PATHOGEN GENOMES AS GLOBAL PUBLIC GOODS (AND WHY THEY SHOULD NOT BE PATENTED)

Jorge L. Contreras*

During past viral outbreaks, researchers rushed to patent genomic sequences of the viruses as they were discovered, leading to disputes and delays in research coordination. Yet similar disputes did not occur with respect to the genomic sequence of SARS-CoV-2, the virus responsible for COVID-19. With respect to COVID-19, global research collaboration occurred rapidly, leading to the identification of new variants, the ability to track the spread of the disease, and the development of vaccines and therapeutics in record time. The lack of patenting of SARS-CoV-2 is likely due the U.S. Supreme Court's 2013 ruling in Association for Molecular Pathology v. Myriad Genetics, which established that naturally occurring genomic sequences are ineligible for patent protection, a decision that has had repercussions around the world. Recently, however, legislative proposals have been made in the United States to overturn this decision. Such legislation, if enacted, would enable researchers, likely based in countries where pathogenic outbreaks first occur, to obtain U.S. patents on pathogen genomes that are critical to disease response. Given that open, global research collaboration will be essential to address future disease outbreaks, and that ample opportunities exist for patenting of diagnostics, vaccines, therapeutics and other downstream biomedical innovations, steps should be taken to ensure that pathogenic sequence data cannot be appropriated by individual researchers, institutions, or states. Accordingly, proposed U.S. legislation seeking to reintroduce pathogen sequence patenting should be rejected and a new international agreement recognizing the genomic sequences of pathogenic agents as global pub-

* James T. Jensen Endowed Professor for Transactional Law and Director of the Program on Intellectual Property and Technology Law, University of Utah S.J. Quinney College of Law. Adjunct Professor, Department of Human Genetics, University of Utah School of Medicine. This essay has benefitted from presentation and discussion at the NYU 28th Annual Herbert Rubin and Justice Rose Luttan Rubin International Law Symposium: "Inter-pandemic Vaccine Regulation: Justice and Global Equity", as well as invaluable feedback from Margo Bagley, Rochelle Dreyfuss, Nicholson Price, Michelle Rourke, Ana Santos Rutschman, Jacob Sherkow, and Peter Yu. New York University provided travel funding to attend the symposium noted above. The author declares no conflicts of interest. For a related discussion by the same author summarizing these issues that was posted after presentation but prior to print production, see Jorge L. Contreras, *How the 'Patent Eligibility Restoration Act' Would Harm American Business and Endanger Global Health by Reintroducing 'Pathogen Patents'*, Patently-O (Jan. 12, 2023), https://patentlyo.com/patent/2023/01/eligibility-restoration-reintroducing.html [https://perma.cc/E3DV-53ZX].

lic goods free from intellectual property protection should be enacted. In addition, the WHO, public health agencies and research funders should adopt policy provisions that deter patenting of pathogen genomic sequences, either directly or through the imposition of rapid data release requirements. Individually or together, measures such as these will reduce the patenting of pathogenic genomic data in the service of global collaboration and innovation during future disease outbreaks.

I. INTRODUCTION

The genomic sequence[1] of SARS-CoV-2 (the virus responsible for COVID-19) was first elucidated in early January 2020 by a team of researchers in China.[2] On January 5, they uploaded the sequence to the publicly accessible GenBank database maintained by the U.S. National Center for Biotechnology Information.[3] On January 11, an Australian researcher

1. Though usages vary across the literature, this essay uses the convention that a "genomic" sequence comprises the entire nucleotide sequence of an organism's DNA or RNA, while "genetic" sequence data comprises a portion of the full sequence. *Compare* Natl. Human Genome Res. Inst., Genetics, https://www.genome.gov/genetics-glossary/Genetics [https://perma.cc/J665-K4YH], *with* Natl. Human Genome Res. Inst., Genome, https://www.genome.gov/genetics-glossary/Genome [https://perma.cc/PB9T-9QZL].

2. Fan Wu et al., *A new coronavirus associated with human respiratory disease in China*, 579 NATURE 265, 265 (2020).

3. Rena M. Conti, *The Determinants of COVID-19 Vaccine Development Success*, WORLD INTELLECTUAL PROPERTY ORGANIZATION [WIPO] at 30–31 (Dec. 31, 2021), https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_covid_

posted the sequence to the website Virological.org and attracted widespread attention to its availability via Twitter.[4] Days later, new diagnostic tests for the virus had been developed.[5] Within months, new COVID-19 vaccines were being tested.[6] By October 2021, nearly five million different sequences of the SARS-CoV-2 virus had been uploaded to public databases,[7] where they continue to be used to monitor the evolution of the virus, to identify virulent mutations, and to trace the spread of infection.[8]

The speed and extent of international research cooperation in response to COVID-19 was immediate and widespread.[9] SARS-CoV-2 sequence data was utilized by a broad range of researchers from geneticists and virologists to epidemiologists

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19_ge_22/wipo_gc_covid_19_ge_22_www_572491.pdf [https://perma.cc/W5ZP-FTH9].

4. John-Sebastian Eden, *Genome sequencing and its use in public health responses to COVID-19*, 42 Microbiology Australia 44, 44 (2021); Conti, *supra* note 3, at 30–31.

5. *See, e.g.*, Victor M. Corman, et al., *Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR*, Euro Surveillance 23, 23 (Jan. 23, 2023) (presenting a new diagnostic methodology to detect the virus).

6. *See, e.g.*, Lisa A. Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, 383 N. Engl. J. Med. 1920 (2020) (discussing findings from trials of vaccine candidate mRNA-1273). *See also* Thomas H. Ehrich & Jeffrey D. Morton, *mRNA vaccines: how to navigate the freedom-to-operate maze*, Intelligent Asset Mgmt. (Jan. 12, 2022), https://www.iam-media.com/mrna-vaccines-and-how-navigate-the-freedom-operate-maze [https://perma.cc/WU8F-6UD8] ("Moderna . . . developed mRNA-1273 within days of receiving the genetic sequence of the SARS-CoV-2 virus that causes covid-19; it was ready for human trials within two months.").

7. Zhiyuan Chen et al., *Global landscape of SARS-CoV-2 genomic surveillance and data sharing*, 54 Nature Genetics 499, 499 (2022).

8. *See* Allison Black, et al., *Ten recommendations for supporting open pathogen genomic analysis in public health*, 26 Nature Med. 832, 832 (2020) ("As access to whole-genome sequencing has grown, greater amounts of molecular data have helped improve the ability to detect and track outbreaks of diseases such as COVID-19, investigate transmission chains and explore large-scale population dynamics, such as the spread of antibiotic resistance.").

9. A similarly rapid effort to develop vaccines occurred in connection with the Zika outbreak in 2016, though that effort was led by the U.S. Army. For discussion of the rapid mobilization of resources to develop a Zika vaccine, see Ana Santos Rutschman, Vaccines as Technology: Innovation, Barriers and the Public Health 63-64 (2022).

and public health officials.[10] As one researcher observed, "[t]he enormous, immediate impact of sharing this data highlights the wealth of information encoded in pathogen genomes, particularly for understanding their origins and potential to cause disease."[11] This sentiment was echoed by the Director of the U.S. Office of Science and Technology Policy (OSTP), who stated that "[i]mmediate public access to COVID-19 research is a powerful case study on the benefits of delivering research results and data rapidly to the people."[12] The COVID-19 pandemic has brought into sharp focus the value of open access to and rapid sharing of pathogenic genomic data in response to infectious disease outbreaks.[13]

Data sharing at the speed and on the scale observed with COVID-19 has not always been the norm. During the H5N1 influenza pandemic and the SARS and MERS coronavirus outbreaks, researchers sought to patent newly identified viral genomic sequences shortly after they were determined.[14] These efforts stymied research cooperation and imposed delays and barriers to the development of diagnostics, vaccines, and therapeutics.

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10. *See* Michelle Rourke et al., *Policy opportunities to enhance sharing for pandemic research*, 368 SCIENCE 716, 716 (2020) (noting the critical value of sequencing data for the global health community but critiquing gaps in international law that impair coordination and sharing). Recognizing the widespread utilization of sequence data, the World Health Organization provided guidance to policymakers and other stakeholders on how to maximize the benefit of sequencing activities. For details on this guidance, see World Health Organization [WHO], *SARS-CoV-2 genomic sequencing for public health goals: Interim guidance* (Jan. 8, 2021) https://www.who.int/publications/i/item/WHO-2019-nCoV-genomic_sequencing-2021.1 [https://perma.cc/EJ2H-YXUR].

