

July 30, 2019

The Honorable Thom Tillis  
*Chairman*  
Committee on the Judiciary,  
Subcommittee on Intellectual Property  
United States Senate  
Washington, D.C. 20510

The Honorable Christopher Coons  
*Ranking Member*  
Committee on the Judiciary,  
Subcommittee on Intellectual Property  
United States Senate  
Washington, D.C. 20510

The Honorable Jerrold Nadler  
*Chairman*  
Committee on the Judiciary  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Doug Collins  
*Ranking Member*  
Committee on the Judiciary  
U.S. House of Representatives  
Washington, DC 20515

Dear Chairman Tillis, Ranking Member Coons, Chairman Nadler, and Ranking Member Collins,

As law professors, former government officials, and scholars, we write to express our support for the congressional effort at reforming patent eligibility doctrine. As Congress considers legislation to bring balance back to the patent system in promoting the high-tech and biopharmaceutical inventions that drive the U.S. innovation economy, it is imperative that its deliberations are based on accurate statements of the law and of the real-world performance of the U.S. patent system.

We are deeply concerned about misapprehensions of law and misleading rhetoric in a recent letter to Congress submitted by the American Civil Liberties Union (ACLU) and other medical and policy organizations that oppose this legislative reform effort. Their claim, for instance, that the “draft legislation if enacted would authorize patenting products and laws of nature, abstract ideas, and other general fields of knowledge” is a profoundly mistaken and inaccurate statement. Rather, the proposed amendments preclude “implicit or judicially created exceptions to subject matter eligibility,” and do not eliminate constitutional and statutory bars to patenting laws of nature, abstract ideas, and general fields of knowledge.

First, pursuant to the constitutional authorization to Congress to enact patent laws “to promote the Progress in . . . the useful Arts,” the patent system secures an exclusive right only in new products, processes, and compositions of matter that constitute the “useful Arts.” Thus, it is a longstanding and fundamental requirement in the patent statutes that only inventions or discoveries falling within the statutory categories in § 101—and in its predecessor statutes dating back to the first Patent Act of 1790—are eligible for patent protection.

The proposed legislative reform to § 101 does not alter this requirement. The draft legislation is designed to eliminate the recently created exceptions to § 101 by the Supreme Court in its *Alice-Mayo* framework that have become infected with subjectivity and aggressively expanded in their application by the lower courts. Historically, patent eligibility has served a secondary role to the primary patentability requirements of utility (§ 101), novelty (§ 102), nonobviousness (§ 103), and enabling written disclosure (§ 112). The historical approach to § 101 precluded only a limited

number of technological inventions from patentability, because §§ 102, 103, and 112 have ensured that the patent system promotes only innovative efforts in inventions and discoveries. Thus, the draft legislation returns the U.S. patent system back to its core function in promoting the innovations—the useful arts—that Congress has long identified in its patent statutes enacted pursuant to the Constitution.

The letter from the ACLU also asserts that the draft legislation would “prevent the discovery of novel treatments for diseases” and would cause “harms to innovation and useful research” in diagnostic tests. Similar to the misstatements about patent law, these claims are profoundly mistaken. First, the letter cites no evidence supporting these allegations. It cannot, because it is an unproven claim. One rigorous empirical study concludes that “on average gene patents have had no quantitatively important effect on follow-on innovation.” Bhaven Sampat & Heidi L. Williams, *How Do Patents Affect Follow-On Innovation? Evidence from the Human Genome*, 109 *American Economic Review* 203 (2019), <https://doi.org/10.1257/aer.20151398>. In fact, the Sampat & Williams’ study found that patents did not limit follow-on innovation as compared to secret databases of the sequenced human genome, such as that created by Celera, precisely because of the disclosure function of the patent system mandated by § 112. *See id.* at 206 (“The sequenced genetic data in both the accepted and the rejected patent applications we analyze were disclosed in a way that enabled open access to the data for all prospective follow-on users.”).

Second, in addition to ignoring the disclosure function of the patent system, the ACLU letter ignores the vitally important commercial function that patents serve in the healthcare market. One of the reasons genetic diagnostic testing became widely accepted and reimbursed by insurance providers is due to biotech companies’ efforts in the 1990s in convincing skeptical insurance providers that cancer could be predicted with cutting-edge genomic testing. *See* Christopher Holman, *The Critical Role of Patents in the Development, Commercialization, and Utilization of Innovative Genetic Diagnostic Tests* 7-8 (July 2014), <http://sls.gmu.edu/cpip/wp-content/uploads/sites/31/2014/04/Holman-Critical-Role-of-Patents-in-Genetic-Diagnostic-Tests.pdf>. Professor Holman further observes that not only do patents recoup the “substantial investment [that] is necessary to support the lengthy and labor-intensive research efforts required to discern and validate the clinical significance of novel biomarkers,” *id.* at 2, they also “play a critical role in incentivizing the substantial investment required to translate the results of basic research into high-quality, commercially available diagnostic tests that meaningfully impact people’s lives.” *Id.* at 5. This role of patent protection also includes promoting substantial investment in educating physicians on the value of new tests, which promotes greater access for patients to cutting-edge, life-saving technologies. It is not true that reforming patent eligibility doctrine would “create barriers to patients’ access to potentially lifesaving genomic tests,” as asserted in the ACLU letter.

