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The Honorable Chuck Grassley
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The Honorable Thom Tillis
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The Honorable Darrell Issa
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Dear Chairman Durbin, Ranking Member Grassley, Chairman Leahy, Ranking Member Tillis, Chairman Nadler, Ranking Member Jordan, Chairman Johnson, and Ranking Member Issa:

I write to you today to address the recently introduced bipartisan Patent Eligibility Restoration Act of 2022.

Critics of this draft legislation echo common complaints about including isolated and purified human genes and other naturally occurring substances as patent-eligible subject matter under 35 U.S.C. § 101. Specifically, these critics argue that the proposed inclusion of isolated and purified human genetic material and other naturally occurring substances as patent eligible subject matter is unnecessary and would both stymie research and obstruct access to medicine. These criticisms rely mostly on narrative and anecdote rather than rigorous empirical evidence, however.

A different narrative – and one that better reflects technological and economic reality, as well as the data – is that including purified and isolated substances as eligible subject matter under 35 U.S.C. § 101 can benefit patients, researchers, and innovation. Senators Tillis and Coons’ draft bill legislatively

overrules the Supreme Court's 2013 decision in *AMP v. Myriad Genetics* in ways that could boost investment in biotechnology R&D. Biotechnological innovation is notoriously long, risky, and resource-intensive. Identifying the existence, location, and sequence of the gene variants in *Myriad*, for example, took decades of effort.¹ New biologic treatments such as gene therapies can require well over \$1 billion. Without patents, many such innovations might never see the light of day.

Furthermore, to the extent anecdotal evidence is relevant, patents also help drive basic research in genetic and other biotech. For example, patents clearly were the focus of university scientists racing to identify the BRCA1 and BRCA2 genes, which identify markedly higher risks of certain cancers, as well as for researchers racing to identify a gene relevant to Alzheimer's.² Patent protection for early-stage research is important in attracting privately sponsored research funding and helping to protect what could be long and uncertain next steps. This is why the U.S. passed the Bayh-Dole Act – to foster development and commercialization of research that would otherwise be underutilized. Professor David Taylor has shown that recent Supreme Court decisions limiting patentable subject matter have decreased the likelihood and size of investments in new technology and that, of these recent decisions, *Myriad* had the largest effect.³

The U.S. has historically led the way in biotechnology, but if the U.S. does not broaden patentable subject matter, many investors and innovators may ship their efforts abroad. While methods of using genes can be patented under current law, such method patents provide much less protection than patents on the genes themselves. The European Union, China, and Japan, for instance, hold purified or isolated substances to be patentable subject matter. The European Union's Biotechnology Directive specifically provides that “[b]iological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.”

Society understandably balks at propertizing human genes. The Tillis-Coons draft bill makes clear that “unmodified” human genes and other materials as they exist in the human body ineligible for patenting; naturally occurring materials must be “isolated, purified, enriched, or otherwise altered by human activity” Genetic material patents do not propertize us or our individuality. Far from it – the genes of most interest for patenting are those that are not unique to any particular individual but instead signify important commonalities.⁴

With regard to safety, privacy, or morality concerns that genetic and other biotech patents may raise, courts have consistently held that the patent system is ill-suited to address these interests, which are better addressed through other areas of law. And to the extent morality does apply, failure to incentivize application of genetic and other substances itself is arguably immoral and violative of human rights to health care.

Some critics nonetheless assert that gene patents deter access to medical care as well as further medical research. This criticism can be levied against any patent, however – any patent can impact further research on its subject matter and allow supracompetitive pricing during its twenty-year term. Indeed, that is the point of the patent system – to provide a temporary pricing advantage to incentivize difficult, expensive innovation that otherwise would not attract investment.

And while patents do have the potential to price patients out of access to diagnostic tests, drugs, and

¹ Jorge L. Contreras, *Association for Molecular Pathology v. Myriad Genetics: A Critical Reassessment*, 27 MICH. TECH. L. REV. 1, 5-9 (2020)

² Robert Dalpé et al., *Watching the Race to Find the Breast Cancer Genes*, 28 SCI. TECH. & HUMAN VALUES 187 (2003); Tania Bubela, Saurabh Vishnubhakat & Robert Cook-Deegan, *The Mouse That Trolled: The Long and Tortuous History of a Gene Mutation Patent That Became an Expensive Impediment to Alzheimer's Research*, 2 J.L. & BIOSCI. 213 (2015).

³ David O. Taylor, *Patent Eligibility and Investment*, 41 CARDOZO L. REV. 2019 (2020). Some have questioned Prof. Taylor's results given the number of survey responses on which they are based. It is not the number of survey responses but rather the statistical significance of the results that matter, however.