11. Eden, *supra* note 4, at 44.

12. Memorandum from Dr. Alondra Nelson, Dep. Assistant, Off. of Sci. and Tech. Pol'y, Exec. Off. of the President, to the Heads of Exec. Dep'ts & Agencies: Ensuring Free, Immediate, and Equitable Access to Federally Funded Research (Aug. 25, 2022), https://www.whitehouse.gov/wp-content/uploads/2022/08/08-2022-OSTP-Public-Access-Memo.pdf [https://perma.cc/NZ22-9XWA].

13. Genomic data includes the complete nucleotide sequence of DNA or RNA comprising an organism's genetic code, together with associated epigenetic data and metadata. Pathogens include viral, bacterial, fungal and other biological agents that cause infectious disease in humans, animals or plants.

14. *See* Part III.A, *infra*. (discussing norms around patenting of pathogen genomic sequences before 2013).

The genomic sequence of SARS-CoV-2 and its many variants, however, were not patented. This lack of patenting activity on a potentially lucrative pathogen is likely due to the unavailability of U.S. patents on naturally occurring genomic sequences following the 2013 Supreme Court decision in *Association for Molecular Pathology v. Myriad Genetics*.[15] Since this decision, U.S. patents have not been available on pathogenic genomes, and while few countries have explicitly followed the U.S. in abolishing patent protection on naturally occurring genomic sequences, such patents have rarely been sought.[16] It is probable that the unavailability of patent protection for pathogenic sequences motivated researchers in China to share SARS-CoV-2 sequence data so rapidly.

Nevertheless, recent legislative proposals in the United States[17] seek to reverse this trend and once again allow the patenting of isolated genetic sequence data. Doing so may result in administrative, financial, and competitive barriers to rapid, global research on emergent disease outbreaks. Yet patents on pathogenic genomes are not necessary to incentivize research on vaccines, therapeutics, or genetic modifications, all of which remain patentable.[18] What's more, nationalistic advocates seeking to bolster U.S. industry through stronger patent protection are misguided in demanding greater patent protection for pathogenic genomes, given that the parties most likely to obtain U.S. patents on newly discovered pathogens are entities based not in the United States, but in the countries where those pathogens are first identified.[19] Accordingly, attempts to amend U.S. patent law to allow pathogen patenting should be resisted.[20] International rules should also

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

16. *See* Part III.C, *infra.* (discussing the apparent global impact of the U.S. Court decision in *Myriad*).

17. *See* Part II.F, *infra.* (discussing the Patent Eligibility Restoration Act).

18. *See* Part IV.A.4, *infra.* (discussing a number of patentable downstream innovations beyond pathogen sequences).

19. *See* Part IV.A.5, *infra.* (arguing that pathogen patents will advantage other countries over the U.S.).

20. *See* Jorge L. Contreras, *COVID-19 as an Example of Why Genomic Sequence Data Should Remain Patent Ineligible, in* COVID-19 POLICY PLAYBOOK: LEGAL RECOMMENDATIONS FOR A SAFER, MORE EQUITABLE FUTURE 137 (Scott Burris et al. eds., 2021) (introducing argument against pathogen patenting).

be established to prevent individual states from enacting legislation to patent pathogen sequence data.

Discussions convened by the World Health Organization (WHO) are currently under way to develop an international instrument on pandemic prevention (widely referred to as the "pandemic treaty") that would address numerous aspects of the international response to future pandemics.[21] Under particular consideration is the treatment of genetic resources. Such an international agreement would ideally ensure continued open access to pathogenic sequence data and prevent this data from being appropriated by individual researchers, institutions, or states through patents.

Finally, the WHO and research-funding bodies can independently deter the patenting of genomic sequence data by incorporating rapid data release requirements into their policies and funding arrangements, emulating the open data sharing model established by the Human Genome Project under its Bermuda Principles.[22] Together or separately, measures like these can help to ensure that pathogenic genomic data remains a global public good in the service of scientific research and public health while leaving in place ample incentives for the private development of biomedical technologies that are based on these shared global resources.

II. Genomic Patenting

A. *Patenting of Genomic Sequences*

Patents have been granted on genetic material in the United States since the late 1950s,[23] and the eligibility of living organisms as patentable subject matter was confirmed by the U.S. Supreme Court in the 1980 case, *Diamond v. Chakrabarty*.[24]

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21. Intergovernmental Negotiating Body, Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting, WHO Doc. A/INB/4/3 (Feb. 1, 2023) [hereinafter WHO Pandemic Treaty Draft].

22. *See* Part II.B, *infra* (explaining how the Bermuda Principles deterred patenting of human genomic data).

23. *See* Jacob S. Sherkow & Henry T. Greely, *The History of Patenting Genetic Material*, 49 Ann. Rev. Genetics 161, 164–65 (2015) (noting patents on nucleotide bases extending back to the 1950s).

24. Diamond v. Chakrabarty, 447 U.S. 303 (1980) (involving a patent claiming a bacterium genetically modified to break down hydrocarbons more efficiently).

After *Chakrabarty*, the debate over patenting genetic material intensified. Biotechnology firms began to file patent applications covering an increasing number of DNA-based inventions, including those claiming human DNA sequences, and the Patent and Trademark Office (USPTO) began to issue these patents in large numbers.[25] Other countries and regions, including Australia, Canada and the European Union, followed suit.[26]

The controversy surrounding the patentability of DNA sequences soon found its way into plans for the Human Genome Project (HGP), the international effort to map the entire sequence of 3 billion DNA base pairs in the human genome.[27] In 1988, as the HGP was being planned, the National Research Council and leading genetics researchers recommended that all human DNA sequences be placed in the public domain.[28] This approach was consistent with norms of collaboration and sharing in the scientific communities from which leading researchers in the HGP came.[29] The U.S. National Institutes of Health, though an early seeker of patents on short DNA seg-

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25. *See, e.g.*, Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L. J. 721, 721 n.4 (1990) (listing several such patents issuing during the 1980s); Andrew W. Torrance, *Gene Concepts, Gene Talk, and Gene Patents*, 11 MINN. J.L. SCI. & TECH. 157, 176–77 (2010) (describing the first patents on human genetic material issued during the late 1970s and early 1980s). *See generally* DAVID KOEPSELL, WHO OWNS YOU? THE CORPORATE GOLD-RUSH TO PATENT YOUR GENES (2009) (discussing philosophical and legal problems related to gene patenting).

26. *See* Dianne Nicol et al., *International Divergence in Gene Patenting*, 20 ANN. REV. GENOMICS & HUM. GENETICS 519, 524–26 (2019) (comparing U.S. developments with movement by the European Patent Office towards patentability of living matter in the 1980s and 90s).

27. Int'l Hum. Genome Sequencing Consortium (IHSGSC), *Initial sequencing and analysis of the human genome*, 409 SCIENCE 860 (2001); Natl. Human Genome Res. Inst., A Brief Guide to Genomics, https://www.genome.gov/about-genomics/fact-sheets/A-Brief-Guide-to-Genomics [https://perma.cc/5JLT-JB6K].

28. NATIONAL RESEARCH COUNCIL (NRC) ET AL., MAPPING AND SEQUENCING THE HUMAN GENOME 8 (1988).

29. The early work of the HGP involved sequencing the genomes of simple model organisms such as the roundworm (*C. elegans*). The researchers that worked on these organisms abided by strong "open science" norms and were accustomed to sharing their data freely with one another, laying a strong precedent for the HGP. IHSGSC, *supra* note 27, at 862–64; Jorge L. Contreras, *Bermuda's Legacy: Patents, Policy and the Design of the Genome Commons*, 12 MINN. J.L. SCI. & TECH. 61, 82 n.81 (2011) (collecting sources).

ments known as expressed sequence tags (ESTs),[30] came to the conclusion that "raw human genomic DNA sequence, in the absence of additional demonstrated biological information, lacks demonstrated specific utility and therefore is an inappropriate material for patent filing."[31]

At a policy level, HGP leadership also felt that the results of the massive taxpayer-funded genome effort should be returned to the public to accelerate the translation of scientific information to health improvements.[32] Finally, many commentators felt that the human genome, representing the shared history of humankind, "belongs to everybody" and should be freely shared with the world.[33] The USPTO and representatives of the biotech industry, however, argued that patents on genes should be encouraged because they could foster new businesses and fuel the discovery of drugs and diagnostic tests.[34]

B. *Bermuda, Data Release and Other Patent Deterrents*

In early 1996, HGP leaders convened in Bermuda and agreed on a new policy that required that all genomic sequence data generated by the HGP to be released to GenBank

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30. *See* Christopher Anderson, *US Patent Application Stirs Up Gene Hunters*, 353 NATURE 485, 485 (1991) (reporting that an NIH researcher filed patents for 337 ESTs, with plans to file more); Leslie Roberts, *Genome Patent Fight Erupts*, 254 SCI. 184, 184 (1991) (discussing NIH plan to patent ESTs).

