



Testimony of
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Hearing on
THE STATE OF PATENT ELIGIBILITY IN AMERICA: PART I

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THE STATE OF PATENT ELIGIBILITY IN AMERICA: PART I

TESTIMONY OF CHARLES DUAN

CHAIRMAN TILLIS, RANKING MEMBER COONS, AND MEMBERS OF THE SUBCOMMITTEE:

Thank you for inviting me to testify before you today on this important topic of patent law. My name is Charles Duan, and I am the Director of Technology and Innovation Policy at the R Street Institute, a nonprofit, nonpartisan organization based in Washington, D.C., that engages in policy research and educational outreach to promote free markets as well as limited yet effective government, including properly calibrated legal and regulatory frameworks that support economic growth and individual liberty.¹

I have researched patent and intellectual property policy for the past five years, at R Street and at my former organization Public Knowledge. I previously practiced as a patent attorney at the law firm Knobbe, Martens, Olson & Bear LLP, where I drafted, prosecuted and litigated patents. My work has been cited by the Supreme Court of the United States and the U.S. Courts of Appeals for the Federal, Ninth and D.C. Circuits. I have also written for the *Wall Street Journal*, the *Los Angeles Times*, *Wired Magazine*, *Slate*, *Ars Technica*, *The Hill* and many others.

The Subcommittee's attention to and work on the difficult area of patent law is important and commendable for that reason. However, as I have already expressed to many of the offices of members of this Subcommittee, I am strongly concerned about the direction of the present legislative effort to change 35 U.S.C. § 101 and the resulting draft legislation.

¹This testimony is made on my own behalf and does not necessarily represent the views of other scholars at the R Street Institute or of any other person. In preparing this testimony, I would like to thank Luis Gil Abinader, Tahir Amin, Michael Carrier, Robert Cook-Deegan, David Jones, Burcu Kilic, Steven Knievel, Priti Krishtel, Joshua Landau, Matthew Lane, Jennifer Leib, James Love, Alexandra Moss, Sasha Moss, Joe Mullin, Sandra Park, Christina Pesavento, Abigail Phillips, Arti Rai, Lauren Rollins, Kathleen Ruane, Joshua Sarnoff, Daniel Takash, and many others who have provided me with valuable thoughts and information. I would also like to thank the staff of the Library of Congress, the Harold Washington Library Center of the Chicago Public Library, and the Rinn Law Library of DePaul University College of Law for their research assistance.

I. SUMMARY

My concerns fall along two lines: substantive concerns with the draft legislation and procedural concerns about the stakeholder roundtables that led up to the draft.

The draft legislation would do harm to economic and social interests of great importance to the American people. Much of this harm relates to the revival of patenting broad concepts of software; my colleague Alexandra Moss of the Electronic Frontier Foundation is eminently qualified to speak as to those issues. My testimony instead will focus on effects for access to medicines and for scientific research.

With respect to the perspectives of medicines and science, the effect of the draft legislation is to reverse centuries of historic precedent that have conclusively rejected patenting of laws of nature and natural phenomena, most notably including scientific discoveries and human genes. History and research show that opening up the patent laws to those subject matter areas will have at least the following problematic effects:

1. The draft legislation will raise drug prices at a time when soaring costs of health care are a top priority for American voters. More drastically, it will likely reduce access to lifesaving medical treatments, and it will leave Americans with health care that is lower in quality and diminished in safety compared to that of other nations.

2. The draft legislation will inhibit scientific research by locking up with patents the laws of nature that are the foundation of scientific progress. It will balkanize ownership over natural resources such as the human genome, forcing scientists to overcome massive legal complexities before they can even begin basic research.

3. The draft legislation will undermine innovation. Inventors of genetic testing and medical diagnostic technologies have recognized that patents on laws and products of nature frequently stymie their work. Those same inventors have further said that patents are not a necessary incentive for their work, and economic data supports their claims. Indeed, several past experiences show that expansive patents on products of nature actually *discouraged* further innovation even by the patent owner, instead leading to destructive

paces that soured collaboration and progress in science.

4. The draft legislation is contrary to scientific norms, medical ethics, and human rights. Patents on scientific discoveries draw scientists away from contributing to the public store of knowledge. Patents on diagnostic test results force medical professionals to choose between infringing patents and giving their patients potentially lifesaving information. And patents on human genes distort notions of bodily integrity and rights of self-determination.

No less concerning than the substance of the draft legislation itself is the process by which it came about. That process entailed five closed-door roundtables with a hand-picked list of invitees weighted toward patent professionals and industry. Yet it failed to include important representatives of other constituencies who stand to be affected—likely negatively—by it. Among others, the omitted constituencies included patient advocates, access-to-medicines groups, law professors, other academics, research scientists, doctors, and think-tank experts. Letters of concern from these communities will be presented through the course of these hearings, and the Subcommittee would do well to give them serious consideration.

I am aware of and appreciate the difficult questions that have arisen in the wake of the Supreme Court's recent decisions on § 101. As a former patent attorney who worked with inventors of groundbreaking technologies, I am furthermore understanding of the critical role that patents play for those inventors and recognize the costs of legal uncertainty to them. Certainly there is a place for informed discussion and further development of the boundaries of the law, perhaps even with a hand from Congress. But the present effort—one born of an incomplete stakeholder process and one that would throw out two centuries of law, including legal results strongly supported by American consumers and American researchers—is not the right approach. Before any bill on this subject moves forward, a more inclusive process and a more tailored legislative proposal are essential.

II. THE DRAFT LEGISLATION WILL PERMIT PATENTS ON LAWS OF NATURE AND NATURAL PHENOMENA, INCLUDING HUMAN GENES AND SCIENTIFIC DISCOVERIES

The draft legislation leaves little room for doubt as to its effect: It will allow for the patenting of human genes, diagnostic test results, and a wide range of scientific discoveries of the laws of nature.

The legislative proposal explicitly eliminates the three historic categories of ineligible subject matter for patenting, notably including laws of nature and natural phenomena. It further abrogates all existing judicial precedent pertaining thereto, including *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*,² which prohibited the patenting of human or other naturally occurring gene sequences; *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,³ which prohibited the patenting of natural correlations between diagnostic tests and treatment adjustments; *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,⁴ which prohibited the patenting of naturally occurring bacteria; and *Diamond v. Chakrabarty*,⁵ which recognized the “relevant distinction” for patent eligibility purposes “between products of nature, whether living or not, and human-made inventions.”

Furthermore, the draft legislation enshrines into law the primary argument that the Supreme Court considered and rejected in *Myriad* when considering the patent eligibility of human gene sequences. *Myriad Genetics*, the patent owner, contended that the BRCA1 and BRCA2 genes at issue in the case were not products of nature because they had been isolated from the rest of the genome, and thus were the product of human intervention rather than nature; the Supreme Court rejected this argument.⁶ By contrast, the draft legislation at section 100(k) provides that patent eligibility inheres in any “invention or discovery” that arises “through human intervention.” The draft legislation thus, by its

²*Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

³*Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

⁴*Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

⁵*Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980).

⁶*Myriad*, 569 U.S. at 593.

plain language, undoes the exact argument that the Supreme Court relied on to reject the patenting of human genes.

The draft legislation further eliminates barriers to patenting scientific discoveries of principles of nature. Besides explicitly abrogating the “laws of nature” exception to patent eligibility, the draft provides in section 101(b) that patent eligibility is to be determined “without discounting or disregarding any claim limitation.” Any competent patent attorney can include a conventional step of receiving information or a test sample prior to reciting a natural law to which the information or test sample is to be applied. That would apparently render the natural law patent-eligible, despite the fact that there would be no practical change to who would infringe the patent.

