

June 8, 2021

The President
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. President,

We, the undersigned civil rights, medical, scientific, technology, patient advocacy, and environmental organizations, write to express our opposition to legislation or regulatory action that would overturn established Supreme Court precedent and expand patent-eligible subject matter to encompass abstract ideas, laws of nature, or natural phenomena. The doctrine of patent subject matter eligibility developed over 150 years of Supreme Court jurisprudence promotes innovation and competition by ensuring that the fundamental building blocks of invention cannot be monopolized. However, for many years, the Patent and Trademark Office interpreted subject matter eligibility more broadly. Recent Supreme Court case law reinvigorated the doctrine. The current law incentivizes and rewards investment in new technology, without hampering innovation, by granting a period of exclusivity to specific new inventions while protecting access to knowledge and ideas. Allowing patents on abstract ideas, laws of nature, or natural phenomena would harm consumers by stymieing competition and thwart technological innovation in areas ranging from medicine, to software, and green technology by restricting use of “the basic tools of scientific and technological work.”¹

The Patent Act allows patents to be granted for any new and useful process, machine, article of manufacture, or composition of matter, as well as for any improvement to such inventions.² The Supreme Court has distinguished between “the building blocks of human ingenuity,” which are ineligible for patent protection, and inventions that “integrate the building blocks into something more,” which if original are entitled to patent protection.³ The Court has developed a robust body of case law clarifying the limits on patent eligibility and establishing important protections to promote free access to abstract ideas, laws of nature, and natural phenomenon.

In 2019, some members of the House and Senate proposed legislation that would abrogate all case law establishing and interpreting this limitation on subject matter eligibility. In March of 2021, in a letter to the Commissioner for Patents, four senators reasserted their belief in the need for congressional action and requested that the Patent and Trademark Office issue a report on

¹ *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

² 35 U.S.C. § 101.

³ *Alice Corp. Pty. Ltd. v. CLS Bank Int’l.*, 573 U.S. 208, 216–17 (2014).

patent eligibility jurisprudence.⁴ And just last week, Senator Tillis announced he will reconvene a Member-driven effort to amend Section 101 in the near future.⁵ Any legislation abrogating Supreme Court precedent and expanding patent subject matter eligibility to include abstract ideas, laws of nature and natural phenomenon would conflict with the goals of the Biden administration.

Current Supreme Court case law prescribing the subject matter that is eligible for patent protection strikes the correct balance between rewarding innovation and protecting competition and further advancement. Specific inventions can be patented, but the “building blocks of human ingenuity” must remain free for others to use.⁶ For example, a telegraph machine is patent eligible, but the idea of using electricity to transmit signs, letters, or characters is not.⁷ A patent can be granted for a specific genetically engineered bacteria,⁸ but not for combining naturally occurring strains of bacteria where the selection of the strains to be combined is informed by their inherent properties.⁹

The law and Supreme Court precedent that informs patent subject matter eligibility has been effective in spurring innovation while allowing competition among solutions to some of our country’s greatest current challenges. Our nation’s pressing need to combat novel health threats has demonstrated the importance of limiting patent eligibility for isolated, naturally occurring genetic sequences. For example, the genetic sequence of the SARS-CoV-2 virus that is responsible for COVID-19 is unpatented and freely available. In contrast, during the 2003 outbreak of severe acute respiratory syndrome (SARS), because the Supreme Court had not yet clarified that naturally occurring genetic sequences are patent ineligible, pharmaceutical and biotechnology companies raced to file patent applications to obtain exclusive rights to the virus and its genetic sequence.¹⁰ In an effort to preserve access to the fundamental research needed to combat the SARS crisis, the U.S. Centers for Disease Control and Prevention was forced to defensively file its own patent applications. A spokesman for the CDC clarified that the intent was to “prevent folks from controlling the technology” and “give the industry and other researchers reasonable access to the samples.”¹¹

⁴ Letter from Sens. Thom Tillis, Tom Cotton, Mazie Hirono & Christopher A. Coons to Drew Hirshfeld, Comm’r of Patents (Mar. 5, 2021), <https://www.tillis.senate.gov/services/files/04D9DCF2-B699-41AC-BE62-9DCA9460EDDA>.