31. *NHGRI Policy Regarding Intellectual Property of Human Genomic Sequence*, NAT'L HUM. GENOME RES. INST. (Apr. 9, 1996), https://web.archive.org/web/20030420213244/http://www.genome.gov/10000926 [https://perma.cc/KD77-HW9G]. The lack of patentable utility in DNA sequences without known function was confirmed by *In re* Fisher, 421 F.3d 1365, 1374 (Fed. Cir. 2005).

32. *See* NRC, *supra* note 28, at 8 (HGP data would be "of little value" if not made accessible to the general research community).

33. Eliot Marshall, *Bermuda Rules: Community Spirit, With Teeth*, 291 SCI. 1192, 1192 (2001).

34. *See, e.g.*, John J. Doll, *The Patenting of DNA*, 280 SCI. 689, 690 (1998) ("Issuance of patents . . . stimulates investment in the research, development, and commercialization of new biologics"); George Poste, *The Case for Genomic Patenting*, 378 NATURE 534, 535 (1995) ("Patents enhance competitiveness by forcing companies to adopt new research strategies and explore new disease targets, thereby catalysing breadth and depth in research innovation").

within *twenty-four hours* after being generated.[35] This unprecedented policy was enshrined in a short document that became known as the Bermuda Principles.[36] In addition to maximizing public access to publicly funded HGP outputs, the "rapid data release" requirement of the Bermuda Principles was designed to deter the patenting of human genomic data.[37]

The Bermuda Principles achieved this goal in several ways. First, they ensured that HGP data would be made public before laboratories performing sequencing work could file patent applications claiming that data.[38] In jurisdictions such as the European Union and Japan, which have so-called "absolute novelty" requirements, an invention may not be patented if it has been publicly disclosed (e.g., deposited in GenBank) before the filing of a patent application.[39] Second, publicly released sequence data would act as prior art, preventing others from patenting the same sequences later, even if indepen-

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35. Kathryn Maxson Jones, Rachel A. Ankeny & Robert Cook-Deegan, *The Bermuda Triangle: The Pragmatics, Policies, and Principles for Data Sharing in the History of the Human Genome Project*, 51 J. HIST. BIOLOGY 693, 693 (2018).

36. *Summary of Principles Agreed Upon at the First International Strategy Meeting on Human Genome Sequencing*, U.S. DEPT. ENERGY GENOME PROGRAM, http://www.ornl.gov/sci/techresources/Human_Genome/research/bermuda.shtml [https://perma.cc/T7RJ-QL7B] (last visited Nov. 4, 2022) [hereinafterBermuda Principles].

37. *See* Contreras, *Bermuda, supra* note 29, at 64 n.6, and accompanying text.

38. The 24-hour period specified in the Bermuda Principles was viewed as almost instantaneous release of the data. Today, with electronic filing of patent applications, it might be possible for researchers to file within this 24-hour window and subvert the intention of the policy (the Author thanks Rochelle Dreyfuss for this observation).

39. *See* 2 BAXTER, WORLD PATENT LAW & PRACTICE § 4.01 (Sept. 2022; Release No. 171) (explaining how novelty is destroyed in various jurisdictions). In the United States, under the then-prevailing rule, a patent application could be filed up to one year after its description in a "printed publication" or its first "public use". 35 U.S.C. § 102(b) (2006); Rebecca S Eisenberg, *The Promise and Perils of Strategic Publication to Create Prior Art: A Response to Professor Parchomovsky*, 98 MICH. L. REV. 2358, 2363-64 (2000) (discussing HGP's rapid data release policy as defeating patenting by sequencing centers). *But see* Margo A. Bagley, *"Just" Sharing: The Virtues of Digital Sequence Information Benefit-Sharing for the Common Good*, 63 HARV. INTL. L.J. 1, 33 (2022) (noting GenBank disclaimer as to patent rights claimed in deposited sequences). For the statutory text, see 35 U.S.C. § 102(b) (2006).

dently discovered.[40] Finally, publicly released sequence data could serve as prior art for purposes of determining whether similar third party sequences are patentable in view of patent law's "nonobviousness" requirement.[41] Taken together, these features effectively prevented the patenting of human genomic data generated by the HGP and contributed to the creation of a large public "commons" of genomic data accessible around the world.[42]

C. *Continued Growth of Gene Patenting*

Despite the patent deterrence mechanisms described in Section II.C above, the U.S. National Institutes of Health (NIH) never adopted a general requirement prohibiting patenting of genomic data generated with the benefit of federal funding. This, coupled with increasing corporate gene discovery activity, resulted in the patenting during the 1990s and early 2000s of thousands of human genes discovered at academic and corporate laboratories, mostly associated with hereditary diseases and traits.[43] The resulting gene patenting

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40. *See* Learning and Resources, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/apply/sequence-listing-resource-center/learning-and-resources [https://perma.cc/WE5V-VKRJ] (last visited Nov. 6, 2022) (noting that examiners may search GenBank for prior art sequence listings).

41. 35 U.S.C. § 103; *see* Jorge L. Contreras, *Genomic Data Sharing and Intellectual Property*, *in* GENOMIC DATA SHARING: CASE STUDIES, CHALLENGES, AND OPPORTUNITIES FOR PRECISION MEDICINE 189 (Jennifer McCormick & Jyotishman Pathak eds., 2023) (explaining the creation of prior art through disclosure of DNA sequences).

42. *See* Jorge L. Contreras & Bartha M. Knoppers, *The Genomic Commons*, 19 ANN. REV. GENOMICS & HUM. GENETICS 429, 429 (2018) (attributing the normalization of free access to scientific data in genomics to the rapid public data release policies of HGP).

43. *See* Kyle Jensen & Fiona Murray, *Intellectual property landscape of the human genome*, 310 SCIENCE 239, 239 (2005) (finding 20% of human genes subject to patent protection by 2005). The patenting of human genes slowed after the early 2000s, however, for a variety of possible reasons. One is the HGP's continuing release of human genomic data; an initial draft of the human genome was released in 2000, with the largely final version released in 2003. Natl. Human Genome Res. Inst., 2003: Human Genome Project Completed, https://www.genome.gov/25520492/online-education-kit-2003-human-genome-project-completed [https://perma.cc/R2SK-WQAF] *See also* Mateo Aboy et al., *Myriad's impact on gene patents*, 34 NATURE BIOTECH. 1119, supp. tbl. 1 (2016) (citing prior empirical studies finding that the patenting of DNA-based discoveries peaked around 2001); *but see* Carl Zimmer, *Scientists Finish the Human Genome at Last*, N.Y. TIMES (Jul. 23, 2021) (noting that it

"gold rush"[44] gave rise to increasing concerns among policymakers and advocates.

D. *The U.S.* Myriad *Decision*

In 2009, a group of twenty plaintiffs represented by the American Civil Liberties Union (ACLU) and Public Patent Foundation brought suit against Myriad Genetics, a Utah-based genetic diagnostic company that held patents claiming the *BRCA1* and *BRCA2* human genes, which were closely associated with hereditary breast and ovarian cancer.[45] The plaintiffs argued that the *BRCA* genes (along with all human genes), are "products of nature" that are ineligible subject matter for patent protection under Section 101 of the U.S. Patent Act. After several years of litigation,[46] the Supreme Court agreed, holding that the sequence of naturally occurring DNA is not patent-eligible subject matter, while human-created sequences not occurring in nature (i.e., cDNA constructs consisting only of the coding regions of a gene) are eligible for patent protection.[47] The *Myriad* decision had an immediate effect in the United States, effectively invalidating all composition of matter claims directed to naturally occurring genetic sequences.[48]

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took an additional two decades to sequence the entirety of the human genome, an effort that was finally completed in 2021).