Accordingly, the draft legislation evinces no limits that would prevent the patenting of human genes or scientific discoveries. If this legislation were enacted, it must be assumed that such patents would issue in due course.

III. THE DRAFT LEGISLATION WILL RAISE DRUG PRICES, REDUCE ACCESS TO MEDICINES, AND HARM AMERICANS IN NEED OF MEDICAL SERVICES

Patents on genes and scientific discoveries, as enabled by the draft legislation, will increase costs and decrease quality and availability of American health care. This result should be especially concerning to the Subcommittee, coming at a time when 30% of American patients report not taking a medicine as prescribed due to cost,⁷ and when American voters consistently rate drug pricing as their number one priority for Congress.⁸

Indeed, even scholars skeptical of the recent Supreme Court decisions on § 101 reject the approach the draft legislation takes. Professor Dreyfuss and colleagues explain

⁷ Ashley Kirzinger et al., *KFF Health Tracking Poll—February 2019: Prescription Drugs*, HENRY J. KAISER FAM. FOUND. (Mar. 1, 2019), <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>.

⁸ See POLITICO & HARVARD T.H. CHAN SCH. OF PUB. HEALTH, AMERICANS’ PRIORITIES FOR THE NEW CONGRESS IN 2019, at 2 (Dec. 2018), <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2018/12/Politico-Harvard-Poll-Dec-2018-Priorities-for-New-Congress-in-2019.pdf>; Rachel Roubein & David Brown, *Politico–Harvard Poll: New Congress Should Fight Hate Crimes, Tackle Drug Prices*, POLITICO (Jan. 3, 2019), <https://www.politico.com/story/2019/01/03/politico-harvard-poll-hate-crimes-drug-prices-1077879>.

that a “dramatic expansion of patentable subject matter” will raise questions as to “the patient access problems that animated the *Myriad* case in the first place.”⁹ After observing that the effect of *Myriad* was that “patient access to BRCA diagnostics improved rapidly,” they write: “Surely, the goal cannot be to roll back the potential for these developments.”¹⁰ Yet that is surely what the present draft text does.

A. PATENTS ON NATURAL CORRELATIONS WILL BE A TOOL FOR DRUG PATENT EVERGREENING

Expanding patent eligibility will enable pharmaceutical companies to extend the duration of patent protection and delay entry of cost-cutting generics and biosimilars. This is because the newly eligible subject matter will be a prime target for the practice of “evergreening,” in which a drug company obtains a patent on a minor modification to a known drug compound, often years after the initial patent application on the drug was filed.¹¹

The most common strategy for evergreening is for a pharmaceutical company to obtain patents on methods of using a drug, such as forms of delivery or dosage amounts.¹² Currently, under *Mayo*, at least one form of evergreening is impermissible: patenting a correlation between a diagnostic test and adjustment of administration of a drug.¹³ The draft legislation, by abrogating *Mayo*, would enable that type of patent as an evergreening strategy. Indeed, drug companies have already repeatedly tried to obtain eligibility-questionable patents in an effort to broaden and preserve their patent monopolies over

⁹Rochelle C. Dreyfuss et al., *Patenting Nature—A Comparative Perspective*, 5 J.L. & BIOSCIENCES 550, 580 (2018), <https://academic.oup.com/jlb/article/5/3/550/5114251>.

¹⁰*Id.*

¹¹*See generally* Gregory H. Jones, Michael A. Carrier, Richard T. Silver & Hagop Kantarjian, *Strategies That Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States*, 127 BLOOD 1398, 1399–400 (2016) (describing “evergreening” or “product hopping” as “a brand-name company switching the market for a drug, prior to its patent expiration date, to a reformulated version that has a later-expiring patent, but which offers little or no therapeutic advantages”).

¹²*See id.* at 1399 (“The newer version, for example, could have a slightly different tablet or capsule dose or a slow-release formulation (given once a day rather than twice daily).”).

¹³*See Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 87 (2012).

drugs and medical treatments.¹⁴

When generic entry is delayed through strategies such as this, American consumers pay the price. Commentators report that “the average markup for patented drugs is nearly 400%,” and “introducing generic competition can cause prices to fall to as little as 6% of the patent-protected price.”¹⁵ A month’s supply of the cholesterol-lowering drug atorvastatin (Lipitor) cost about \$165 while under patent and \$15 after the patent expired.¹⁶ All these cost savings stand to be lost if inventors can extend their patents by delaying filing. Extending the patent on Lipitor, for example, would have cost Americans about \$41 million *per day*.¹⁷

The draft legislation also appears to abrogate, perhaps unintentionally, the doctrine of obviousness-type double patenting, a “judicially-created doctrine” which derives from § 101.¹⁸ That doctrine is recognized as exceptionally important to prevention of evergreening.¹⁹

¹⁴See, e.g., *Vanda Pharm. Inc. v. W.-Ward Pharm. Int’l Ltd.*, 887 F.3d 1117, 1120–21 (Fed. Cir. 2018) (disputing under § 101 a method-of-use patent that would extend patent protection by 11 years), *petition for cert. filed sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc.*, No. 18-817 (U.S. petition filed Dec. 27, 2018); *Esoterix Genetic Labs. LLC v. Qiagen Inc.*, 133 F. Supp. 3d 349 (D. Mass. 2015) (rejecting under *Mayo* a patent directed to a “correlation between a naturally-occurring mutation in a cancer cell, and the likelihood that a particular type of known pharmaceutical compound will be effective in treating that type of cancer”).

¹⁵Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 284–85 (2016) (citing FDA and other studies); Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. MGMT. STRATEGY 75, 83–84 & tbl.2 (1997) (finding that generic drug prices drop to below 50% of the patent-based price within 3 years of patent expiration).

¹⁶See W. Nicholson Price II, *Expired Patents, Trade Secrets, and Stymied Competition*, 92 NOTRE DAME L. REV. 1611, 1622 & n.67 (2017) [hereinafter Price 2017], <http://ndlawreview.org/wp-content/uploads/2017/05/7-Nicholson-Price-II.pdf>.

¹⁷That number is computed as follows: The U.S. Census Bureau estimates the population of Americans aged 40 and over at 147 million in 2012. The CDC reports that 27.9% of that population used a cholesterol-lowering medication, and 20.2% of them used atorvastatin. See QIUPING GU ET AL., NAT’L CTR. FOR HEALTH STATISTICS, CTRS. FOR DISEASE CONTROL & PREVENTION, NCHS DATA BRIEF NO. 177, PRESCRIPTION CHOLESTEROL-LOWERING MEDICATION USE IN ADULTS AGED 40 AND OVER: UNITED STATES, 2003–2012, at 1–2 (Dec. 2014), <https://www.cdc.gov/nchs/data/databriefs/db177.pdf>. Thus, 8.29 million Americans used atorvastatin in 2012. The difference between the on-patent and off-patent daily cost is \$5 (\$150 per month divided by 30 days), leading to a nationwide cost of \$41.45 million per day.

¹⁸See *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001); *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 619 F.3d 1329, 1341 (Fed. Cir. 2010).

¹⁹See Douglas L. Rogers, *Double Patenting: Follow-on Pharmaceutical Patents that Suppress Competition*, 14 NW. J. TECH. & INTELL. PROP. 317 (2017), <https://scholarlycommons.law.northwestern.edu/njtip/vol14/iss3/3>.

Evergreening is valuable for drug companies—and costly to American patients and consumers. The draft legislation, by enabling a wholly new class of evergreening, would be a win for the pharmaceutical industry and a loss to everyone else.

