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

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

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

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

<sup>&</sup>lt;sup>5</sup> Alice Corp., 573 U.S. at 217.

<sup>&</sup>lt;sup>6</sup> Myriad, 569 U.S. at 583.

<sup>&</sup>lt;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).

Id.
 Id.

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

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

<sup>&</sup>lt;sup>14</sup> Press Release, Statement by NIH Dr. Francis Collins on U.S. Supreme Court Ruling on Gene Patenting (Jun. 13. 2013) <a href="https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-director-francis-collins-us-supreme-court-ruling-gene-patenting">https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-director-francis-collins-us-supreme-court-ruling-gene-patenting</a>.

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

<sup>&</sup>lt;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, <a href="mailto:kruane@aclu.org">kruane@aclu.org</a>, or Jennifer Leib, Association for Molecular Pathology, <a href="mailto:jennifer@ipolicysolutions.com">jennifer@ipolicysolutions.com</a>.

## 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
Cancer Care

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

Curii 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

Mucolipidosis 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