44. KOEPSELL, *supra* note 25.

45. Under the Patent Act, eligible subject matter for patenting includes machines, articles of manufacture, processes, and compositions of matter. 35 U.S.C. § 101. Composition of matter claims are powerful, as they enable the patentee to control all uses of a new form of matter such as a synthetic fiber or metallic alloy. *See* Jorge L. Contreras, *Association for Molecular Pathology v. Myriad Genetics: A Critical Reassessment*, 27 MICH. TECH. L. REV. 1, 38–39 (2020).

46. For a detailed account of this litigation see JORGE L. CONTRERAS, THE GENOME DEFENSE: INSIDE THE EPIC LEGAL BATTLE TO DETERMINE WHO OWNS YOUR DNA 181, 240, 312 (2021).

47. *Myriad*, 569 U.S. at 576. Though not expressly discussed in the case, its holding would also support the patent eligibility of altered or synthetic molecules, including genetically engineered pathogens, so long as their nucleotide sequences are not found in nature.

48. While the genomic sequences of pathogens such as viruses consist of single-stranded RNA rather than double-stranded DNA, it would be surprising if the holding of *Myriad* did not apply with equal force to DNA and RNA, which are nearly identical from a chemical standpoint and serve related information-carrying functions. See Natl. Human Genome Res. Inst.,

E. *Genomic Sequence Patenting Outside the U.S.*

While the *Myriad* decision had a direct impact on the availability of genomic sequence patents in the United States, it is not binding in other jurisdictions and there has been little attempt to harmonize national laws in this regard.[49] Thus, while the Australian Supreme Court invalidated Myriad's *BRCA*-related patents on grounds different from those relied upon by the U.S. Supreme Court,[50] courts in Germany and the UK have found claims to isolated genetic material to be valid,[51] while the situation remains unclear in Canada, China, India, and elsewhere.[52] Even so, users and public health agencies in countries such as Canada successfully ignored patents held by companies like Myriad, even when issued in their countries.[53]

F. *Legislative Proposals to Reinstate Genomic Patenting in the U.S.*

Critics have portrayed the *Myriad* decision as contributing to the elimination of patents for genetic diagnostic products—a potentially devastating result for the genetic diagnostics in-

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Ribonucleic Acid (RNA), https://www.genome.gov/genetics-glossary/RNA-Ribonucleic-Acid [https://perma.cc/UX3P-RCGM] (visited Apr. 23, 2023).

49. *See* Nicol et al., *supra* note 26, at 520 (observing "an increasing level of inconsistency in the patent eligibility of genes and related subject matter across countries"). *See also* Molly Jamison, *Note: Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate*, 15 CHICAGO J. INTL. L. 688, 691 (2015) (observing that Myriad's gene patents remain valid in many countries other than the United States).

50. *See* Nicol et al., *supra* note 26, at 530 (discussing *D'Arcy v. Myriad Genetics, Inc.* (2015) 258 CLR 334). *See also* Rochelle C. Dreyfuss, Jane Nielsen & Dianne Nicol, *Patenting Nature—a Comparative Perspective*, 5 J.L. & BIOSCI. 550, 550 (2018) (comparing U.S. and Australian law).

51. *See* Nicol et al., *supra* note 26, at 532 (discussing German and U.K. cases).

52. *See id.* at 532–33 (discussing the lack of definitive jurisprudence from Canada and China on the matter); *see* Rebant Juyal, *Patent Eligibility of the Human Genome in India*, 23 AUSTRALIAN J. ASIAN L. 77, 88 (2022) (acknowledging "a certain degree of legislative ambiguity regarding the grant of gene patents.").

53. E. Richard Gold & Julia Carbone, *Myriad Genetics: In the eye of the policy storm*, 12 GENETICS MEDICINE S39, S54 (2010).

dustry.[54] The emergence of the COVID-19 pandemic led to renewed calls for increased patent protection of biomedical discoveries. As a result, advocates of stronger patent protection have repeatedly sought to overturn the *Myriad* decision through legislative means.[55]

In 2022, Senator Thom Tillis (R-NC) introduced the Patent Eligibility Restoration Act—a bill that, if enacted, would explicitly overturn the Supreme Court's ruling in *Myriad* and other patent eligibility cases.[56] The proposed Act would expressly allow patenting of "a human gene or natural material that is isolated, purified, enriched, or otherwise altered by human activity."[57] The result would directly negate the Supreme Court's holding in *Myriad* that "genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material."[58] Accordingly, the Act attempts to return pathogenic and other non-human genomic sequences, as well as

54. *See, e.g.*, Rebecca S Eisenberg, *Diagnostics Need Not Apply*, 21 J. SCI. TECH. L. 256 (2015) (claiming that the Supreme Court's position on laws of nature leaves little room for diagnostics patent protection).

55. *See* Jorge L. Contreras, *Another Legislative Attempt to Revive Gene Patenting*, BILL OF HEALTH BLOG (Aug. 4, 2022), https://blog.petrieflom.law.harvard.edu/2022/08/04/another-legislative-attempt-to-revive-gene-patenting/ [https://perma.cc/ZA3Y-Y9LA] (discussing prior legislative attempts).

56. Patent Eligibility Restoration Act of 2022, S.4734, 117th Cong. (2022). The bill is intended to address numerous areas in which the Supreme Court's patent eligibility jurisprudence has been criticized, including, in addition to genetic sequences, "medical diagnostics, biotechnology, personalized medicine, artificial intelligence, 5G, and blockchain". *Tillis Introduces Landmark Legislation to Restore American Innovation*, THOM TILLIS, U.S. SENATOR FOR NORTH CAROLINA (Aug. 3, 2022), https://www.tillis.senate.gov/2022/8/tillis-introduces-landmark-legislation-to-restore-american-innovation [https://perma.cc/ZA3Y-Y9LA]. For the 2023 version of the Act, which contains essentially the same text, see Patent Eligibility Restoration Act of 2023, S.2140, 118th Cong. (2023). All references in this paper, however, are to the 2022 version of the Act.

57. Patent Eligibility Restoration Act § 101 (b)(2)(B) (2022).

58. *Myriad*, 569 U.S. at 596.

newly-discovered human genetic variants,[59] back to the category of patentable subject matter.[60]

III. Pathogenic Sequence Patenting

Though the debate over genomic patenting discussed in Part II and the *Myriad* case itself related to the patenting of human DNA,[61] significant patenting activity has also occurred with respect to genomic sequences of non-human organisms

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59. New *human* genomic variants are discovered on a regular basis. *See, e.g.*, Nicoletta Lanese, *Woman diagnosed with 12 tumors in her lifetime has a never-before-seen genetic mutation*, LiveScience (Nov. 6, 2022), https://www.livescience.com/woman-with-genetic-mutation-tumor-prone [https://perma.cc/K45W-8TZM] (identifying gene codes for a protein called MAD1); Colette Gallagher, *Mayo Clinic researchers pinpoint genetic variations that might sway course of COVID-19*, Mayo Clinic News Net. (July 25, 2022), https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-researchers-pinpoint-genetic-variations-that-might-sway-course-of-covid-19/ [https://perma.cc/9RWF-PN34] (identifying variants that can lead to increase or decrease in protein expression, linked in turn to COVID-19 susceptibility and severity). *See also* Megan Molteni, *Eight years after a landmark Supreme Court ruling on DNA ownership, its ramifications are becoming clearer*, STAT News (Oct. 25, 2021), https://www.statnews.com/2021/10/25/jorge-contreras-genome-defense-supreme-court-ruling-dna-ownership/ [https://perma.cc/Y6R9-HLX2] (interviewing Jorge Contreras). This issue is beyond the scope of this essay.