B. LIFESAVING TESTS AND TREATMENTS WILL NOT BE DEVELOPED DUE TO PATENTS ON NATURAL LAWS AND PRODUCTS

Patents on genes and natural principles will not simply raise prices for health care; they will delay or perhaps even prevent the development of critical treatments. As will be discussed below, science researchers report that patents on genes or discoveries of natural laws often stall their research. When they are unable to conduct research, they cannot produce improved diagnostic tests or even new medicines and treatments.

The possibility that important and threatening disorders will go unresearched and thus untreated is no mere hypothesis; it is proven by history. Prior to the Supreme Court’s 2013 *Myriad* decision, patents on genes were routinely issued. During that period, multiple studies found examples of important research being stalled. The Department of Health and Human Services reported that owners of gene patents used those patents to stop research on breast cancer, hearing loss, Alzheimer’s disease, long QT syndrome, Canavan disease, and leukemia among others.²⁰ Indeed, gene patents demonstrably failed to speed up innovation. After researching numerous instances of gene patents, researchers found that “in no case that was studied was a holder of exclusive intellectual property rights to a gene the first to develop a test. Rather, intellectual property rights are typically invoked only after numerous laboratories have already developed testing and then are used to clear the market of competition.”²¹

Furthermore, gene patents during that period prevented patients from obtaining

²⁰SEC’Y’S ADVISORY COMM. ON GENETICS, HEALTH, & SOC’Y, DEP’T OF HEALTH & HUMAN SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 40–42 (Apr. 2010) [hereinafter SACGHS REPORT], https://osp.od.nih.gov/wp-content/uploads/2013/11/SACGHS_patents_report_2010.pdf.

²¹James P. Evans, *Putting Patients Before Patents*, 12 GENETICS MED. S3, S3 (2010), <https://www.nature.com/articles/gim2010139.pdf>.

critical genetic tests at all. As Dr. Roger Klein observed in 2007, “Holders or licensees of patents on genes, genetic variants and their biological correlations are already using the threat of litigation to prevent pathologists and other laboratory professionals from performing clinical, diagnostic molecular genetic tests.”²² A 10-year-old girl named Abigail was reportedly unable to obtain a test for long QT syndrome due to assertion of a patent on the gene; she died as a result.²³

The pharmaceutical industry often tries to pin the blame for lack of access to medical treatments on health insurance policy, in an attempt to avoid responsibility due to patents. Yet the 2010 HHS report considered this argument and flatly rejected it, noting that a patent holder had full discretion to refuse to perform testing under health insurance plans; “It is the decision of a [patent] rights-holding sole provider . . . that has caused access problems for some patients,” not problems with insurance policy.²⁴

C. PATENTS ON GENES AND DIAGNOSTICS WILL PREVENT PATIENTS FROM OBTAINING SECOND OPINIONS

Expansion of patentable subject matter will further injure American health care by preventing patients from obtaining second opinions. It is a time-honored practice that a patient, before undergoing major medical treatment in view of a single practitioner’s diagnosis, seek a second opinion. A second opinion “remains the best method of ensuring the highest diagnostic accuracy for cancer patients and patients with other serious

²²Roger D. Klein, *Gene Patents and Genetic Testing in the United States*, 25 NATURE BIOTECHNOLOGY 989, 989 (2007).

²³See *Stifling or Stimulating—The Role of Gene Patents in Research and Genetic Testing: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 110th Cong. 40 (Oct. 30, 2007), <https://www.govinfo.gov/content/pkg/CHRG-110hrg38639/pdf/CHRG-110hrg38639.pdf> (statement of Dr. Marc Grodman, CEO of Bio-Reference Laboratories, Inc.). Apparently the test was unavailable at the relevant time because the patent owner, University of Utah, licensed the relevant patents to only one testing firm at a time; the licensee in 2002 went bankrupt, leaving no available testing service until 2004. See *id.* at 48–50 (statement of Dr. Wendy Chung); Misha Angrist, Subhashini Chandrasekharan, Christopher Heaney & Robert Cook-Deegan, *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Long QT Syndrome*, 12 GENETICS MED. S111, S120 (2010), <https://www.nature.com/articles/gim2010145>.

²⁴SACGHS REPORT, *supra* note 20, at 45.

conditions who go to an institution for definitive treatment.”²⁵

Yet where the owner of a patent on a human gene refuses to license the patent to other testing services in order to clear the market of competitors—a common practice when gene patents were considered valid²⁶—no alternative exists, meaning no second opinion is possible. As a result, medical professionals warned that patents on genes were “eliminating patient opportunities . . . to confirm the accuracy of test results.”²⁷

To the extent that American patients are unable to obtain second opinions because of diagnostic or gene patents, the quality of health care suffers. More troublingly, there will be at least some patients who opt for surgery or serious medical treatment, who would not have done so had they obtained a conflicting second opinion.²⁸ The granting of patents on genes or diagnostics that blockade second opinions will thus impose wasteful costs on the health care system—not to mention traumatic costs to patients who receive unnecessary mastectomies or other treatments.

D. AMERICAN CONSUMERS WILL FACE LESS-EFFECTIVE, LESS-SAFE MEDICAL TESTS

To make matters worse, there is historical reason to believe that even the limited services made available by holders of gene or diagnostic patents will be subpar in both quality and safety, producing wrong or even dangerous results.

While regulatory systems such as Food and Drug Administration approval ensure a baseline level of efficacy and safety of medical treatments, it has always been the case

²⁵Timothy Craig Allen, *Second Opinions: Pathologists’ Preventive Medicine*, 3 ARCHIVES PATHOLOGY & LABORATORY MED. 310, 310 (2013), <https://www.archivesofpathology.org/doi/full/10.5858/arpa.2012-0512-ED>.

²⁶See SACGHS REPORT, *supra* note 20, at 33.

²⁷Klein, *supra* note 22, at 990; Robert Cook-Deegan et al., *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers with Colon Cancers*, 12 GENETICS MED. S15, S30 (2010), https://patentdocs.typepad.com/files/impact_of_gene_patents_and_licensing_practices_on.4.pdf (“Myriad’s patent position has made it in effect a sole provider of clinical *BRCA* testing in the United States . . .”).

²⁸See Suzanne Zuppello, *I Had a Mastectomy to Lessen My Risk of Breast Cancer. Does New Science Say That Was a Mistake?*, THE OUTLINE (Sept. 18, 2018), <https://theoutline.com/post/6257/i-had-a-mastectomy-to-lessen-my-risk-of-breast-cancer-does-new-science-say-that-was-a-mistake>.

that the strongest driver of quality is market competition. Competition forces firms to out-innovate each other and to produce better products at lower costs compared to their rivals. Absent competition—such as when a firm faces no rivals because it possesses a patent—that firm has diminished incentives both to ensure that its product is of high quality and to improve upon its product offerings. This is no less true in the medical diagnostics industry.