⁴ Thus, contrary to assertions by some, patenting genetic materials does not raise issues of individual consent.

other health care, the effect of patents depends on context. A study by Robert Cook-Deegan and others at the Duke University Center for Genome Ethics (included in an oft-cited report by the Department of Health and Human Services), found that the BRCA1 and BRCA2 patents had little consistent effect on the price of diagnostic testing. Instead, testing costs seemed to be affected more by insurance coverage and which testing methods were available. Even now after the Court's decision in *Myriad*, genetic screening for BRCA1 and BRCA2 can still cost anywhere from \$200 to \$5,000, depending on whether a test screens for only three variants or the more than 1000 that have been identified.

The effects of patents on R&D are also context-dependent. Patents on genes or other naturally occurring matter do have the potential to obstruct further research and development. But so do patents on other foundational inventions such as the PCR technique for gene amplification or the scanning tunneling microscope used in nanotechnology research. Indeed, any patented invention can impact follow-on R&D, regardless of how similar or different it is from naturally occurring phenomena. On the other hand, many patents, including those on products or laws of nature, are quite narrow in scope, with little effect on downstream research.⁵ A study by Bhavan Sampat and Heidi L. Williams suggests that patents on genes had little effect on follow-on innovation and in fact were preferable to keeping the gene sequences as trade secrets. As Sampat and Williams note, underlying much of the criticism of gene patenting "seems to be an assumption that if genes are not patented, they would be placed in the public domain."⁶ Furthermore, patents on genes are not in fact patents on the information encoded in them – that information is still free for others to use, even if the underlying genetic material itself may not be. Indeed, the patent system often accelerates invention of new technologies, such as protein screening and nanopore genetic sequencing, that effectively design around existing patents.

It also should be remembered that, even before the *Myriad* decision, patents on genetic material and purified natural substance faced various limitations. The Federal Circuit's 2005 decision on *In re Fisher*, for example, held that to be patentable expressed sequence tags (short snippets of cDNA) had to possess more utility than merely as research intermediates. The Federal Circuit's 2009 decision in *In re Kubin* held that gene sequences are unpatentably obvious if the amino acid sequences of the proteins for which they code are already known. The written description requirement frequently has been used to narrow the scope and patentability of genetic material and other biotech inventions. Anticipation of genetic sequences, particularly short sequences such as oligonucleotides, has become easier to demonstrate as more genetic sequencing becomes prior art.⁷ Senators Tillis and Coons also are considering an experimental-use exception, such as those employed in other countries' patent systems, which could also alleviate any perceived deterrence of downstream research.

Genetic material is valuable for more than just its informational content, moreover. Genetic materials can function physically and biochemically as promoters, enhancers, primers, telomeres, transfer units, plasmids, and deoxyribozymes. Most importantly, genetic materials have now been developed into gene therapies for some types of metabolic disorders, neurologic disorders in children, hemophilia and thalassemia, and blindness, and for many types of cancer. Because we currently lack the ability to create living organisms or even to manufacture most biological materials through non-naturally occurring

⁵ Moreover, genetic material patents or other allegedly "evergreening" pharmaceutical patents can often be avoided. Lipitor (atorvastatin) – cited to the Subcommittee on Intellectual Property during hearings to illustrate the dangers of gene patenting – saw marked generic entry in 2011 despite several other Orange Book listed patents, expiring as late as 2017. See also Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECH. 1091, 1092 (2006) ("The [predicted] effects are much less prevalent than would be expected if [the] hypothesized [anticommons] mechanisms were in fact operating.").

⁶ Bhavan Sampat & Heidi L. Williams, *How Do Patents Affect Follow-On Innovation? Evidence from the Human Genome*, 109 AM. ECON. REV. 203, 207 (2019).

⁷ To the extent that it is relevant, the viral statistic that twenty percent of the human genome had been patented prior to *Myriad* has long since been debunked. See, e.g., Christopher M. Holman, *Will Gene Patents Derail the Next Generation of Genetic Technologies?: A Reassessment of the Evidence Suggests Not*, 80 UMKC L. REV. 563, 572-93 (2012); Lisa Larrimore Ouellette, *Access to Bio-Knowledge: From Gene Patents to Biomedical Materials*, 2010 STAN. TECH. L. REV. N1, 17 (2010).

processes, categorically prohibiting patents on genes and other naturally occurring substances could hamper investment in biotech R&D. As Justice Breyer once observed, “[R]esearch into such matters [as phenomena of nature] may be costly and time-consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race.” *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126–27 (2006).

At their core, the proposed amendments to § 101 seek to create certainty. Patentable subject matter decisions have long been seen as nothing more than intuition. Judges, administration officials, and members of Congress have grumbled for over a decade about the uncertainty of patentable subject matter, which the decisions in *Mayo v. Prometheus* and *Alice Corp. v. CLS Bank* have only aggravated. Certainty is valuable to patent rights holders and the public alike and would be served by the bill’s efforts to draw clearer lines, even if one might disagree with where the bill draws those lines. As the Supreme Court noted in *Mayo*, “we must recognize the role of Congress in crafting more finely tailored rules where necessary.”

Thank you very much for your time and consideration of this letter.



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