60. Even if newly discovered genomic sequences are treated as patent-eligible subject matter under Section 101 of the Patent Act, these "inventions" must also be shown to be non-obvious in order to merit patent protection, a hurdle that may be difficult to overcome. *See* Arti K. Rai, *Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials*, 2 Wash. U.J.L. & Pol'y 199, 205-06 (2000) (arguing that the Court of Appeals for the Federal Circuit has interpreted nonobviousness in a way that "skew[s] the balance . . . significantly against the public domain"); Brief for Christopher M. Holman & Robert Cook-Deegan as Amici Curiae in Support Of Neither Party at 14, Ass'n for Molecular Pathology v. Myriad Genetics, 569 U.S. 576 (2013), No. 2010-1406 (comparing doctrines of patent eligibility and nonobviousness); Kristin Wall, *Patently Obvious: Why the District Court's Ruling in Association for Molecular Pathology v. USPTO is Incomplete*, 93 J. Pat. & Trademark Off. Soc'y 237, 251 (2011) (arguing that, under the current state of patent law, "DNA sequences can be nonobvious no matter how easy or routine the isolation process is"). In addition, pathogenic sequences must be "useful" in order to be patented. However, unlike the EST sequences found not to have patentable utility in *In re Fisher* (*see supra* note 31) the genomic sequences of disease-causing pathogens have a known and specific utility: researching and developing vaccines, diagnostics and therapeutics to counter that disease.

61. *See* Lori B. Andrews & Laura A. Shackelton, *Influenza genetic sequence patents: where intellectual property clashes with public health needs*, 3 Future Virol-

such as animals, plants, and pathogens. Unlike human DNA, the fundamental, "wild type" sequence of which was decoded and publicly released by the HGP, pathogens are continually evolving and new variants are discovered only after causing disease in their hosts (plants, animals, or humans), giving rise to new opportunities for patenting.

A. *Pathogen Patenting Before* Myriad

Prior to *Myriad*, research laboratories that identified a new pathogenic variant routinely filed patent applications covering its genomic sequence.[62] This Section II.A describes pathogen patenting in the context of several high-profile disease outbreaks. Numerous other pathogen sequences were also patented prior to 2013.[63]

1. *Hepatitis C Virus (HCV) (1987)*

Because the genomic sequences of viruses are considerably shorter and simpler than those of more complex organisms,[64] researchers succeeded in sequencing viral genomes long before it was possible to sequence the complete genomes of other organisms. The first widely reported patent on a pathogenic genome claimed the hepatitis C virus (HCV), a blood-borne infection largely transmitted through transfusions. HCV was sequenced in 1987 by a team of researchers at Chiron Corporation using samples from infected chimpanzees provided by the U.S. Centers for Disease Control and Preven-

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OGY 235, 238 (2008) (noting human DNA focus in debate over genomic sequence patenting).

62. *See* Carrie Arnold, *Gene patents remain controversial in biomedical research*, 382 LANCET 495, 496 (2013) (citing researcher stating that patenting viral sequences is "a common occurrence in research circles"); Debora Mackenzie, *Saudis say Dutch patent on MERS virus hampers research*, NEW SCIENTIST (May 24, 2013), https://www.newscientist.com/article/dn23593-saudis-say-dutch-patent-on-mers-virus-hampers-research/ [https://perma.cc/2J7Q-DR3B] ("All labs that discover viruses routinely patent the sequences they work to uncover, and their prospective applications." (citing researcher)).

63. *See, e.g.*, Maureen A. O'Malley, Adam Bostanci & Jane Calvert, *Whole-genome Patenting*, 6 NATURE BIOTECH. 502, 503 tbl. 1 (2005) (listing pathogen patents).

64. For example, the complete genome of the SARS-CoV-2 virus consists of a single RNA strand comprising approximately 30,000 nucleotide bases. Wu, *supra* note 2, at 266. In contrast the human genome consists of approximately 3.2 billion DNA nucleotide base pairs. IHSGSC, *supra* note 27.

tion (CDC).[65] Chiron obtained over one hundred patents in more than twenty countries covering the viral components of HCV.[66] It then enforced its exclusive rights to the HCV genome to prevent other providers from developing and distributing diagnostic and therapeutic products utilizing the sequence.[67]

2. *Severe Acute Respiratory Syndrome (SARS) (2002-03)*

Shortly after the 2002 outbreak of the Severe Acute Respiratory Syndrome (SARS) epidemic in China, several institutions joined in a contentious international "race" to identify and patent the sequence of the emergent SARS-CoV coronavirus.[68] Research institutions around the world including the CDC, Health Canada (on behalf of the British Columbia Cancer Agency), Versitech Ltd. (the technology transfer arm of the University of Hong Kong), and CoroNovative BV (a company spun out of Erasmus Medical Centre) filed patent applications on the SARS genomic sequence.[69] When issued, the resulting patents would be, according to the WHO, "sufficiently broad to allow their holders to claim rights in most di-

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65. Heidi Ledford, *The unsung heroes of the Nobel-winning hepatitis C discovery*, 586 NATURE 485, 485 (2020). In 2020, the leader of the Chiron team, Michael Houghton, received the Nobel Prize in Physiology or Medicine for the identification of HCV. *Id.*

66. NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA 42 (2002), https://www.nuffieldbioethics.org/assets/pdfs/The-ethics-of-patenting-DNA-a-discussion-paper.pdf [https://perma.cc/86K5-SHG7].

67. *Id.* at 42. *See also* LUIGI PALOMBI, GENE CARTELS: BIOTECH PATENTS IN THE AGE OF FREE TRADE 283–93 (2009) (describing Chiron's HCV patents and litigation).

68. Matthew Rimmer, *The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines*, 5 MELBOURNE J. INTL. L. 335, 335 (2004). *See also* Aude S. Peden & Antoinette F. Konski, *Coronavirus Innovation Guideposts on the Eve of the COVID-19 Pandemic*, NAT'L L. REV. (July 30, 2020), https://www.natlawreview.com/article/coronavirus-innovation-guideposts-eve-covid-19-pandemic [https://perma.cc/KV5K-JC2D] (describing patents covering SARS viral sequence); Peter K. Yu, *Virotech Patents, Viropiracy, and Viral Sovereignty*, 45 ARIZ. ST. L.J. 1563, 1592–96 (2013) (discussing SARS patenting race). For details on the SARS outbreak itself, see Vivaldo Gomes da Costa, et al., *The emergence of SARS, MERS and novel SARS-2 coronaviruses in the 21st century*, 165 ANNALS VIROLOGY 1517 (2020).

69. James H.M. Simon et al., *Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling*, 83 BULL. WORLD HEALTH ORG. 707, 709 (2005).

agnostic tests, drugs, or vaccines that have been or would be developed to cope with the outbreak."[70] As observed by Professor Eileen Kane, the "question of patent rights" in the SARS viral sequence "complicated the coherence of an international public health strategy to contain the epidemic."[71] The WHO warned that "the manner in which SARS patent rights are pursued could have a profound effect on the willingness of researchers and public health officials to collaborate regarding future outbreaks of new infectious diseases."[72]

Among other outcomes of this patenting race were fears of an emerging patent "thicket" in SARS research, where the need to obtain authorization to conduct research and product development from multiple independent rights holders could slow or prevent research.[73] Accordingly, the WHO and NIH recommended that the holders of patent rights on the SARS virus explore the formation of a patent pool to aggregate their rights for more efficient licensing.[74] Though the primary patent holders agreed to participate in such a pool and signed a nonbinding letter of intent to that effect, the pool was never formed given the natural decline in SARS cases by the time the pool's legal structure and other details had finally been agreed.[75]

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70. WHO, *Patent Applications for SARS Virus and Genes* (May 29, 2003), https://web.archive.org/web/20040603035657/http://www.who.int/ethics/topics/sars_patents/en/print.html.

71. Eileen M. Kane, *Achieving Clinical Equality in an Influenza Pandemic: Patent Realities*, 39 SETON HALL L. REV. 1137, 1155 (2009).

72. WHO SARS Patent Statement, *supra* note 70.

73. Dana Beldiman, *Patent Choke Points in the Influenza-Related Medicines Industry: Can Patent Pools Provide Balanced Access?*, 15 TUL. J. TECH. & INTELL. PROP. 31, 57–58 (2012); Simon et al., *supra* note 69, at 708.

