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# COVID-19 as an Example of Why Genomic Sequence Data Should Remain Patent Ineligible

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**SUMMARY.** The researchers who determined the genomic sequence of the SARS-CoV-2 virus did not seek to patent it, but instead released it in the publicly-accessible GenBank data repository. Their release of this critical data enabled the scientific community to mobilize rapidly and conduct research on a range of diagnostic, vaccine, and therapeutic applications based on the viral RNA sequence. Had the researchers sought patent protection for their discovery, as earlier research teams had during the SARS, H1N1 and H5N1 outbreaks, global research relating to COVID-19 would have been less efficient and more costly. One of the reasons that patents are no longer sought on genomic sequences is the U.S. Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, which established that a sequence of naturally-occurring nucleotides is an unpatentable "product of nature" (*Association for Molecular Pathology v. Myriad Genetics, 2013*). Yet, in the midst of the COVID-19 crisis, patent advocates are calling on Congress to overturn the Myriad decision and once again allow patenting of genomic sequences. This Chapter argues that the COVID-19 pandemic illustrates why the "product of nature" exclusion under patent law, which prevents the patenting of genomic sequence data, should be preserved and strengthened under U.S. law.

## Introduction

From the beginning of the COVID-19 pandemic, governments, health care advocates, and scholars around the world expressed concern that patents could slow the manufacture and distribution of medical supplies, equipment, vaccines, and therapies to populations most in need of them. Chapter 21 of *Assessing Legal Responses to COVID-19: Volume I*, discusses potential policy responses to these concerns, including the exercise of government use rights, the imposition of access conditions on research funding and public procurement, and the encouragement of patent pools. Yet amidst the debate over patents relating to the pandemic response, one significant discovery has remained free from patent claims: the genomic sequence of the SARS-CoV-2 virus itself.

## Genomic Patents in the United States

The genomic RNA sequence of SARS-CoV-2 (the viral infectious agent responsible for COVID-19) was first elucidated in January, 2020, by a team of 19 researchers at four Chinese universities and public health agencies. They published their findings in the journal *Nature* and released the sequence to the publicly-accessible GenBank database maintained by the U.S. National Center for Biotechnology Information (Wu et al., 2020). The SARS-CoV-2 sequence and its many emerging variants have proved invaluable to research concerning the virus. Yet these sequences are not known to be subject to any pending or issued patent claims and are

thus available without restriction to public and private researchers around the world.

## Myriad and Products of Nature

One reason that the SARS-CoV-2 sequence has not been patented, at least in the United States, is due to the U.S. Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, which established that a sequence of naturally-occurring nucleotides is an unpatentable "product of nature" (technically, the case related to DNA rather than RNA sequences, but the Court's reasoning applies to both molecules with equal force) (*Association for Molecular Pathology v. Myriad Genetics, 2013*). While the Court held that patents might be available on "new applications of knowledge," genes themselves, and their nucleotide sequences, are ineligible subject matter for patent protection.

## Legislative Efforts to Overrule Myriad

The *Myriad* decision, together with the Supreme Court's earlier decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, have been portrayed as effectively eliminating the possibility of patents for genetic diagnostics – a potentially devastating result for the diagnostics industry (Eisenberg, 2015; *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 2012). As a result, advocates of stronger patent protection have steadfastly sought to

overturn the *Myriad* and *Mayo* decisions through legislative means. In 2019, Senators Chris Coons and Thom Tillis introduced legislation that would have abrogated any “implicit or judicially created exceptions to [patent] subject matter eligibility including ‘abstract ideas,’ ‘laws of nature,’ or ‘natural phenomena.’” The effect of these provisions would have been to permit, once again, the patenting of any previously undiscovered natural substance or genomic sequence.

In addition to genetic data, the Coons-Tillis proposal sought to address the patentability of other controversial inventions including software, medical diagnostic methods, and methods of conducting business. As a result, opposition arose from numerous quarters. Notably, 160 civil rights, medical, scientific, patient advocacy, and women’s health organizations openly opposed the Coons-Tillis bill, arguing that if the bill were enacted, “Patients will again be at risk of lacking access to information about their genes, about their very selves. We likely will again see high prices for tests with no competition in the market, and harms to innovation and useful research with no guarantee that the law would eventually provide the same protections that it now offers” (American Civil Liberties Union et al., 2019). The Senate Judiciary Committee held three sets of hearings on the bill in 2019, after which the draft legislation stalled.