⁵ Although we disagree with the senators’ assertion that the current jurisprudence has “adversely impacted investment and innovation in critical technologies,” *id.* at 2, to the extent that the administration pursues the requested study or any action in this arena, a broader set of stakeholder agencies beyond the Patent and Trademark Office must be consulted, including the White House Office of Science and Technology Policy, U.S. Department of Health and Human Services, and the U.S. Trade Representative.

⁶ *Alice*, 573 U.S. at 216.

⁷ See *O’Reilly v. Morse*, 56 U.S. 62 (1854).

⁸ See *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

⁹ See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130–31 (1948).

¹⁰ Paul Elias, *Race to Patent SARS Virus Renews Debate*, ASSOCIATED PRESS (May 5, 2003), <https://apnews.com/article/145b4e8d156cddc93e996ae52dc24ec0>.

¹¹ *Id.*

Public access to the unpatented genetic sequence of the virus responsible for the COVID-19 pandemic has not inhibited innovation. Indeed, it has encouraged multiple solutions to the problems presented by COVID-19, enabling researchers to develop and companies to commercialize a variety of diagnostic tests and vaccines at unprecedented speed, promoting consumer access and choice.¹² Consumers can choose between rapid but less-accurate antigen tests and slower but more-accurate nucleic acid-based tests¹³ and have the opportunity to receive one of a growing number of vaccines.¹⁴ The diversity of vaccine and diagnostic options gives us the tools we need to fight the COVID-19 pandemic where a single test or vaccine has not been produced in sufficient quantity or with sufficient speed to meet our health care needs.

Nothing in the Supreme Court’s interpretation of patent subject matter eligibility prevents innovators from obtaining patents.¹⁵ Rather, the Patent Office has rewarded parties for investing time and resources into combatting the COVID-19 and other health crises with patents on their specific innovations. The pharmaceutical companies Moderna and BioNTech have patented specific aspects of their COVID-19 vaccines.¹⁶ Diagnostic Hybrids and Cytovia were granted patents for specific inventions directed towards the diagnosis and treatment of SARS.¹⁷ Expanding patent eligibility to include laws of nature or natural phenomena is likely to reduce the variety and quantity of diagnostic tests and vaccines available to the public, increase prices and healthcare costs, and stymie the nation’s efforts to control future pandemics.

The state of genetic testing for cancer before the Supreme Court decided *Association for Molecular Pathology v. Myriad Genetics* also illustrates the harm to innovation and consumers posed by a single company monopolizing a natural phenomenon and “wall[ing] off an entire domain of [n]ature from observation.”¹⁸ Prior to this decision, Myriad Genetics held patents on the isolated form of the *BRCA1* and *BRCA2* genes, mutations in which are associated with a high

¹² *NCBI SARS-CoV-2 Resources*, NAT’L LIBRARY OF MED., <https://www.ncbi.nlm.nih.gov/sars-cov-2/> (last visited Mar. 7, 2020).

¹³ *Coronavirus Disease 2019 Testing Basics*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics> (last visited Mar. 7, 2020).

¹⁴ *Different COVID-19 Vaccine Types*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html> (last visited Mar. 7, 2020).

¹⁵ Since the Supreme Court’s 2013 decision in *Association for Molecular Pathology v. Myriad Genetics*, the U.S. Patent Office has issued about 2.5 million new patents (over 20% U.S. patents ever issued).

¹⁶ Mario Gaviria & Burcu Kilic, *BioNTech and Pfizer’s BNT162 Vaccine Patent Landscape*, PUB. CITIZEN, (Nov. 16, 2020), <https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/>; Mario Gaviria & Burcu Kilic, *mRNA-1273 Vaccine Patent Landscape (For NIH-Moderna Vaccine)*, PUB. CITIZEN, <https://www.citizen.org/article/modernas-mrna-1273-vaccine-patent-landscape/> (last visited Mar. 7, 2020).

¹⁷ U.S. Patent No. 7,504,382; U.S. Patent No. 7,129,042. See generally *Coronavirus Innovation Guideposts on the Eve of the COVID-19 Pandemic*, Nat’l L. Rev. (July 3, 2020), <https://www.natlawreview.com/article/coronavirus-innovation-guideposts-eve-covid-19-pandemic>.