74. Simon et al., *supra* note 69, at 709.

75. Beldiman, *supra* note 73, at 58 ("Because it took an extended period of time to agree which patents to include, to craft the pool structure agreement and its licensing terms, and to ensure that antitrust and other regulations were met, the SARS outbreak was contained before the pool was ever completed."); Ed Levy et al., *Patent Pools and Genomics: Navigating a Course to Open Science?*, 16 B.U. J. SCI. & TECH. L. 75, 91–92 (2010). *See also* Hillary Greene, *Patent Pooling Behind the Veil of Uncertainty: Antitrust, Competition Policy, And The Vaccine Industry*, 90 B.U. L. REV. 1397, 1397 (2010) (discussing challenges to SARS patent pool formation).

3. *H5N1 Influenza (2005-07)*

Unlike the SARS-CoV virus, which was relatively unknown until its emergence in 2002, various influenza strains have infected human populations for centuries. The H5N1 "avian" flu was first identified in Chinese poultry in 1996, then migrated to human populations in Hong Kong.[76] The H5N1 strain re-emerged in avian populations in 2003 then spread around the world, becoming a significant threat to human health from 2005-07.[77]

Patenting of the avian H5N1 viral sequence and related technologies began in 2004.[78] Among the entities seeking patents was the CDC.[79] In response to concerns over the patenting of influenza, the WHO commissioned a 2007 study by the World Intellectual Property Organization (WIPO).[80] WIPO found that patenting of H5N1-related inventions had accelerated significantly in the years prior to 2007, and opined that although "[b]are genetic information or genetic isolates routinely extracted from a wild organism or flu virus are generally not considered patentable . . . certain genetic isolates and similar derivatives have been found in many cases to be genuine inventions under the law of a number of countries."[81]

In late 2006, a consortium called the Global Initiative on Sharing Avian Influenza Data (GISAID) was formed to facili-

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76. *Emergence and Evolution of H5N1 Bird Flu*, CTR. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/flu/avianflu/communication-resources/bird-flu-origin-infographic.html [https://perma.cc/MBQ4-KVCS] (last visited Nov. 2, 2022); Nat'l Acad. Sci., The Threat of Pandemic Influenza: Are We Ready? 13 (Stacey L. Knobler, Alison Mack, Adel Mahmoud, Stanley M. Lemon, eds., 2005).

77. *See* Maurice Cassier, *Flu Epidemics, Knowledge Sharing, and Intellectual Property* in INFLUENZA AND PUBLIC HEALTH: LEARNING FROM PAST PANDEMICS 219, 219–220 (Tamara Giles-Vernick & Susan Cradock eds., 2010) (discussing the H5N1 pandemic's impact on debates around intellectual property).

78. *Id.* at 228–29.

79. Edward Hammond, *WHO-linked centre lays patent claim related to bird flu virus*, THIRD WORLD NETWORK INFO SERVICE ON HEALTH ISSUES (Aug. 19, 2008), https://www.sunsonline.org/PRIV/article.php?num_suns=6539&art=1.

80. Sixtieth World Health Assembly [WHA], *Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits*, WHA60.28 (May 23, 2007).

81. WIPO, *Patent issues related to influenza viruses and their genes*, at 18–19 (2007), https://www.wipo.int/export/sites/www/policy/es/global_health/pdf/influenza.pdf.

tate the sharing of avian influenza sequence data.[82] GISAID based its policies on those of the HGP, calling on its members to voluntarily "set aside" proprietary rights and "barriers of exclusivity such as the filing of patents" to enable research collaboration and data sharing.[83]

Then, in late 2006, the government of Indonesia announced that it would no longer share H5N1 samples with the WHO. It claimed, among other things, that foreign companies had impermissibly patented data generated from influenza samples previously provided by Indonesia and other countries.[84] As explained by David Fidler,

> Developing countries provided information and virus samples to the WHO-operated system; pharmaceutical companies in industrialized countries then obtained free access to such samples, exploited them, and patented the resulting products, which the developing countries could not afford.[85]

Indonesia insisted that it was entitled to "access and benefit sharing" from discoveries, such as vaccines and antivirals, arising from samples originating within its borders.[86] Other

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82. Peter Bogner et al., *A global initiative on sharing avian flu data*, 442 NATURE 981 (2006).

83. Cassier, *supra* note 77, at 228 (quoting GISAID FAQ, 2008 (no longer available online)).

84. *See* David P. Fidler, *Influenza Virus Samples, International Law, and Global Health Diplomacy*, 14 EMERGING INFECTIOUS DISEASES 88, 88 (2008) (detailing how foreign companies received patents using viral samples provided by Indonesia without Indonesia's consent). Indonesia had numerous other grounds for this refusal. For an extensive analysis, see Yu, *supra* note 68, at 1605–15.

85. Fidler, *supra* note 84, at 88.

86. The requirement for "access and benefit sharing" of genetic resources (ABS) arises under the 1992 United Nations Convention on Biological Diversity (CBD) and its 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (NP) (the United States is not a party to either of these instruments, though most other countries have ratified one or both). In the context of pathogenic sample sharing, the assertion of ABS rights by different countries has led to international tensions and disputes. *See* Bagley, *supra* note 39, at 10–22 (discussing these international instruments as well as persistent fears by the Indonesian government of exploitation in data sharing); Yu, *supra* note 68, at 1611–18 (describing actions of Indonesia and other countries in challenging norms around ABS rights). Some commentators contend that countries asserting their ABS rights have become impediments

countries, including India and Thailand, soon followed suit,[87] resulting in the WHO's adoption in 2011 of the Pandemic Influenza Preparedness (PIP) Framework.[88] Though proposals were made during the negotiation of the PIP Framework to include express prohibitions on patenting influenza biological materials,[89] these did not succeed. The final Framework document says little about intellectual property, offering only an ambiguous provision appended in a template material transfer agreement which states that neither the provider nor the recipient of a shared virus sample "should seek to obtain any intellectual property" in those "materials".[90] This statement is of questionable binding force ("should" rather than "must" or "shall"), and even the "materials" referred to are unclear.[91] Nevertheless, this is as far as WHO has gone with respect to constraining the patenting of pathogenic genomic sequences.[92]

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to global research collaboration and sharing of pathogenic samples and genetic information. *See, e.g.*, Mark Eccleston-Turner & Michelle Rourke, *Arguments Against the Inequitable Distribution of Vaccines Using the Access and Benefit Sharing Transaction*, 70 INTL. & COMPARATIVE L.Q. 825, 826 (2021) (arguing that the global norm of sharing pathogen samples has eroded); Rourke et al., *supra* note 10, at 716 (arguing that objectives of the CBD and NP "are not necessarily aligned with the WHO's mission, especially during health emergencies"); Sam Halabi, *Viral Sovereignty, Intellectual Property, and the Changing Global System for Sharing Pathogens for Infectious Disease Research*, 28 ANNALS HEALTH L. 101, 116–17 (2019) (describing processes for obtaining biological samples after the CBD and NP and its administrative complexities).

87. *See* Yu, *supra* note 68 , at 1615 (describing actions by India and Thailand).

88. WHA, *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, WHA64.5 (May 24, 2011). For thorough discussions of the PIP negotiation process, see Amy Kapczynski, *Order without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539 (2017) and Yu, *supra* note 68, at 1616.

89. *See* Beldiman, *supra* note 73, at 37 n.25 (describing anti-patenting proposal made by Bolivia).

90. WHA, *supra* note 88, at annex 1, para. 6.1 (Standard Material Transfer Agreement) (2011).

91. *See* Beldiman, *supra* note 73, at 40 (discussing ambiguities in clause); Kapczynski, *supra* note 88, at 1586 (critiquing clause).