Third, human genes are no longer patentable today under current patent law. Such discoveries are no longer novel (§ 102) or nonobvious (§ 103). The total sequence of human genes has been made publicly available since the turn of the twenty-first century, due in part to the efforts of Sir John Sulston and others. They made the human genome public to prevent the further patenting of human genes. The Court of Appeals for the Federal Circuit held ten years ago that efforts like this were successful, ruling that gene sequences were no longer patentable discoveries under

§ 103. See *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009). The proposed reform of § 101 does nothing to alter these facts of science or law.

Congressional reform of patent eligibility doctrine under § 101 of the Patent Act is vitally important to sustain U.S. global leadership in innovation, resulting in increased jobs, economic growth, and a flourishing society. Unfortunately, U.S. innovators, especially in the high-tech and biopharmaceutical sectors, are suffering under extreme uncertainty about how patent examiners or judges will apply the *Alice-Mayo* framework that was recently created by the Supreme Court. With high rates of rejections of patent applications at the U.S. Patent & Trademark Office and high rates of invalidations of patents by courts, the only certainty that does exist is that the U.S. no longer secures the fruits of inventive labors with reliable and effective patent rights. This represents a fundamental change in the incentives the U.S. has provided to inventors for over two centuries, as its “gold standard” patent system closes its doors to twenty-first-century innovation in the vital high-tech and biopharmaceutical fields. Congress should reform § 101 and it should not be diverted by misleading policy rhetoric or mistaken statements about the patent laws.

Sincerely,

Michael B. Abramowicz  
Oppenheim Professor of Law  
The George Washington University School of Law

John R. Allison  
Mary John and Ralph Spence Centennial Professor of Business Administration  
McCombs School of Business  
University of Texas at Austin

Loletta Darden  
Associate Professor of Law  
Suffolk University Law School

The Honorable Q. Todd Dickinson  
Former Under Secretary of Commerce and Director  
United States Patent & Trademark Office

Richard A. Epstein  
Laurence A. Tisch Professor of Law,  
New York University School of Law  
James Parker Hall Distinguished Service Professor of Law Emeritus,  
University of Chicago Law School

Hugh Hansen  
Professor of Law  
Fordham University School of Law

David Hricik  
Professor of Law  
Mercer University School of Law

Christopher Holman  
Professor of Law  
UMKC School of Law

The Honorable David J. Kappos  
Former Under Secretary of Commerce and Director  
United States Patent & Trademark Office

Jeffrey Lefstin  
Professor of Law  
UC Hastings College of Law

Daryl Lim  
Professor of Law  
John Marshall Law School

The Honorable Paul Michel  
Chief Judge (Ret.)  
United States Court of Appeals for the Federal Circuit

Adam Mossoff  
Professor of Law  
Antonin Scalia Law School  
George Mason University

Lateef Mtima  
Professor of Law  
Howard University School of Law

Kevin Noonan  
Adjunct Professor of Law  
DePaul University College of Law

Professor Xuan-Thao Nguyen  
Gerald L. Bepko Chair in Law  
Indiana University McKinney School of Law

Kristen Osenga  
Professor of Law  
University of Richmond School of Law

The Honorable Randall R. Rader  
Chief Judge (Ret.)  
United States Court of Appeals for the Federal Circuit

Michael Risch  
Professor of Law  
Charles Widger School of Law  
Villanova University

Ted Sichelman  
Professor of Law  
University of San Diego School of Law

Toshiko Takenaka  
WRF/W. Hunter Simpson Professor of Technology Law  
University of Washington School of Law

David O. Taylor  
Robert G. Storey Distinguished Faculty Fellow  
Associate Professor of Law  
SMU Dedman School of Law

Shine (Sean) Tu  
Professor of Law  
West Virginia College of Law

Saurabh Vishnubhakat  
Associate Professor of Law  
Texas A&M University School of Law

cc:

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

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

The Honorable Andrei Iancu  
Under Secretary of Commerce for Intellectual Property  
and Director of the U.S. Patent & Trademark Office  
U.S. Patent & Trademark Office – Madison Building  
600 Dulany Street  
Alexandria, VA 22314