Experience with Myriad’s patents on breast cancer testing show these concerns to be real. Researchers have observed that Myriad’s testing protocol failed to identify numerous mutations of the relevant genes, and because Myriad was the exclusive provider of such testing in view of its patents, no better testing protocol was publicly available in the United States.²⁹ A comparative study of breast cancer screening between the United States and France determined that, because Myriad limited the American market to a single testing technique while French hospitals used several, patients in France enjoyed substantially lower costs for services of equal quality.³⁰ And Myriad’s use of its patents against science researchers meant that “technology assessment research by third parties, for example to evaluate test performance metrics such as sensitivity, specificity, or positive predictive value, is particularly jeopardized.”³¹

Certainly it is the nature of patents generally that they will diminish competitive pressure toward quality and safety; this observation should not be taken to mean that medical technology ought categorically to be unpatentable. But the effects of patent exclusivity on genetic and diagnostic tests are especially severe—errors lead to improvident

²⁹See Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 J. AM. MED. ASS’N 1379, 1380 (2006), <https://jamanetwork.com/journals/jama/fullarticle/202583>; Cook-Deegan et al., *supra* note 27, S30; Sophie Gad et al., *Identification of a Large Rearrangement of the BRCA1 Gene Using Colour Bar Code on Combed DNA in an American Breast/Ovarian Cancer Family Previously Studied by Direct Sequencing*, 38 J. MED. GENETICS 388, 388 (2001), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1734901/pdf/v038p00388.pdf>.

³⁰See Christine Sevilla et al., *Impact of Gene Patents on the Cost-Effective Delivery of Care: The Case of BRCA1 Genetic Testing*, 19 INT’L J. TECH. ASSESSMENT HEALTH CARE 287, 295–96 (2003).

³¹Vural Ozdemir et al., *Shifting Emphasis from Pharmacogenomics to Theragnostics*, 24 NATURE BIOTECHNOLOGY 942, 943 (2006).

surgery or undiagnosed deadly disorders—and as I will show below, the incentive value of patents for gene and diagnostic discoveries is particularly low.³² Furthermore, unlike patents on human-created technologies, patents on genes or diagnostic correlations cannot be designed around: One cannot change one’s own genetic code to avoid patent infringement. Those consequences are good reason for the patent system specifically to exclude human genes and laws of nature from eligibility for patenting.

IV. THE DRAFT LEGISLATION WILL INHIBIT SCIENTIFIC RESEARCH

It has long been recognized that patents on the laws and products of nature can stifle important scientific research. As the Supreme Court explained in *Funk Bros.*, natural laws and phenomena, “like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge” and as such are “free to all men [and women] and reserved exclusively to none.”³³ By abrogating this decision among others, the draft legislation is thus to the detriment of the storehouse of knowledge and to the detriment of the progress of science that the storehouse of knowledge may beget.

Again, history and experience prove what theory suggests: Patents on human genes—products of nature—have forestalled research into genetics, and patents on diagnostics—laws of nature—have forestalled research in other fields. Insofar as basic research has been foundational to innumerable advances in science and technology, the possibility that the patent system could interfere with that foundation should be of great concern.

A. PATENTS ON NATURAL LAWS AND PRODUCTS HAVE HISTORICALLY DETERRED IMPORTANT RESEARCH ON LIFE-THREATENING DISORDERS

Recent experience shows that patents on natural phenomena, in particular patents on human genes, have deterred important research. Prior to its patents being deemed ineligible in 2013, Myriad used its patents not just to shut down competitors but also to

³²See Section IV.B *infra* p. 16; Section V.B *infra* p. 20.

³³*Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

stop research. Yale genetic researcher Allen Bale reportedly was forced to stop a large-scale study on breast cancer because Myriad refused to allow him to sequence the BRCA1 gene.³⁴ Though empirical evidence on Myriad's impact on research is sparse, scientists have noted several dramatic cases in which researchers reported stopping work because of Myriad's patents and further observed that Myriad's ambiguous stance on patent enforcement against researchers "equates to a chilling effect in zones of uncertainty."³⁵

Problems for researchers were not limited to Myriad's patents. A 2003 survey of 122 directors of genetic testing laboratories found that 53% of them had "decided not to develop or perform a test/service for clinical or research purposes because of a patent."³⁶ Another study of 119 laboratories found that 30% were not testing for a genetic indicator of hemochromatosis at least partly because of a patent on the relevant gene.³⁷ An economic study found that one firm's intellectual property on certain genes "appears to have generated economically and statistically significant reductions in subsequent scientific research and product development, on the order of 20–30 percent."³⁸ Thus, "what the empirical evidence demonstrates is a real fear on behalf of clinical laboratory directors and researchers based on the belief that patent holders can and will prevent them from conducting their research."³⁹

As a result of these negative effects of gene patents on scientific research, scientists have vocally opposed such patents. Dr. Francis Collins, director of the National

³⁴See Kimberly Blanton, *Corporate Takeover: Exploiting the US Patent System, a Single Company Has Gained Control over Genetic Research and Testing for Breast Cancer. And Scientists, Doctors, and Patients Have to Play by Its Rules*, BOSTON GLOBE MAG., Feb. 24, 2002, https://web.archive.org/web/20021014222141/http://www.boston.com:80/globe/magazine/2002/0224_patent_part1.htm.

³⁵Cook-Deegan et al., *supra* note 27, S28.

³⁶Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 5 (2003).

³⁷See Jon F. Merz et al., *Diagnostic Testing Fails the Test: The Pitfalls of Patents Are Illustrated by the Case of Haemochromatosis*, 415 NATURE 577, 578 (2002).

³⁸Heidi L. Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome*, 121 J. POL. ECON. 1, 4 (2013).

³⁹E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS MED. S39, S66 (2010), <https://www.nature.com/articles/gim2010142.pdf> (citing Cho et al., *supra* note 36; Merz et al., *supra* note 37).

Institutes of Health and former director of the National Human Genome Research Institute, wrote in 2010 that human genetics “is so fundamental, and requires so much further research to understand its utility, that patenting it at the earliest stage is like putting up a whole lot of unnecessary toll booths on the road to discovery.”⁴⁰ Sir John Sulston, a Nobel Prize-winning biologist, said that patents on human genes are “going to get in the way of treatment” and “going to get in the way of research,” and thus admonished that “scientists and lawmakers must resist attempts by corporations and individuals to patent human genes.”⁴¹ A 2001 survey of 1,229 geneticists found that “a clear majority (75%) disapprove of patenting DNA altogether”; indeed, “61% of industry scientists disapprove.”⁴²

Scientist opposition to patent rights in discoveries is not a new phenomenon. A similar effort was made in the 1920s and 1930s to create a right of “scientific property,” much like the draft legislation would do today.⁴³ A report of the American Association for the Advancement of Science⁴⁴ reported several scientific communities’ views on this proposal:

- NATIONAL RESEARCH COUNCIL: It is “the almost unanimous opinion of its members that the protection by law of a scientist’s property rights to his discoveries is not feasible, and it is of doubtful desirability.”
- AMERICAN ENGINEERING COUNCIL, in a survey of other organizations and societies: “The majority of those who have taken action are adverse to any plan for protecting discoveries in pure science, on the ground that it is not only impractical but unnecessary Seven societies take the view that ‘to extend into pure science research the privilege of patenting a mere scientific fact would enable the Patent Office and the courts to go far beyond the points safe for engineering and industry.’”

⁴⁰FRANCIS COLLINS, *THE LANGUAGE OF LIFE: DNA AND THE REVOLUTION IN PERSONALISED MEDICINE* 113 (2010).

⁴¹Alok Jha, *Human Genome Project Leader Warns Against Attempts to Patent Genes*, THE GUARDIAN (June 24, 2010), <https://www.theguardian.com/science/2010/jun/24/human-genome-project-patent-genes>.

⁴²Isaac Rabino, *How Human Geneticists in US View Commercialization of the Human Genome Project*, 29 NATURE GENETICS 15, 15 (2001).

⁴³See Charles Duan, *A Century-Old Debate Over Science Patents Is Repeating Itself Today*, SLATE (Feb. 25, 2019), <https://slate.com/technology/2019/02/patenting-nature-francesco-ruffini-history-tillis-coons.html>.