92. It is not clear whether this WHO policy influenced patenting behavior during the 2008-09 H1N1 "swine flu" influenza pandemic, as patents on the H1N1 viral sequence do not appear to have been obtained. *See* Cassier, *supra* note 77, at 13–14 (noting that sequencing data of H1N1 was placed in the public domain via GISAID). Yet the H1N1 pandemic was not without patent disputes. *See* Greene, *supra* note 75, at 1400 (discussing Medimmune's

4. *Middle Eastern Respiratory Syndrome (MERS) (2012)*

A year after the WHO's adoption of the PIP Framework for influenza, a new coronavirus-based infection named the Middle Eastern Respiratory Syndrome (MERS) emerged in Saudi Arabia. Researchers at the Erasmus Medical Centre in the Netherlands quickly filed a patent application claiming the genomic sequence of the MERS-CoV virus based, in part, on a patient sample from Saudi Arabia.[93] The Saudi government claimed that Erasmus's patenting activity delayed the development of diagnostics for the new viral strain and interfered with the Saudi public health response to the outbreak.[94] Erasmus freely distributed samples of the virus to other researchers, but only pursuant to written material transfer agreements that were criticized for being too restrictive and for slowing research on the virus.[95] According to the head of Canada's National Microbiology Laboratory, the Erasmus patent resulted in "a lot of negotiation and a lot of lawyers involved both with us and the Americans and others around the world . . . which slowed things down quite a bit."[96] At a meeting of the World Health Assembly in Geneva, WHO Director-General Margaret Chan publicly stated that "No intellectual property should stand in the way of [countries] protecting [their] people".[97] Despite the controversy, Erasmus continued to prosecute its

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exclusive license of patents covering "reverse genetics" technology important to developing a vaccine).

93. Eccleston-Turner & Rourke, *supra* note 86, at 834–35.

94. Lucas Laursen, *SARS-like virus reignites ownership feuds*, 31 NATURE BIOTECH. 671 (2013).

95. Carsten D. Richter, *European Patent Office grants controversial patent protecting virus: lessons from the Middle East respiratory syndrome coronavirus outbreak*, 39 NATURE BIOTECH. 287 (2021). *See also* Halabi, *supra* note 86, at 118–19 (highlighting evidence that suggests that material transfer agreements in pathogen research and the delays that they cause to research).

96. Kai Kupferschmidt, *As Outbreak Continues, Confusion Reigns Over Virus Patents*, SCI. INSIDER (May 28, 2013) (quoting Frank Plummer), https://www.science.org/content/article/outbreak-continues-confusion-reigns-over-virus-patents [https://perma.cc/RFT5-HPGU] (quoting Frank Plummer).

97. *In Discussion Of MERS-CoV At WHA, WHO DG Says Patents Will Not Hinder Public Health*, KFF (May 24, 2013), https://www.kff.org/news-summary/in-discussion-of-mers-cov-at-wha-who-dg-says-patents-will-not-hinder-public-health/ [https://perma.cc/KTR8-4MXV].

patent application, which was eventually granted by the European Patent Office in 2021.[98]

B. *Pathogen Patenting After* Myriad

1. *Ebola (2014)*

The Ebola virus emerged in Zaire in 1976 and reemerged sporadically over the next several decades. In 2008, following an outbreak of the Ebola Bundibugyovirus (EboBun) strain in Uganda, the CDC filed a patent application claiming the genomic sequence of the virus.[99] In 2014, another major Ebola outbreak occurred in West Africa and soon spread to countries outside the region, including the United States.[100] By that time, the sequence of the virus had been uploaded to GenBank by a German researcher who had obtained virus samples from Guinea.[101] The CDC abandoned its U.S. patent application on the Uganda strain in 2015,[102] though it continued to prosecute a Canadian patent with similar claims that was ultimately issued in 2022.[103]

A 2021 study of the patenting landscape of the Ebola virus identified numerous patents covering Ebola-related medical countermeasures and interventions, but none covering the viral genomic sequence itself.[104] Thus, while the Ebola outbreak of 2014–16 resulted in international tensions and claims by

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98. B. L. Haagmans, et al., Human betacoronavirus lineage V and identification of N-terminal dipeptidyl peptidase as its virus receptor, European Patent No. EP2898067B1 (issued Jan. 15, 2020).

99. *Id.*

100. *2014–2016 Ebola Outbreak in West Africa*, U.S. CENTERS FOR DISEASE CONTROL & PREVENTION https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/index.html [https://perma.cc/3C3N-CGV8] (last visited Nov. 4, 2022).

101. Bagley, *supra* note 39, at 3.

102. *13/125,890 — CDC-13802/38: Human Ebola Virus Species and Compositions and Methods Thereof*, U.S. PAT. & TRADEMARK OFF. PAT. CTR., https://patentcenter.uspto.gov/applications/13125890 [https://perma.cc/Q4WS-8QHM] (showing abandonment of published application for failure to respond to an office action on Sep. 3, 2015). The application was a division of U.S. Patent Application No.61/108,175 (filed Oct. 24, 2008).

103. Human Ebola Virus Species and Compositions and Methods Thereof, CA 2741523, (issued June 21, 2022) (Can.).

104. Nasir Mohajel & Arash Arashkia, *Ebola as a case study for the patent landscape of medical countermeasures for emerging infectious diseases*, 39 NATURE BIOTECH. 799, 802 (2021).

West African countries that their sovereign rights in viral samples were violated by Western companies that profited from drugs developed using those samples, these claims do not appear to have involved patents on the viral sequence itself.[105]

2. *Zika (2013-16)*

The Zika virus was first identified in 1947 at the Virus Research Institute in Entebbe, Uganda, an institute funded by the U.S.-based Rockefeller Foundation.[106] Following the outbreak of Zika in humans in Brazil in 2013,[107] a rumor circulated that Rockefeller had patented the virus.[108] This rumor has been denied by Rockefeller and there is no evidence of such a patent.[109] Other literature concerning Zika discloses patents on vaccine candidates,[110] but not on the viral genomic sequence itself. Likewise, despite international disputes over viral samples involving Brazil,[111] and criticism of the exclusive licensing of patents covering the Zika vaccine developed by

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105. *See* Eccleston-Turner & Rourke, *supra* note 86, at 836 (stating that, despite of the clear international legal framework supporting their claim, West African countries could not exercise sovereignty rights over the Ebola virus samples taken without their informed consent); *see* Bagley, *supra* note 39, at 3–5 (discussing the development of Ebola treatments from 2014, and critiquing the lack of benefit-sharing between African countries and drug companies).

106. ROCKEFELLER FOUND., Background on The Rockefeller Foundation and Zika (n.d.), *Background on The Rockefeller Foundation and Zika*, https://www.rockefellerfoundation.org/zika-statement/ [https://perma.cc/86P4-S5DF] (last visited Nov. 2, 2022).

107. Theodore C. Pierson & Michael S. Diamond, *The emergence of Zika virus and its new clinical syndromes*, 560 NATURE 573, 573 (2018).

108. ROCKEFELLER FOUND., *supra* note 106; *Fact check: List of US patents is not evidence that viruses are manmade*, REUTERS (Oct. 27, 2020), https://www.reuters.com/article/uk-factcheck-patents/fact-check-list-of-us-patents-is-not-evidence-that-viruses-are-manmade-idUSKBN27C1PA [https://perma.cc/U4US-TVA4].

109. ROCKEFELLER FOUND., *supra* note 106; REUTERS, *supra* note 108.

110. *See, e.g.*, Kimberly A. Dowd et al., *Rapid development of a DNA vaccine for Zika virus*, 354 SCIENCE 237, 240 (2016) (discussing evidence that DNA vaccination could be a successful approach to protecting against Zika, and acknowledging that a relevant patent application has been filed).

111. *See* Eccleston-Turner & Rourke, *supra* note 86, at 845–46 (observing the confusion the Brazilian domestic ABS legislation had created delayed the U.S.-Brazil negotiation).

the U.S. Army,[112] these disputes did not involve patents on the Zika viral genomic sequence.

3. *COVID-19 (2019-22)*

The SARS-CoV-2 viral genomic sequence was uploaded to the public GenBank database almost immediately after its identification in China.[113] From 2020 to 2023, there have been several studies of the patenting landscape of SARS-CoV-2 and COVID-19 diagnostics, vaccines and treatments.[114] While these studies have identified numerous patents in each of these areas, no patents or published patent applications have been identified as claiming the genomic sequence of the SARS-CoV-2 virus or any of its variants.

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112. *See* RUTSCHMAN, *supra* note 9, at 86–89 (discussing federal agencies' power under the U.S. Patent Act to grant exclusive licenses to their inventions in situations where exclusivity constitutes a "reasonable and necessary incentive" for attracting investment, and questioning whether granting exclusive licenses for the Zika vaccine development was appropriate).

113. *See supra* notes 2–3, and accompanying text (summarizing initial identification of the genomic sequence).