Despite the failure of this legislative attempt to reverse the *Myriad* decision, the emergence of the COVID-19 pandemic in early 2020 led to renewed calls for increased patent protection of biomedical discoveries. Thus, at the same time that advocates and governments around the world were calling for the relaxation of patent restrictions to address the supply of critical supplies and equipment in response to the pandemic, patent advocates blamed the lack of reliable diagnostic tests, vaccines, and treatments for COVID-19 on too little patent protection. Senator Tillis commented in one interview, “The way the current jurisprudence sits, there’s almost no incentive to develop new, innovative diagnostic testing methods or other life-saving treatments. As the COVID-19 pandemic is unfortunately showing us, having these tests in the pipeline are crucial for public and economic health, well-being, and safety” (Quinn, 2020).

During the course of the pandemic, the U.S. Patent and Trademark Office (PTO) introduced new programs to accelerate the examination and issuance of patents covering COVID-19 related inventions, and Senator Ben Sasse introduced legislation that would, among other things, add 10 years to the term of COVID-related patents (Facilitating Innovation to Fight Coronavirus Act, 2020).

In early 2021, new legislative proposals to strengthen patents, including by Senators Tillis and Coons, began to percolate as the Biden administration prepared to take office. Yet despite unsubstantiated claims that increased patent protection would have facilitated the speedier development and deployment of COVID-related diagnostics, vaccines, and therapies, there is ample evidence to suggest that, at least in the case of genomic sequences, a return to the days of patenting would have been counterproductive.

## The Value of Open Genomic Data The Genomic Commons

Since the Human Genome Project (HGP) (1988–2003), the field of genomic research has been characterized by norms of international collaboration and data sharing. Explicit patent deterrence strategies were embodied in the data sharing policies adopted by the governmental and philanthropic funding agencies that supported this research, resulting in a vast aggregation of genomic data that is available to researchers around the world – the “Genomic Commons” (Contreras & Knoppers, 2018). Contributions to this public store of knowledge were made not only by governmental and academic laboratories, but by pharmaceutical and biotechnology companies (Contreras & Knoppers, 2018). Research has shown that the public availability of genomic data from the HGP has significantly enhanced scientific research as compared to data that is maintained as proprietary (Williams, 2013).

## The Gene Patenting Race

Despite the growth of the public genomic commons, a countervailing trend emerged in the late 1980s and early 1990s toward private patenting of genomic discoveries. The patents issued to Myriad Genetics covering the BRCA1 and BRCA2 genes, which are linked to familial breast and ovarian cancer, were examples of this growing phenomenon. By 2005, two MIT researchers estimated that a full 20% of known human genes were covered by patents (Jensen & Murray, 2005). While the PTO rejected the patentability of short DNA segments having unknown utility, larger segments of DNA constituting full genes were deemed to be patentable as new “compositions of matter” (Sherkow & Greely, 2015).

## The Virus Patent Races

Patents during this period were not limited to human genomic sequences. Nucleotide sequences of plants, model organisms, bacteria and viruses were also being patented. As documented by Queensland University of Technology professor Matthew Rimmer, a contentious international “race” to identify and patent the RNA sequence of the SARS virus occurred shortly after the outbreak of the epidemic in 2002 (Rimmer, 2004). Research institutions in North America, Europe, and Asia each rushed to file patent applications “broad enough to allow their holders to claim rights in most diagnostic tests, drugs, or vaccines that have been or would be developed to cope with the outbreak” (Rimmer, 2004). Among the negative outcomes of this patenting race was the emergence of a patent “thicket” in the area of SARS research and the unsuccessful attempt to pool these patents for broader use (Beldiman, 2012). Similarly dysfunctional scenarios played out a few years later with the H1N1 and H1N5 influenza outbreaks (Greene, 2010; Beldiman, 2012).

Unlike these prior outbreaks, there does not appear to have been a rush to patent the SARS-CoV-2 genomic sequence. This lack of patenting is due both to the rapid public release of the sequence by the researchers who first identified it (i.e., acting as prior art to defeat patents that might later be filed (Contreras & Knoppers, 2018)) and the presumption against genomic sequence patents

established in the United States by the *Myriad* decision. This “patent free zone” enabled rapid international collaboration on basic research concerning COVID-19.

### Why Patents on Genomic Sequences Should Not, and Need Not, Be Allowed

Despite vociferous calls for more patenting of technologies pertinent to COVID-19, Congress should resist legislative attempts to overrule the *Myriad* decision and its ban on patenting genomic sequence information.

