[Date]

Senator Chris Coons
218 Russell Senate Office Building
Washington D.C., 20510

Senator Thom Tillis
113 Dirksen Senate Office Building
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Representative Doug Collins
1504 Longworth House Office Building
Washington D.C., 20515

Representative Hank Johnson
2240 Rayburn House Office Building
Washington D.C., 20515

Representative Steve Stivers
2234 Rayburn House Office Building
Washington D.C., 20515

Dear Sens. Coons and Tillis, and Reps. Collins, Johnson and Stivers:

We, the undersigned civil rights, medical, scientific, patient advocacy, and women's health organizations, write to express our opposition to the recent proposal to amend Section 101 of the Patent Act. The draft legislation if enacted would authorize patenting products and laws of nature, abstract ideas, and other general fields of knowledge. Most troublingly, the legislation would permit patenting of human genes and naturally-occurring associations between genes and diseases. 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 would 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 medical 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.

Section 101 of the Patent Act[1] permits issuing patents on new and useful processes, machines, manufacture or compositions of matter or any new and useful improvement therefor. For over 150 years, the Supreme Court has held that laws of nature, natural phenomena, and abstract ideas

[1] 35 U.S.C. § 101.

are not patent-eligible under the Patent Act.[2] Recent cases from 2012-2014, all issued by a unanimous Supreme Court, affirm and clarify these important exceptions to patent-eligibility. Specifically, 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.[3] The biological relationship between the metabolite level and the appropriate drug dosage was a natural law, not one invented by the patentee. In *Association for Molecular Pathology v. Myriad Genetics*, a fully united Court extended its reasoning in *Mayo* to human genes isolated from the body, finding that the genes were not significantly altered by isolation, and that such patents lock up genetic information, preventing others from scientific and medical work.[4] Finally, 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.[5]

These cases have created a legal foundation that is promoting innovation across numerous sectors. Of specific interest to signers on this letter were the issues before the Court in *Myriad*. In that case, Myriad Genetics (Myriad) claimed patents over two human genes – *BRCA1* and *BRCA2* – mutations in which correlate to a much greater risk of various forms of cancer (e.g., 50-80% risk of breast cancer and 20-50% risk of ovarian cancer, among others).[6] These patents granted Myriad a monopoly over the genes, which had serious consequences for patients.[7] Myriad had exclusive rights to clinical testing of the *BRCA1* and *BRCA2* genes.[8] Myriad shut down genetic testing performed by other laboratories, even when those laboratories used different testing methods, which meant patients had no access to confirmatory testing.[9] Myriad prevented other laboratories from providing more comprehensive testing of the genes, though its test 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.[10] And because it had no competition, the cost of its test rose dramatically over time, even as the cost of genetic testing was dropping.[11] The patents authorized Myriad to block all manner of scientific inquiry into the genes shutting down research at academic medical centers throughout the country.

The *Myriad* decision recognized a fundamental truth: genes and other naturally occurring matter and relationships should never be granted to anyone as intellectual property. Many diverse

[2] Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 216 (2014).
[3] Mayo Collaborative Services v. Prometheus Labs., 566 U.S. 66 (2012).
[4] Assoc. for Molecular Pathology v. Myriad Genetics, 569, U.S. 576 (2013).
[5] Alice Corp., 573 U.S. at 217.
[6] *Myriad*, 569 U.S. at 583.
[7] 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).
[8] *Id*.
[9] *Id*.
[10] 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).
[11] Brief for Am. Med. Ass'n, *supra* note 8 at 11-15.

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 Stieglitz, 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.[12] The decision also had practical benefits for patients and the competitive marketplace. 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.[13] 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."[14] In an era where scientists, medical professionals, and laboratories offer whole genome sequencing to patients, permitting exclusivity over genes or naturally-occurring correlations between genes and diseases will only impede the progress of medicine and healthcare.

The draft legislation released by your offices not only rewrites Section 101 of the Patent Act, it states explicitly that any judicially created exception to patent-eligibility will be abrogated, thereby overturning the *Mayo, Myriad,* and *Alice* decisions. If enacted, this threatens to take us back to a time of greater uncertainty regarding patent eligibility. The draft goes further than that, as well. Beyond explicitly abrogating judicial precedent holding that genes, isolated from the genome, are not patentable, the legislation also would define the concept of what is useful to mean "any invention or discovery that provides specific and practical utility in any field of technology through human intervention." This language essentially adopts the argument for patenting isolated genes that the Supreme Court rejected in *Myriad*. Myriad argued for, and the PTO granted,[15] the patents on the *BRCA1* and *BRCA2* genes because the DNA was "isolated" from the cell through an act of human intervention. Isolation is required for scientific work with DNA, and permitting patents on isolated DNA resulted in the issuance of patents covering an estimated 20% of the human genome.[16] Defining "useful" to include essentially any invention or discovery that was developed through human intervention reinvigorates the argument that human genes are patent-eligible.

One hundred and fifty years of case law will be wiped out by this bill and the legal battles central to and correctly decided in each of the cases mentioned will have to be fought again. Patients will again be at risk of lacking access to information about their genes, about their very selves.

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[12] Brief for the United States. as Amici Curiae Supporting Neither Party, 566 U.S. 66 (2012) (No. 12-398).
[13] 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.
[14] 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.
[15] *See* Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).
[16] *See* K Jensen & F. Murray, *Enhanced: Intellectual Property Landscape of the Human Genome*, 310 Science 239-40 (Oct. 14, 2005).

We likely will again see high prices for tests with no competition in the market, and harms to innovation and useful research with no guarantee that the law would eventually provide the same protections that it now offers.

We oppose the draft legislation rewriting Section 101 of the Patent Act. To the extent that there are problems with the current application of the law that must be solved, narrower paths to addressing them are preferable to rewriting current 101 standards and overturning over a century of precedent, including three recent unanimously decided Supreme Court cases. If you have questions, please contact Kate Ruane, American Civil Liberties Union, kruane@aclu.org, or Jennifer Leib, Association for Molecular Pathology, jennifer@ipolicysolutions.com.

Sincerely,