⁴⁴Joseph Rossman et al., *The Protection by Patents of Scientific Discoveries: Report of the Committee on Patents, Copyrights and Trade Marks*, 79 SCIENCE SUPP., 38, 40 (Jan. 1934).

- AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE: “no effort should at present be made to develop a plan for protecting scientific property. There appears to be no need for such legal protection from the view-point of incentive to the scientist or public policy.”

The exception to patent infringement for experimental use does not overcome these concerns. As the Federal Circuit held in *Madey v. Duke University*, that exception is “very narrow and strictly limited” to use of a patent “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”⁴⁵

As an attempt to allow corporations and individuals to patent human genes, the draft legislation is directly contrary to the expressed views of these and other research scientists. If nothing else, that suggests an urgent need for the Subcommittee to solicit the views of the research science community on this legislative proposal. Indeed, when the League of Nations made a similar effort to expand patentability to scientific discoveries in the 1920s, the patent experts did solicit the opinions of the American Association for the Advancement of Science, whose resulting report (quoted above) was critical input to the dialogue over the League of Nations proposal.⁴⁶ It is disappointing that, to my understanding, no similar outreach to the scientific community has been made so far.

B. RESEARCH SCIENTISTS HAVE LONG VIEWED PATENTS AS UNNECESSARY AND IN FACT DETRIMENTAL TO THEIR RESEARCH WORK

Perhaps the inhibitory effect of patents on other scientists’ research might be tolerable if the holders of those patents were encouraged by virtue of their patent rights to engage in more research themselves. Yet there is little reason to believe that this is the case: Research scientists appear not to be strongly motivated by patent rights.

The 2010 HHS report on gene patents concluded that, as a general matter, scientists are motivated by incentives other than patents, including “the desire to advance understanding, help their patients by developing treatments for disease, advance their

⁴⁵*Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

⁴⁶See Duan, *supra* note 43.

careers, and enhance their reputations.”⁴⁷ Interviews with Alzheimer’s researchers found that they “expressed ambivalence about patenting” and were primarily “driven by wanting priority of scientific discovery, prestige, scientific credit, and the ability to secure funding for additional research based on scientific achievement.”⁴⁸ A study commissioned by the National Research Council found that only 7% of academic researchers found patents to be of moderate importance to the work they pursued; far more important were scientific importance (97%), personal interest (95%), feasibility of the study (88%), and access to funding (80%).⁴⁹ “If patents added ‘the fuel of interest to the fire of genius,’ in Abraham Lincoln’s famous phrase, it was here at best a tiny pile of kindling at the outer margin of a large conflagration.”⁵⁰

Nor do patents on natural laws or products appear to be necessary to stimulate investment in research. While the HHS report found that patents do encourage private investment in genetics, public funding of research plays an especially outsized role in stimulating basic research.⁵¹ Thus, to the extent that subject matter such as genes are ineligible for patenting, public funding is a tested and effective supplement.

It is sometimes suggested that the possibility of patents on discoveries spurs “races” that speed up those discoveries, but history repeatedly shows those races to be detrimental to scientists’ collaborations and to the research itself.⁵² Perhaps most instruc-

⁴⁷SACGHS REPORT, *supra* note 20, at 20 (citing John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101 (2001)).

⁴⁸Katie Skeehan et al., *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Alzheimer’s Disease*, 12 GENETICS MED. S71, S77 (2010), <https://www.nature.com/articles/gim2010143.pdf>.

⁴⁹See JOHN P. WALSH ET AL., PATENTS, MATERIAL TRANSFERS AND ACCESS TO RESEARCH INPUTS IN BIOMEDICAL RESEARCH: FINAL REPORT TO THE NATIONAL ACADEMY OF SCIENCES’ COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN-RELATED INVENTIONS 13 (Sept. 20, 2005), <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.531.1401&rep=rep1&type=pdf>; COMM. ON INTELLECTUAL PROP. RIGHTS IN GENOMIC & PROTEIN RESEARCH & INNOVATION, NAT’L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 122 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006), <https://www.nap.edu/read/11487/chapter/1>.

⁵⁰Skeehan et al., *supra* note 48, S77.

⁵¹See SACGHS REPORT, *supra* note 20, at 25–26.

⁵²See Phyllida Brown & Kurt Kleiner, *Patent Row Splits Breast Cancer Researchers*, NEW SCIENTIST (Sept. 24, 1994), <https://www.newscientist.com/article/mg14319440-300-patent-row-splits-breast-cancer-researchers/> (research laboratory “decided to stop working with the researchers at the University of Utah

tive is the “patent race” between the Human Genome Project and Celera in 1990s.⁵³ HGP had pledged to make the results of its sequencing the human genome “freely available and in the public domain for both research and development, in order to maximize its benefit to society”; Celera, by contrast, attracted \$400 million in investment on the promise that it would patent its discovered genes. Those favoring broad patentability might have predicted that Celera would have the incentives to win this race, but in fact the opposite was true: Celera failed to keep up and in fact ended up *copying the public project’s results wholesale* to keep up appearances that it was moving forward. As Dr. Francis Collins, leader of the public project, wrote:

Today, virtually all observers agree that the complete and immediate public availability of the human genome sequence was a critical component of its success. . . . Had the cries for privatization of this effort won out in 1999, this would now be a very different world.

The evidence that patents on scientific discoveries will encourage research is mixed at best and condemnatory at worst. I urge the Subcommittee to consider carefully the above evidence before upending longstanding expectations of the scientific community.

V. THE DRAFT LEGISLATION WILL UNDERMINE INNOVATION

Against these concerns about impediments to medical treatment and scientific research weighs the possibility that expanded patent protection for laws and products of nature will stimulate invention and innovation. Yet there is substantial reason to doubt this and to worry, in fact, that patents on genes and diagnostic tests will undermine innovation rather than advance it.

because of disagreement over the ethics of patenting DNA”; laboratory director “fears that the split will weaken future research”).

⁵³This is based on COLLINS, *supra* note 40, at 301–05.

A. GENE PATENTS THAT BALKANIZE THE HUMAN GENOME WILL FREEZE THE DEVELOPMENT OF GENETIC TESTING SERVICES

The particular nature of genetic testing means that gene patents are especially detrimental to innovation. Because the cost of sequencing is relatively cheap, genetic testing services often sequence complete genomes. Furthermore, genetic diagnostics are generally not based on identification of a single gene, but combinations of genes.

As a result, where patents are issued on individual genes, innovators will need to obtain licenses to many or all of them. A whole-genome sequencing service would theoretically need to obtain a license for “all or many of the thousands of human genome sequences subject to patent protection,” for example.⁵⁴ This leads to a problem that scholars have called the “tragedy of the anticommons”: When the field of genetics is finely subdivided among thousands of patent owners, it creates “a spiral of overlapping patent claims in the hands of different owners, reaching ever further upstream in the course of biomedical research,” thereby “adding to the cost and slowing the pace of downstream biomedical innovation.”⁵⁵ “Navigating the complex intellectual property landscape of DNA patents,” write two scientists, “could slow some promising clinical technologies.”⁵⁶

In considering his experience as a laboratory researcher, NIH Director Dr. Francis Collins found gene patents to be an impediment rather than an incentive for innovation in genetics. After noting the ordinary merit of patents for encouraging commercialization

⁵⁴See, e.g., Dan Vorhaus & John Conley, *Whole-Genome Sequencing and Gene Patents Coexist (For Now)*, GENOMICS L. REP. (RENAMED PRIVACY REP.) (Aug. 11, 2009), <https://theprivacyreport.com/2009/08/11/whole-genome-sequencing-and-gene-patents-coexist-for-now/>. Some scholars have disputed this, claiming that there are whole-genome sequencing technologies that avoid infringing gene patents. See, e.g., W. Nicholson Price II, *Unblocked Future: Why Gene Patents Won't Hinder Whole Genome Sequencing and Personalized Medicine*, 33 CARDOZO L. REV. 1601, 1606 (2012) [hereinafter Price 2012], https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1914560; Dreyfuss et al., *supra* note 9, at 551 & n.5. These arguments underestimate the capability of skilled patent practitioners, and they further assume the continued viability of *Mayo*, which the draft legislation would abrogate. See Price 2012, *supra*, at 1618.