#### Genomic Sequence Data is a Basic Research Tool that Should be Broadly Available

A vast array of basic scientific research is enabled by knowledge of an organism's genomic sequence. This research can lead to a better understanding of biochemical mechanisms and to medical innovations such as vaccines and therapeutics. As such, genomic sequence data are a form of basic “research tool” — a resource that can be used by multiple researchers to address different research questions. There is a broad policy consensus that research tools should be made as broadly available as possible to the research community (National Institutes of Health, 1999). Allowing one or a handful of entities to own this basic scientific information can hinder research when speed and international collaboration are needed most. Studies have shown that researchers were reluctant to study the patented BRCA genes, thereby reducing overall knowledge and scientific advancement, something that cannot be afforded in the face of an emergent global pandemic.

#### Composition of Matter Patents Preempt all Uses of a Sequence

Because patents can claim genomic sequences as new “compositions of matter” (like polymers or metallic alloys), they preempt all possible uses of the patented sequences, whether or not envisioned by the patent holder (Contreras, 2020). The Supreme Court correctly recognized in *Myriad* that genomic sequences of biological organisms are not new forms of matter, even if they are isolated and purified in the laboratory. Reversing this holding would again allow individual patent holders to control all uses of a particular genomic sequence, thereby creating significant bottlenecks to effective research and development and granting patent holders a windfall with respect to applications of a discovery that they did not actually make.

#### Composition of Matter Patents Discourage Improvements

Because broad composition of matter patents cover all uses of a patented gene or variant, any improvement to a diagnostic test that the patent holder makes will likely be covered by its own patents. And because competitors are not permitted to offer competing diagnostic tests, a patent holder has little incentive to improve its own diagnostic tests once a patent is issued. That is, its broad patent is likely to cover both the original and improved tests, and no competing tests are allowed, giving the patent holder little motivation to improve the tests over which it already has monopoly control.

#### Patents Are Not Needed to Incentivize the Discovery of Genomic Sequences

As noted above, today a vast body of human and non-human genomic sequence data is available to researchers in public

repositories (Contreras & Knoppers, 2018). The discovery of this data was largely supported by government and philanthropic funding sources. With advances in sequencing technology and a global recognition that genomic sequence data represent a scientific resource for all, the sequencing of new biological entities such as emergent viral strains can be, and is, accomplished quickly and efficiently through existing government-funded programs. The sequencing of the SARS-CoV-2 virus by a coalition of Chinese university and public health agencies (Wu et al., 2020), with no attempt to patent their results, demonstrates this reality. Since then, substantial scientific advances have been made as new variants and mutations of the SARS-CoV-2 virus have emerged during the course of the pandemic. As such, arguments that patenting is required to induce private actors to invest in this work are simply not applicable to the derivation of genomic sequence data today.

#### There is Ample Opportunity for Patent Protection of Medical Innovations Without Claiming Genomic Sequences

A large number of patents exist and continue to be obtained on innovations relating to COVID-19, including protective equipment, medical devices, tracing and modeling algorithms, diagnostic kits, vaccines, and therapeutics (Tietze et al., 2020). As such, ample private incentives — both in terms of patent royalties and procurement payments — exist to promote the development of needed technologies like these. Basic genomic structures, however, are research tools, not products or product components. As such, allowing them to be patented does no more than enable the holders of those patents to impose a tax on the industry that is developing products that rely on this basic scientific information. Had the basic genomic sequence of the SARS-CoV-2 been patented, as had the sequences of the SARS, H1N1 and H1N5 viruses, the development of desperately needed vaccines and therapies would have been delayed or, at best, made more costly to consumers and health care providers.

#### Patents on Genomic Sequences Increase Costs and Reduce Access to Medical Innovations

Myriad Genetics priced its genetic tests at a level beyond the means of many individuals, leading to widespread criticism of the company and the patents that gave it a monopoly over testing the BRCA1/2 genes. Issues surrounding access to genetic testing thus lay at the heart of the *Myriad* litigation. The issue of access was central to the American Civil Liberties Union, which brought the case, and its recruitment of numerous patient advocacy groups, health care providers, and medical societies as plaintiffs and *amicus curiae* (Contreras, 2020). The Supreme Court's decision invalidating most of Myriad's gene patents was widely heralded as a victory for health care access. A return to the days of genomic sequence patents would reverse this victory and again enable private firms to wield legal exclusivity to increase patient costs, burden the health care system, and exclude those most in need from critical medical innovations. 🌟

# Recommendation for Action

## Federal government:

- Congress should reject legislative proposals that seek to overrule the ban on patenting naturally-occurring genomic sequences that was established by the Supreme Court in *Association for Molecular Pathology v. Myriad Genetics, Inc.*

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