groups is necessary and we encourage the Subcommittee to convene these groups to hear their perspective.

We fully agree with Chairman Tillis and Ranking Member Coons that soliciting input from a diverse array of stakeholders is key to a good legislative process and we appreciate that the Subcommittee is devoting time to hearings about this issue. However, important groups of stakeholders are missing from the groups invited to testify. As we mentioned at the outset, patient advocacy organizations have an interest in this discussion as well, as do the medical professionals and researchers who develop and provide genetic testing and make other advancements. We would encourage the Subcommittee to convene these groups at a hearing to focus on the effect that the proposed reforms to patent-eligibility could have on patients and their families. As *Myriad* demonstrated, patent-exclusivity can cause real harm to real people if they cannot obtain the information and the care that they need due to exorbitant costs and lack of competition. Input from patient advocates is necessary to guard against any unintended consequences of patent reform legislation.

V. Conclusion

If enacted, the draft will greatly expand what can be patented, opening the door to a world in which private parties could claim 20-year monopolies on, for example, human genes, associations between genes and diseases, naturally occurring associations or processes, or common abstract practices, like hedging risk, through clever drafting by patent lawyers. By eradicating categories of subject matter ineligible to receive patents, the legislative proposal would no longer disallow patents on what should properly remain in the commons.

The Tillis-Coons framework’s expansion of patent eligibility would also trigger constitutional questions. The framework would permit government-sanctioned monopolies to private parties over fields of knowledge, limiting information sharing and free experimentation, raising serious concerns about whether the patent system would be blocking, rather than promoting, progress.

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<sup>62</sup> *Id.* at 10.