⁵⁵See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698–99 (1998), <https://science.sciencemag.org/content/sci/280/5364/698.full.pdf>.

⁵⁶Subhashini Chandrasekharan & Robert Cook-Deegan, *Gene Patents and Personalized Medicine—What Lies Ahead?*, 1 GENOME MED. 92, 93 (2009), <https://genomemedicine.biomedcentral.com/articles/10.1186/gm92>.

of inventions, he wrote:

I think this argument falls flat when it comes to diagnostic applications. . . . [T]he supposed need to provide an incentive for companies to develop DNA diagnostics is unconvincing. In that situation, many of us would argue that it would be better for the public to have competition in the marketplace, in order to provide an incentive for higher quality and lower price.⁵⁷

That perspective, characteristic of many prominent figures in the scientific community, should give this Subcommittee pause given the draft legislation's contrary view.

B. RECENT EVIDENCE SUGGESTS THAT RESTRICTIONS ON DIAGNOSTIC TEST AND GENE PATENTS HAVE NOT SLOWED INNOVATION AND MAY BE ENCOURAGING BETTER INNOVATION

By contrast, the lack of patent eligibility for human genes and diagnostic tests since 2012 does not appear to have diminished innovation in these spaces. Research by Professors Arti Rai and Colleen Chien found “[n]o clear evidence” of any decline in innovation in diagnostic methods following the *Mayo* decision restricting patents in that space, and indeed find increases in biomarker transactions and FDA diagnostics approvals since the decision.⁵⁸ As they explain, “We looked for clear evidence of a sustained decline in diagnostic patent applications and transactions post-*Mayo*. **We didn't find it.**”⁵⁹ As Professor Shubha Ghosh said, “When *Myriad* was decided in 2013, everybody sounded the death knell of biotechnology. . . . It certainly isn't that.”⁶⁰

⁵⁷COLLINS, *supra* note 40, at 112.

⁵⁸Arti K. Rai with Colleen Chien, Presentation at the Duke Center for Applied Genomics and Precision Medicine: Intellectual Property in Precision Medicine 24–26 (Feb. 15, 2018), <https://precisionmedicine.duke.edu/about/calendar/genomic-and-precision-medicine-forum-arti-rai-jd>.

⁵⁹Colleen V. Chien & Arti K. Rai, Presentation at the USPTO Roundtable on Section 101: Dx Innovation in Decline? An Empirical Analysis Post-*Mayo* 19 (Dec. 5, 2016), <https://www.uspto.gov/sites/default/files/documents/RT2%206-2%20Colleen%20Chien.pdf>.

⁶⁰Turna Ray, *Supreme Court Patent Cases Haven't Hindered Diagnostics Innovation, Preliminary Data Suggest*, GENOMEWEB (Dec. 5, 2016), <https://www.genomeweb.com/molecular-diagnostics/supreme-court-patent-cases-havent-hindered-diagnostics-innovation-preliminary>. By contrast, Professor Taylor's forthcoming survey purports to find evidence of startup investors' choices of investments being affected by the Supreme Court's decisions. See David O. Taylor, *Patent Eligibility and Investment*, 41 CARDOZO L. REV. (forthcoming Apr. 3, 2019), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3340937. There are several reasons to question the usefulness of this study, though. The response rate to his survey was less than 4%; given that his survey invitation specifically asked about views on the Supreme Court decisions, a reasonable

In a study of barriers to the development of personalized medicine (PM) technology, researchers reviewed 32 articles on intellectual property and 20 on incentives for PM development. After noting commentary both supporting and opposing expanded patent rights for personalized medicine, the researchers concluded:

What is clear from the literature is a lack of consensus on whether (i) patents act as necessary incentives to PM investment, innovation, and development such that they should be strengthened, or (ii) patents stifle innovation and investment, particularly in the device space, such that novel incentives are needed and patent rights should be curtailed.⁶¹

Similarly, economists find no increase in innovation resulting from patents on genes. In a study of gene patents in the early 2000s, two economists find that those genes for which a patent is applied tend to be economically more valuable (unsurprisingly, since one would not spend the money applying for a patent on something without value), but find no evidence that the presence of a patent stimulated greater research and development compared to the denial of one.⁶²

The views of genetic testing services themselves are significant in this respect. In an *amicus curiae* brief filed with the Supreme Court, two genetic testing laboratories explained that they were perfectly happy to have their discoveries of particular genes be published in academic literature and entered into the public domain. Noting that they were able to obtain patents on “applications of laws of nature such as new drugs, reagents,

inference is that 96% of investors do not care about them. *See id.* at 29, 24 n.113. Taylor further concedes that those who responded to his survey were uncharacteristic of the overall population, further limiting the reliability of his results. *See id.* at 29–30, 64.

⁶¹Lori Knowles et al., *Paving the Road to Personalized Medicine: Recommendations on Regulatory, Intellectual Property and Reimbursement Challenges*, 4 J.L. & BIOSCIENCES 453, 493 (2017).

⁶²*See* Bhaven Sampat & Heidi L. Williams, *How Do Patents Affect Follow-On Innovation? Evidence from the Human Genome*, 109 AM. ECON. REV. 203, 232 (2019), <https://economics.mit.edu/files/15451>. The authors take this conclusion also to mean that patents do not deter follow-on research by others, but this conclusion is questionable for several reasons. For one thing, the authors hypothesize that the USPTO’s requirement of especially detailed disclosure of gene sequences is the actual driver of follow-on research. *See id.* at 231. Other fields of research do not trigger the same stringent disclosure requirements, so the same level of follow-on research should not be expected elsewhere. *See id.* Furthermore, the thrust of the paper is to reject the hypothesis that the grant of a patent will deter innovation while the denial of a patent application will not, but that ignores the fact that the filing of the application itself may be sufficient to deter follow-on innovation in the first place.

or equipment,”⁶³ the laboratories asserted that publication, not patenting, of discoveries of genes would “allow for inventions to be created and for doctors to treat patients more effectively.”⁶⁴ The laboratories accordingly would continue to research and even publish new genes even without the possibility of patent protection.⁶⁵

The views of those labs echo the Supreme Court’s words in *Chakrabarty* when it considered the patentability of naturally-occurring bacteria:

The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides.⁶⁶

In the end, the evidence from the research and development community suggests that patents for human genes and other natural phenomena are likely not a significant factor in stimulating innovation. Given the potentially immense harms to the public and to scientific research that those patents could cause, the balance of public policy ought to tilt heavily against upsetting the historic limitations on patent ineligibility of natural laws and phenomena.

VI. THE DRAFT LEGISLATION IS CONTRARY TO SCIENTIFIC NORMS, MEDICAL ETHICS, AND HUMAN RIGHTS

Scholars and commentators have recognized that patents on laws and products of nature are in tension with important normative and societal values. These tensions ought to be of concern to the Subcommittee.

