

June 3, 2019

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

Senator Thom Tillis  
113 Dirksen Senate Office Building  
Washington D.C., 20510

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<sup>1</sup> 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

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<sup>1</sup> 35 U.S.C. § 101.

are not patent-eligible under the Patent Act.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup>

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).<sup>6</sup> These patents granted Myriad a monopoly over the genes, which had serious consequences for patients.<sup>7</sup> Myriad had exclusive rights to clinical testing of the *BRCA1* and *BRCA2* genes.<sup>8</sup> 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.<sup>9</sup> 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.<sup>10</sup> And because it had no competition, the cost of its test rose dramatically over time, even as the cost of genetic testing was dropping.<sup>11</sup> 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

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<sup>2</sup> *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 573 U.S. 208, 216 (2014).

<sup>3</sup> *Mayo Collaborative Services v. Prometheus Labs.*, 566 U.S. 66 (2012).

<sup>4</sup> *Assoc. for Molecular Pathology v. Myriad Genetics*, 569, U.S. 576 (2013).

<sup>5</sup> *Alice Corp.*, 573 U.S. at 217.

<sup>6</sup> *Myriad*, 569 U.S. at 583.

<sup>7</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>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</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>11</sup> 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.<sup>12</sup> 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.<sup>13</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>14</sup> 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,<sup>15</sup> 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.<sup>16</sup> 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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<sup>12</sup> Brief for the United States, as Amici Curiae Supporting Neither Party, 566 U.S. 66 (2012) (No. 12-398).

<sup>13</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>14</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>15</sup> See Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

<sup>16</sup> 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](mailto:kruane@aclu.org), or Jennifer Leib, Association for Molecular Pathology, [jennifer@ipolicysolutions.com](mailto:jennifer@ipolicysolutions.com).

Sincerely,

A Breath of Hope Lung Foundation  
AFE Foundation  
AliveAndKickn  
Alstrom Syndrome International  
Ambry Genetics  
American Board of Genetic Counseling  
American Civil Liberties Union  
American College of Medical Genetics and Genomics  
American Physiological Society  
American Society for Clinical Pathology  
American Society for Investigative Pathology  
American Society for Pharmacology & Experimental Therapeutics  
American Society for Transplantation and Cellular Therapy  
American Society of Human Genetics  
Angioma Alliance  
Angiosarcoma Awareness Inc  
Answer Cancer Foundation  
ARUP Laboratories  
Association for Creatine Deficiencies  
Association for Molecular Pathology  
Association of Community Cancer Centers  
Association of Pathology Chairs  
Barth Syndrome Foundation  
Basser Center for BRCA  
Batten Disease Support and Research Association

Baylor Genetics; Baylor College of Medicine  
Biotia, Inc.  
Brave Bosom  
BRCA Advanced 101 & 102 Journal Club  
BRCA Sisterhood  
Breast Cancer Action  
BridgeOmics LLC  
Bright Pink  
Broad Institute of MIT and Harvard  
Canavan Research Illinois  
Cancer ABCs  
CancerCare  
CARES Foundation, Inc.  
Chicago Genetic Consultants, LLC  
Children's Cardiomyopathy Foundation  
Chordoma Foundation  
Citizens for Quality Sickle Cell Care, Inc.  
College of American Pathologists  
Colon Cancer Coalition  
Colorectal Cancer Alliance  
Concert Genetics  
Costello Syndrome Family Network  
Count Me In  
CrowdCare Foundation  
Cure GM1 Foundation  
Cure HHT  
Curi Corporation  
Dante Labs  
Dysautonomia International

e-Patient Dave, LLC  
EFF-Austin  
EGFR Resisters  
Ehlers-Danlos Society  
Endocrine Society  
EveryLife Foundation for Rare Diseases  
Exakta Laboratories  
Five P Minus Society  
FORCE: Facing Our Risk of Cancer  
Empowered  
Foundation for Ichthyosis & Related Skin  
Types  
Foundation for Prader-Willi Research  
Geisinger Health  
GeneDx, Inc  
GeneMatters, LLC  
Genetic Alliance  
Genetic Cancer Risk Assessment Program  
Genome Medical  
Genomes2People Research Program  
Georgia Association of Genetic Counselors  
Global Alliance for Genomics and Health  
GO2Foundation for Lung Cancer  
GoInvo  
Grey Genetics, LLC  
Hannah's Hope Fund Fkr GAN  
Hereditary Neuropathy Foundation  
Hermansky-Pudlak Syndrome Network  
HIS Breast Cancer Awareness  
Huntington's Disease Society of America  
Hypertrophic Cardiomyopathy association  
ICAN, International Cancer Advocacy  
Network  
Innovation Policy Solutions LLC  
International Pemphigus and Pemphigoid  
Foundation  
International Society of Nurses in Genetics  
International WAGR Syndrome Association  
Invitae Corporation  
Jeffrey Modell Foundation  
Jonah's Just Begun-Foundation to Cure  
Sanfilippo Inc.  
Kneading Hope

Lacuna Loft  
Loop & Tie  
Lunenfeld-Tanenbaum Research Institute  
Lung Cancer Research Foundation  
LUNgevity Foundation  
M-CM Network  
Mahnaz  
Malecare Cancer Support  
Mayo Clinic Laboratories  
McPherson Strategies  
MIB Agents Osteosarcoma Alliance  
Mighty Casey Media  
Minnesota Ovarian Cancer Alliance  
(MOCA)  
MLD Foundation  
Mucopolidosis Type IV Foundation  
My Gene Counsel, LLC  
National Heart and Lung Institute, Imperial  
College London  
National Organization for Rare Disorders  
(NORD)  
National Society of Genetic Counselors  
National Urea Cycle Disorders Foundation  
NBIA Disorders Association  
NeoGenomics Laboratories  
New York Genome Center  
Northern Nevada Genetic counseling  
Norton & Elaine Sarnoff Center for Jewish  
Genetics  
NothingPink  
Onegevity Health  
Organic Acidemia Association  
Ovarian Cancer Research Alliance (OCRA)  
PCD Foundation  
Pediatric Infectious Diseases Society  
Phelan-McDermid Syndrome Foundation  
Phoenix Nest Inc.  
Prevent Cancer Foundation  
PreventionGenetics  
Prostate Cancer International, Inc.  
PTEN World  
PXE International  
R Street Institute

Rare Army  
Sage Bionetworks  
Sema4  
SHARE Cancer Support  
Sharsheret  
Simple Health  
Smart Digital, LLC  
Society of Toxicology  
Spastic Paraplegia Foundation  
Startup Buenos Aires  
STEMBOARD  
Stickler Involved People  
Sudden Arrhythmia Death Syndromes  
Foundation  
Susan G. Komen  
Texas Oncology PA  
The Association for Frontotemporal  
Degeneration  
The Jewish Federations of North America  
The Light Collective  
The Marfan Foundation  
The MDS Foundation, Inc.  
The Rivkin Center for Ovarian Cancer  
The ROS1ders  
The Variant Interpretation for Cancer  
Consortium (VICC)  
Triage Cancer  
TSF Inc. DBA Team Sanfilippo Foundation  
Tuberous Sclerosis Alliance  
UC Santa Cruz Genomics Institute  
United Leukodystrophy Foundation  
United Mitochondrial Disease Foundation  
University of Washington  
Usher 1F Collaborative  
Usher Syndrome Coalition  
Usher Syndrome Society  
Variant Bio  
Vinetta  
Watershed DNA  
Wearable X  
Women's March