¹⁸ Brief for Amicus Curiae Eric S. Lander in Support of Neither Party at 24, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

risk of breast and ovarian cancer. As such, the company had the sole right to market and conduct genetic tests that could identify mutations in the *BRCA* genes and inform patients about their risk of developing hereditary breast and ovarian cancer. It prevented others from developing and administering tests for *BRCA* mutations that were more comprehensive than its own, which needlessly increased the cost of testing and gave consumers a potentially misleading impression of their genetic risks. The United States, as represented by the U.S. Solicitor General serving the Obama-Biden administration, opposed these patents in the Supreme Court, contradicting the Patent Office.¹⁹ After the Supreme Court held that isolated DNA sequences were outside the scope of patentable subject matter,²⁰ several companies immediately announced that they would offer their own tests, quickly providing screening for additional *BRCA* mutations, lowering costs, and decreasing time between clinical research and commercialization.²¹ Following the decision, a competitive genetic testing industry flourished and investment in the life sciences sector increased from \$6.21 billion in 2013 to \$17.72 billion in 2018.²²

Current law establishing patent subject matter eligibility also promotes healthy competition and encourages innovation in the technology industry. Discovery of a correlation between genetic information and a medical condition is currently treated as unpatented pre-competitive information, which does not prevent the patenting of new and better ways to detect a specific mutation. For that reason, there is no shortage of effort being expended in discovering new mutations and their relevance, but permitting a “land-grab” of claims to newly identified correlations would thwart efforts to interpret one’s full complement of genetic information, impeding innovation and competition.

The software industry, also, has continued to thrive in the years following the Supreme Court’s decisions clarifying patent subject matter eligibility limitations, suggesting that the current restrictions do not harm software developers or businesses. Investment in research and development for the software industry doubled in 2018,²³ four years after *Alice* “clarif[ied] that the addition of a generic computer was not enough” for subject matter eligibility,²⁴ and venture

¹⁹ Brief for United States, Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

²⁰ Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

²¹ Andrew Pollack, *After Patent Ruling, Availability of Gene Tests Could Broaden*, N.Y. TIMES (Jun. 13, 2013), <https://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html>.

²² *The State of Patent Eligibility in America: Part II Before the S. Subcomm. on Intellectual Property*, 116th Cong. (2019) (statement of Sean George, CEO, Invitae Corp.), <https://www.judiciary.senate.gov/imo/media/doc/George%20Testimony.pdf>.

²³ *The State of Patent Eligibility in America: Part II Before the S. Subcomm. on Intellectual Property*, 116th Cong. (2019) (statement of David W. Jones, Exec. Dir., High Tech Innovators All.), <https://www.judiciary.senate.gov/imo/media/doc/Jones%20Testimony1.pdf>; strategy&, *PWC 2018 Global Innovation 1000 & What the Top Innovators Get Right* (Oct. 2018), slide 28, <https://www.strategyand.pwc.com/gx/en/insights/innovation1000/2018-global-innovation-1000-fact-pack.pdf>.

²⁴ *Netflix Inc. v. Rovi Corp.*, 114 F. Supp. 3d 927, 934 (N.D. Cal. 2015).

capital funding for software start ups was the highest it had ever been.²⁵ Courts have fostered competition by ruling that basic abstract ideas such as storing scanned data,²⁶ content streaming,²⁷ and sending money transfers²⁸ cannot be patented. This healthy entrepreneurial ecosystem is crucial to developing technologies to address common problems, such as improving access to health care. Telehealth reveals other examples of abstract ideas that cannot be monopolized under the Supreme Court’s current interpretation of patent subject matter eligibility.²⁹ Innovative companies across the country are implementing new tools to assist in connecting underserved communities to qualified providers, or improving outcomes and reducing costs by increasing patient and provider engagement. That progress and those benefits are possible because courts have correctly concluded that no one can patent underlying ideas of scheduling appointments or collecting, analyzing, and transmitting patient data. These ideas should remain patent ineligible to guarantee that all Americans have access to affordable, quality health care. Congress should not act to overturn this precedent and allow monopolies to drive up costs and limit access.

Section 101 also has a critical role to play in weeding out low-quality patents, especially the types of low-quality patents that are routinely asserted against startups and small businesses. Indeed, broad, preemptive patents directed to abstract ideas—those appropriately deemed ineligible under current law—are especially concerning because they can be, and are, asserted against numerous accused infringers based on routine business activities or use of generic technology. Section 101 is valuable, and needed especially now, to focus the U.S. patent system on technological advances, improvements, and solutions, as well as to curb the amount of and expense associated with litigation over low-quality patents.