⁶³Brief for ARUP Laboratories, Inc. and Laboratory Corporation of America Holdings (d/b/a LabCorp) as *Amici Curiae* in Support of Petitioners at 19, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (Sept. 9, 2011) (No. 10-1150), https://www.americanbar.org/content/dam/aba/publishing/previewbriefs/Other_Brief_Updates/10-1150_petitioneramcuarupandlabcorp.pdf.

⁶⁴*Id.* at 17.

⁶⁵*See id.* at 16–17.

⁶⁶*Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).

SCIENTIFIC NORMS. Under the generally accepted Mertonian view of scientific ethics, “The substantive findings of science are a product of social collaboration and assigned to the community,” so the responsibility of the scientist is to share discoveries with the world such that all may benefit from those discoveries and conduct further research based on them.⁶⁷ The National Research Council has said that “scientific progress requires that research results be open for all to use, attempt to replicate, and evaluate.”⁶⁸ The Royal Society similarly has said: “Only by having knowledge unencumbered by property rights can the scientific community disseminate information and take science forward”; thus, “pure knowledge about the physical world should not be patentable under any circumstances.”⁶⁹

Patents on scientific discoveries obviously are irreconcilable with these principles of openness and collaboration in science.

MEDICAL ETHICS. Like scientists, doctors have ethical responsibilities to “continue to study, apply, and advance scientific knowledge” and to “make relevant information available to patients, colleagues, and the public.”⁷⁰ The American Medical Association specifically warns against patents on natural products, noting in its ethics opinions that “patents on processes, e.g. to isolate and purify gene sequences, are ethically preferable to patents on the substances themselves,” and that any medical patents “should be carefully constructed to ensure that the patent holder does not limit the use of a naturally occurring form of the substance in question.”⁷¹ Patents on products of nature and scientific discoveries are contrary to these principles.

⁶⁷Robert K. Merton, *A Note on Science and Democracy*, 1 J. LEGAL & POL. SOC. 115, 121 (1942).

⁶⁸NAT’L RESEARCH COUNCIL, *A PATENT SYSTEM FOR THE 21ST CENTURY* 26 (Stephen A. Merrill et al. ed., 2004), <https://www.nap.edu/catalog/10976/a-patent-system-for-the-21st-century> (citing ROBERT K. MERTON, *THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS* (1973)).

⁶⁹THE ROYAL SOC’Y, *KEEPING SCIENCE OPEN: THE EFFECTS OF INTELLECTUAL PROPERTY POLICY ON THE CONDUCT OF SCIENCE* para. 3.5, at 8 (Apr. 2003).

⁷⁰AM. MED. ASS’N, *AMA PRINCIPLES OF MEDICAL ETHICS* sec. VII (2001), <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/principles-of-medical-ethics.pdf>.

⁷¹COUNCIL ON ETHICAL & JUDICIAL AFFAIRS, *AM. MED. ASS’N, AMA CODE OF MEDICAL ETHICS* sec. 7.2.3(c) (2016), <https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview>, <https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview>.

Patents on diagnostic tests further conflict with doctors' obligations toward their patients because they potentially force doctors to withhold medical information from those patients. Consider an example proffered by the Cato Institute, in which a discovery is made that the presence of gum disease correlates with a risk of heart attack.⁷² That discovery is patented. A dentist, in the course of a routine cleaning, observes that indicative gum disease. Is the dentist to inform the patient and infringe the patent, or to honor the patent and thus let potentially lifesaving information go unmentioned?⁷³

HUMAN RIGHTS. Gene patents have been considered to infringe rights of human integrity and self-determination.⁷⁴ Multiple international bodies have recognized a human right to one's genetic resources and further observed that the patenting of another person's genes, particularly without consent, can be concerning from a human rights perspective. The United Nations Educational, Scientific and Cultural Organization's *Universal Declaration on the Human Genome and Human Rights*, adopted by the General Assembly of the United Nations, provides: "Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual."⁷⁵ Over 80 religious groups have opposed

⁷²See Brief of *Amici Curiae* Cato Institute et al. in Support of Petitioners at 26, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (Sept. 9, 2011) (No. 10-1150), https://www.americanbar.org/content/dam/aba/publishing/previewbriefs/Other_Brief_Updates/10-1150_petitioneramcucatoinst-reasonfound-andcei.pdf (citing Kevin Emerson Collins, *Constructive Nonvolition in Patent Law and the Problem of Insufficient Thought Control*, 2007 WIS. L. REV. 759, 760, <https://www.repository.law.indiana.edu/facpub/1747/>).

⁷³See *id.* at 27 (noting that the consequence of such a patent is to render mere thought to be infringement). It is unclear whether the exception to patent infringement for medical *treatments* would apply to medical *diagnoses*. See 35 U.S.C. § 287(c)(2)(a) ("the term 'medical activity' means the performance of a medical or surgical procedure on a body"). Even if it does, there are plenty of equally concerning situations imaginable. Is it inducement of patent infringement, for example, for a medical instructor to teach the correlation between gum disease and risk of heart attack?

⁷⁴See Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL'Y L. & ETHICS 403, 409–11 (2005), <https://digitalcommons.law.yale.edu/yjhple/vol5/iss1/13/>.

⁷⁵*Universal Declaration on the Human Genome and Human Rights*, Gen. Conf. Res. 16, UNESCO, 29th Sess., at art. 12(a), Doc. 29 C/Resolutions (1997), <https://unesdoc.unesco.org/ark:/48223/pf0000110220>, adopted by G.A. Res. 53/152, U.N. GAOR 3d Comm., 53d Sess., Agenda Item 110(b), U.N. Doc. A/RES/53/152 (Mar. 10, 1999), https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/53/152.

gene patents for similar reasons.⁷⁶

VII. THERE ARE MYRIAD BETTER ALTERNATIVES TO THE DRAFT LEGISLATION'S DRASTIC ALTERATION OF PATENT LAW

To the extent that any revision of § 101 is to be considered, it must be in tandem with substantial other revisions to related sections of the patent laws. Multiple scholars have recognized this fact, and the Subcommittee should as well.

For example, Professor Dreyfuss and colleagues—no friends of the current § 101 case law—agree that any alterations of that law must be joined with changes to other patent laws to facilitate research and to lower drug prices. The authors note that the 2010 HHS report called for “creation of exemptions from patent infringement for use of genetic tests for patient care purposes and for use of patent-protected DNA sequences for research purposes,” and in particular expansion of the currently inoperative defense of experimental use.⁷⁷ They also contend that any changes to patent subject matter eligibility should be tied to concomitant limitations on patents, including compulsory licensing, or federal government provision of services competitive with the patent owner’s, or even government cost controls.⁷⁸

Similarly, Professor Karshedt proposes revising subject matter eligibility under § 101 in tandem with the utility and 35 U.S.C. § 112 written description requirements, and specifically calls for a unified “completeness doctrine” either “barring all patent claims directed to objects of basic research” or creating a *sui generis* “partial or intermediate patent right for inventions that . . . fail completeness,” likely “a limited patent that comes only with the remedy of a compulsory license.”⁷⁹ These proposals of Professors Dreyfuss, Karshedt and others are further consistent with the League of Nations’ consensus view

⁷⁶See Fred B. Charatan, *US Religious Groups Oppose Gene Patents*, 310 BRIT. MED. J. 1351 (1995), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2549785/pdf/bmj00594-0013.pdf>.

⁷⁷Dreyfuss et al., *supra* note 9, at 580 (citing SACGHS REPORT, *supra* note 20, at 89, 94–95).