Access to abstract ideas, laws of nature, and natural phenomena is important now more than ever. The availability of these fundamental principles is critical in supporting the development of innovative fields of research that are still in their infancy and critical to the interests of the Biden administration. One such field is personalized or “precision” medicine, which uses patient-specific variables such as genetics, lifestyle, and environment to identify susceptibility to particular diseases and tailor treatments to the individual. Early studies suggest that treatment for severe COVID-19 cases, cancer, and opioid addiction may benefit from precision medicine. For example, five key gene variants appear to be responsible for the antiviral immunity and lung inflammation associated with severe COVID-19.³⁰ Identifying which patients have higher

²⁵ Jones, *supra* note 21; National Venture Capital Association, *Venture Monitor*, 4Q 2018 at 19, https://files.pitchbook.com/website/files/pdf/4Q_2018_PitchBook_NVCA_Venture_Monitor.pdf.

²⁶ See *Content Extraction & Transmission LLC v. Wells Fargo Bank, N.A.* 776 F.3d 1343 (Fed. Cir. 2014).

²⁷ See *Intellectual Ventures I v. Symantec Corp.*, 838 F.3d 1307 (Fed. Cir. 2016).

²⁸ See *Integrated Tech. Sys., Inc. v. First Internet Bank of Ind.*, No. 2:16-cv-00417 (E.D. Tex. Jan. 30, 2017).

²⁹ *CardioNet v. InfoBionic*, 816 F. App’x 471, 475-77 (Fed. Cir. 2020); *Am. Well Corp. v. Teladoc, Inc.*, No. 1:15-cv-12274, Op. at 10, 16–17 (D. Mass. June 13, 2016).

³⁰ Max Kozlov, *Key Genes Related to Severe COVID-19 Infection Identified*, *SCIENTIST* (Dec. 14, 2020), <https://www.the-scientist.com/news-opinion/key-genes-related-to-severe-covid-19-infection-identified-68276>.

genetic risk could enable more effective treatment. Advanced gene testing can also inform cancer treatments by targeting specific proteins or mutations that drive the cancer's growth.³¹ Investment in such testing was a key recommendation of the Cancer Moonshot Blue Ribbon Panel led by then-Vice President Biden.³² Similarly, evidence is emerging that gene therapy may be a promising treatment for opioid addiction.³³ In *Mayo Collaborative Services v. Prometheus Labs*, the Supreme Court held that a patent cannot be obtained for the medical correlation between a body's metabolite levels and adjusting the dose accordingly.³⁴ Overturning that precedent would allow one company to use a patent to prevent competitors from developing their own methods of tailoring treatment to the individual patient, impeding many of the goals of precision medicine. Public access to laws of nature and natural phenomena is a crucial prerequisite to nurturing scientific discoveries and uncovering treatments that stand to benefit millions of Americans.

Protecting access to abstract ideas is also necessary to cultivate innovative technology that defends against climate change. The administration's goal of net zero economy-wide emissions by 2050 will be substantially more feasible if no single company can patent the scientific concepts behind green technologies. Hydrogen produced with a low to zero-carbon footprint, air conditioner and heat pump refrigerants with no global warming potential, and affordable grid-scale energy storage are examples of promising innovations that can be achieved at a lower cost than polluting alternatives,³⁵ as long as market competition is not stifled by patents covering abstract ideas. Excluding abstract ideas and laws of nature from patentable subject matter still allows innovators to patent specific applications of those principles, encouraging multiple complementary or competing solutions. For example, a company should not be able to monopolize the idea of converting algae into sustainable fuel, but manufacturers may patent particular methods of extracting oil and producing renewable diesel from biomass.³⁶ This balance allows nations across the world to safeguard the future of green technology, reduce their contributions to the climate crisis, and defend their citizens against natural disasters caused by climate change.

³¹ See AM. MED. ASS'N, REPORT 3 ON THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-16): THE PRECISION MEDICINE INITIATIVE (2016), <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/about-ama/councils/Council%20Reports/council-on-science-public-health/a16-csaph3.pdf>.

³² See CANCER MOONSHOT BLUE RIBBON PANEL, PRECISION PREVENTION AND EARLY DETECTION WORKING GROUP RECOMMENDATION: CANCER PREVENTION AND EARLY DETECTION IN INDIVIDUALS AT HIGH RISK FOR CANCER (Oct. 2016), <https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel/prevention-screening-working-group-report.pdf>.