⁷⁸See *id.* at 585–88.

⁷⁹See Dmitry Karshedt, *The Completeness Requirement in Patent Law*, 56 B.C. L. REV. 949, 951, 958–59 (2015), <https://lawdigitalcommons.bc.edu/bclr/vol56/iss3/4/>.

in the 1920s on creating a right of scientific property, which would only have entailed a right to royalties and no right to exclude.⁸⁰

Comprehensive changes to the disclosure requirements under § 112(a) would also likely be necessary as well. Multiple independent scholars have noted that patents systematically fail to disclose sufficient information on the workings of patented inventions, meaning that the public grants a valuable exclusivity while not receiving adequate knowledge in return.⁸¹ Indeed, the inadequacy of patent disclosure, in combination with the draft legislation, means that a clever patent lawyer *could patent a law of nature before it is proven by science*, with obvious repercussions for downstream research.⁸²

Good disclosure is important for ensuring that patents promote innovation. In one study purporting to show that gene patents did not deter innovation,⁸³ the authors note that “the USPTO’s specific (and more stringent) requirements for the disclosure of sequenced genetic data may have made the disclosure function particularly effective.” Thus, to the extent that patentability is extended to natural laws and products beyond genes, the required disclosures in patents should be increased. In the software space, for example, many have called for complete disclosure of source code to satisfy the § 112(a) requirement.⁸⁴

It is noted that the draft legislation makes a revision to § 112(f), but that revision is neither necessary nor sufficient. By affecting only the interpretation of means-plus-function claims that are generally only noteworthy in software, the amendment to § 112(f) has minimal effect on gene patents or patents on scientific discoveries. It also makes no

⁸⁰See Comm. on Intellectual Cooperation, League of Nations, *Report on Scientific Property*, § 14, art. 5, at 25, League of Nations Doc. A.38.1923.XII A (Sept. 1, 1923) (prepared by F. Ruffini), <https://www.scribd.com/document/400469172/Ruffini-Report>.

⁸¹See Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 551 (2009); Price 2017, *supra* note 16, at 1612–13.

⁸²See Janet Freilich, *Prophetic Patents* 3–4, in 2018 NAT’L BUREAU ECON. RES. SUMMER INST.: INNOVATION, http://papers.nber.org/conf_papers/f104433.pdf.

⁸³See Sampat & Williams, *supra* note 62. *But see* discussion *supra* note 62 (noting substantial limitations of their study).

⁸⁴See, e.g., Kenneth Canfield, *The Disclosure of Source Code in Software Patents: Should Software Patents Be Open Source?*, 7 COLUM. SCI. & TECH. L. REV. 6 (2006).

improvement to the state of patent disclosure as discussed above, which is governed by § 112(a), not § 112(f).

That being said, the Subcommittee should consider changes to claiming practice, but the correct section to amend would be not § 112(f), but § 112(b) and in particular the doctrine of enablement of “the full scope of the claimed invention”⁸⁵ and the propriety of single-species disclosures for patent claims covering a broader genus of which the disclosed species is just one example.⁸⁶ The Subcommittee also ought to look to improving clarity of the indefiniteness doctrine under § 112(b) and the obviousness doctrine under 35 U.S.C. § 103, both of which in my view have been construed too narrowly,⁸⁷ and clarifying the obviousness-type double-patenting doctrine, on which the Federal Circuit is currently irreconcilably divided.⁸⁸

VIII. THE STAKEHOLDER PROCESS THAT LED TO THE DRAFT LEGISLATION INCLUDED INADEQUATE REPRESENTATION OF CRITICAL INTERESTS

The many unresolved substantive issues with the draft legislation are more than sufficient reason not to move it forward in anything near its current form. But the defects in the procedure by which the draft was developed give more cause for concern.

The present draft was reached after a series of closed-door, invitation-only

⁸⁵*In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993); see Bernard Chao, *Rethinking Enablement in the Predictable Arts: Fully Scoping the New Rule*, 2009 STAN. TECH. L. REV. 3 (arguing that “the full scope rule is extremely difficult to apply and will cause unnecessary litigation”).

⁸⁶See *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (written description sufficient for a genus claim “requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus”); with *id.* at 1366 (Newman, J., dissenting) (“Under this new doctrine, patent applicants will face a difficult burden in discerning proper claiming procedure under this court’s unpredictable written description of the invention requirement.”).

⁸⁷See Brief of Public Knowledge and the Electronic Frontier Foundation as *Amici Curiae* in Support of Petitioner, *Nautilus, Inc. v. Biosig Instruments, Inc.*, No. 15-561 (U.S. Nov. 16, 2015), <https://www.publicknowledge.org/documents/pk-eff-nautilus-ii-cert>; Brief of *Amici Curiae* Public Knowledge and the Electronic Frontier Foundation in Support of Petitioner, *K/S HIMPP v. Hear-Wear Techs., LLC*, 135 S. Ct. 1439 (Jan. 22, 2015) (No. 14-744) (cert. denied), <https://www.publicknowledge.org/documents/pk-and-eff-brief-himpp-v-hear-wear>.

⁸⁸See Brief of the R Street Institute and Public Knowledge as *Amici Curiae* in Support of the Petition at 5–8, *Mylan Pharm. v. UCB, Inc.*, No. 18-692 (U.S. Dec. 21, 2018), https://www.supremecourt.gov/DocketPDF/18/18-692/77397/20181221151024017_brief-mylan-ucb-petition.pdf.

roundtable discussions populated largely by industry and patent professionals. I am unaware of any participation by academics, patient advocates, access-to-medicines groups, or basic science researchers, among others. Those exclusions continued despite my own repeated attempts to obtain an invitation either for myself or for several of my colleagues among those groups.

I am appreciative of the fact that the present hearings have sought to be more inclusive, and indeed include one group that I specifically asked to have included: the American Civil Liberties Union, which litigated the *Myriad* case. But that still excludes a significantly wider community of organizations and experts on access to medicines. Organizations like Public Citizen, the Campaign for Sustainable Rx Pricing, Citizen Outreach, Knowledge Ecology International, the Alliance for Retired Americans, the National Coalition on Health Care, the American Medical Student Association, Doctors for America and many others have all agreed that the “radical change” effected by this legislation “will impede drug development and access to medicines.”

To that end, attached to my testimony is a letter signed by those organizations and experts, expressing concern about the legislation. My hope is that this letter serves to highlight that the interests of these organizations and individuals are important and worthy of this Subcommittee’s consideration before it moves forward with any legislation on this topic.

IX. A GREAT DEAL OF FURTHER WORK IS NEEDED ON THE DRAFT LEGISLATION

For the foregoing reasons, I do not believe that the draft legislation should advance beyond this Subcommittee. Furthermore, I do not believe that mere alterations to the existing text can rehabilitate the draft, both because the problems I have described above inhere in the core components of the draft text and because no quantity of changes can overcome the tainted procedure that led to the original.

Instead, I recommend that the Subcommittee return to the drawing board and hold open roundtables that include the many stakeholder constituencies I have identi-

fied above, along with others as the Subcommittee may find. No doubt this will make for a more difficult process than one composed of elite patent experts, and the window for agreement will no doubt be narrower. But that is the very nature of deliberative republicanism—not to move quickly, but to move correctly. It is the responsibility of this Subcommittee and of each of its members to advance policy not just in the interest of the patent bar, not just in the interest of particular industries, but in the interest of the American people.

I thank the Subcommittee for inviting me to testify before you, and am happy to answer any questions you may have.

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