³³ See Shao-Cheng Wang, Yuan-Chuan Chen, Chun-Hung Lee, and Ching-Ming Cheng, *Opioid Addiction, Genetic Susceptibility, and Medical Treatments: A Review*, 20 INT. J. MOL. SCI. 4294 (2019).

³⁴ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

³⁵ *Biden-Harris Administration Launches American Innovation Effort to Create Jobs and Tackle the Climate Crisis*, WHITEHOUSE.GOV (Feb. 11, 2021), <https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/11/biden-harris-administration-launches-american-innovation-effort-to-create-jobs-and-tackle-the-climate-crisis/>.

³⁶ See U.S. Patent No. 9,115,332.

The existing case law regarding subject matter eligibility reflects a consistent judicial approach that promotes certainty for innovators. The Supreme Court has made clear its support for the limitations on patenting abstract ideas, laws of nature, and natural phenomena, issuing unanimous holdings in the four most recent cases on subject matter eligibility.³⁷ These decisions build on 150 years of case law distinguishing between specific inventions, which can be patented, and the underlying natural phenomena, laws of nature, and abstract ideas, which cannot.³⁸ While the tests applied have been refined over the years, despite sometimes divergent interpretations implemented by the PTO, the basic distinction is an old one that has been successfully applied to a broad range of technologies, from pharmaceuticals to genetically manipulated organisms to combinations of bacteria, from computerized financial techniques³⁹ to the telephone⁴⁰ to pencils with rubber erasers.⁴¹ Contrary to statements by proponents of legislation to expand patent eligibility, uprooting 150 years of case law would create new uncertainty, risking a slew of costly new litigation as the boundaries of this new legal landscape develop from scratch. Moreover, any repeal of the Section 101 patent-eligibility limitations would risk violating the U.S. Constitution, particularly the First Amendment and Article I’s authorization of only patents that “promote the progress of science and the useful arts.”

The current state of subject matter eligibility strikes the proper balance between allowing innovators to protect their investments and encouraging healthy competition that benefits consumers. We oppose any expansion of patent eligibility that would eliminate the limitations necessary to achieve affordable and quality health care, technological innovation, and climate change solutions. Any revision of the Patent Act should maintain free access to abstract ideas, laws of nature, and the products of nature. For any further questions, please contact Kate Ruane, American Civil Liberties Union, kruane@aclu.org, or Sandra Park, American Civil Liberties Union, spark@aclu.org.

Sincerely,

American Civil Liberties Union
ACT | The App Association
AliveAndKickn
Alstrom Syndrome International
American College of Medical Genetics and Genomics
American College of Neuropsychopharmacology

³⁷ See *Alice*, 573 U.S. 208; *Myriad*, 569 U.S. 576; *Mayo*, 566 U.S. 66; *Bilski v. Kappos*, 561 U.S. 593 (2010).

³⁸ *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853) (“A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.”).

³⁹ See *Alice*, 573 U.S. at 212.

⁴⁰ See *The Telephone Cases*, 8 S. Ct. 778, 781–82 (1888).

⁴¹ See *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. 498, 499–500 (1874).

American Physiological Society
American Society for Clinical Pathology
American Society for Investigative Pathology
American Society of Human Genetics
AnCan
ARUP Laboratories
Association for Molecular Pathology
Association of Pathology Chairs
Biotia
BRCA Advanced & Other Hereditary Cancers Journal Club
Breast Cancer Action
Bridge the Gap - SYNGAP Education and Research Foundation
Broad Institute of MIT and Harvard
Cactus Cancer Society (formerly Lacuna Loft)
Coalition Against Patent Abuse
College of American Pathologists
Consortium for Science, Policy & Outcomes
Developers Alliance
Dysautonomia International
Electronic Frontier Foundation
Endocrine Society
Engine
GeneMatters
Global Alliance for Genomics and Health
Invitae Corporation
Lupus and Allied Diseases Association, Inc.
MLD Foundation
My Gene Counsel
Onegevity
Society of Biological Psychiatry
Society of Toxicology
The Light Collective

cc: The Honorable Eric Lander, Director, White House Office of Science and Technology Policy
The Honorable Xavier Becerra, Secretary, U.S. Department of Health and Human Services
The Honorable Andrew Hirshfeld, Acting Under Secretary of Commerce for Intellectual Property and Director, U.S. Patent and Trademark Office, U.S. Department of Commerce