114. *See, e.g.*, Cynthia Liu, et al., *Research and Development on Therapeutic Agents and Vaccines for COVID-19 and Related Human Coronavirus Diseases*, 6 ACS CENTRAL SCI. 315, 318–21 (2020) (providing an overview of research and development in antivirals for coronavirus diseases, including lists of patents associated with potential drugs for COVID-19 as of early 2020); José Adão Carvalho Nascimento Jr. et al., *Trends in MERS-CoV, SARS-CoV, and SARS-CoV-2 (COVID-19) Diagnosis Strategies: A Patent Review*, 8 FRONTIERS PUB. HEALTH (October 2020), at 1 (conducting a patent search in relation to SARS-CoV, MERS-CoV, and SARS-CoV-2 diagnostics); José Adão Carvalho Nascimento Jr. et al., *SARS, MERS and SARS-CoV-2 (COVID-19) treatment: a patent review*, 30 EXPERT OP. THERAPEUTIC PAT. 567, 570–571 (2020) (listing patents published in relation to the treatment of SARS and MERS); Pratap Devarapalli et al., *Patent intelligence of RNA viruses: Implications for combating emerging and remerging RNA virus based infectious diseases*, 219 INT'L J. BIOLOGICAL MACROMOLECULES 1208, 1208 (2022) (identifying technological trends related to RNA virus treatment through review of patent applications and granted patents); Conti, *supra* note 3, at 39–42 (discussing patented technologies such as spike proteins and lipid nanoparticles that have contributed to the response to SARS-CoV-2); Kausalya Santhanam, *Analysis of COVID-Related Patents for Antibodies and Vaccines*, South Centre Research Paper No. 173 (2023) (analysis of patents for certain antibody combinations and vaccines used for COVID-19); Dorkina Myrick, Laura Barnabei & Enrico Bonadio, *COVID-19, Its Variants, and Patent Disclosures*, 2023 EUR. INTELL. PROP. REV. (forthcoming 2023) (discussing the relation between patent disclosure requirements and efficacy of vaccines with regards to SARS-CoV-2 variants).

C. *The Impact of* Myriad *on Global Pathogen Patenting*

As shown in Part III.A, attempts by research groups to patent pathogenic genomic sequences were fairly routine prior to the 2013 U.S. Supreme Court decision in *Myriad*.

These patents, however, resulted in disruption and delays to research during major disease outbreaks such as SARS, H5N1 influenza and MERS. After *Myriad*, though the sharing of pathogenic sequences has not always been without political controversy,[115] patents on genomic sequences appear to have played little or no role in these disputes. Though some patents on pathogenic sequences have recently been issued in, for example, Europe (MERS)[116] and Canada (Ebola),[117] these are largely the result of legacy applications filed prior to the *Myriad* decision. Few patents claiming pathogenic genomic sequences have been filed anywhere after the *Myriad* decision.[118]

Why does *Myriad*, a U.S. Court decision, seem to carry such weight on a global scale? One possibility is that the demise of genomic sequence patents in the United States established a new set of international norms and expectations around pathogenic patenting. Researchers identifying a new pathogenic strain, aware that patents are unavailable in the United States, might not find it worthwhile to file elsewhere when research, development, and production could proceed there unimpeded by such patents.

IV. Avoiding a Return to Pathogen Patenting

In this Part IV, I summarize arguments against the re-introduction of pathogen patenting in the United States (and

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115. *See, e.g.*, Bagley, *supra* note 39 (discussing controversy around benefit-sharing in the event of countries providing researchers with sequence information); Eccleston-Turner & Rourke, *supra* note 86, at 851–856 (describing a variety of policy proposals for how and when international pathogen sharing should be facilitated).

116. *See* note 98, *supra*, and accompanying text (discussing grant of patent in 2021).

117. *See* note 103, *supra*, and accompanying text (identifying a patent filed in Canada on a strain of Ebola).

118. *See* Bagley, *supra* note 39, at 44 n. 221 ("While isolated genomic DNA sequences may be eligible for patent protection outside of the United States, not surprisingly, there appears to be no major effort underway to patent, at considerable cost, the large quantities of DNA sequence information obtained during non-commercial research expeditions.").

elsewhere) and make three specific policy proposals to prevent it in the future.

A. *Arguments Against a Return to Pathogen Patenting*

Despite the unavailability of patents in the United States on genomic sequences following *Myriad*, proposals have been made in the United States to repeal its holding via legislative means.[119] Furthermore, patenting of pathogenic sequences remains possible in other jurisdictions.[120] This Section summarizes arguments against pathogen patenting.

1. *Pathogen Sequences are Unpatentable Products of Nature*

Pathogens that emerge naturally are not human inventions and should thus remain beyond the scope of patent protection. Though genomic sequencing was once a rarified skill requiring substantial scientific expertise, the sequencing of a pathogen today is a routine matter performed using inexpensive equipment that is readily available around the world.[121] Thus, there is little justification for issuing patents claiming whole pathogen genomes, which are naturally occurring molecules.

2. *Pathogen Patents Impose Barriers to Research*

Pathogen genomic sequences enable research into disease origins, etiology, spread, response, and cure.[122] As discussed above, patenting these sequences has been shown to delay research collaboration, impose legal requirements for licensing and collaboration agreements, and exclude others from the conduct of research and the development, manufacture, and distribution of diagnostics, vaccines, and therapeutics, as well as the monitoring of the spread and evolution of diseases. As a result, Margaret Chan, then Director-General of

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119. *See* Section I.F, *supra* (discussing the proposed Patent Eligibility Restoration Act).

120. *See* Section I.E, *supra* (acknowledging the continued validity of claims to genetic material in Germany and the United Kingdom, as well as the legal ambiguity in several jurisdictions).

121. *See infra* notes 148–150, and accompanying text (discussing broad availability of genomic sequencing equipment).

122. *See supra* notes 10–12, and accompanying text (highlighting the value of SARS-CoV-2 sequence data).

the WHO, criticized these patents as impediments to public health.[123] Even when relevant patent holders have shown a willingness to cooperate and pool their patents —as several patent holders did towards the end of the SARS outbreak—the legal and administrative arrangements necessary to effectuate such pooling arrangements are resource-intensive and time-consuming, resulting in substantial delays.[124]

3. *Patents are Unnecessary to Incentivize Pathogen Detection and Sequencing*

In the United States, Congress is constitutionally authorized to enact a patent system to incentivize the creation of new and useful inventions.[125] The exclusivity conferred by patents has played an important role in encouraging private biopharmaceutical firms to make large investments in costly R&D, clinical trials and regulatory approvals.[126] Yet this instrumentalist rationale does not justify patents that claim pathogen genomic sequences.[127] First, the identification of new pathogens in disease outbreaks is rarely undertaken by private parties seeking to develop commercial products.[128] Instead, the identification of emergent pathogens is typically undertaken by public health authorities and academic institutions in geographic proximity to the outbreak. Unlike vaccines and therapeutics, the development of which is costly, risky, and

123. Arnold, *supra* note 62, at 496 (citing Margaret Chan).

124. *See supra* note 75, and accompanying text (tracing difficulties in the SARS case study).

125. U.S. CONST., art. I, § 8, cl. 8 (authorizing Congress to establish laws granting inventors exclusive rights to their discoveries for the express purpose of promoting "the progress of science and useful arts").

126. *See* Bhaven N. Sampat & Kenneth C. Shadlen, *The COVID-19 Innovation System*, 40 HEALTH AFFAIRS 400, 401 (2021) ("The dominant pull for the private sector has been through the patent system. Patents allow innovators to avoid competition for limited periods of time. The absence of competition allows innovators to charge higher prices than they would otherwise. Patents promote innovation through the lure of high profits.").

127. Criticism of patents covering diagnostics, vaccines, and therapeutics have also been made over the years. *See, e.g.*, sources cited *infra* note 132. These issues are beyond the scope of this article.

128. The 1987 discovery of the Hepatitis C virus (HCV) by researchers at Chiron (see *supra* note 65) is an early exception and, as a blood-borne disease that was transmitted largely through blood transfusions in U.S. hospitals, presents a very different factual pattern from the other pathogenic outbreaks discussed in this essay.

time-consuming,[129] sequencing a new pathogen genome is relatively inexpensive and requires little unique expertise.[130] Thus, the financial incentives offered by patent exclusivity are not necessary to incentivize this activity, which is performed primarily by state actors in their public capacities.[131]

4. *There Are Ample Opportunities to Patent Downstream Innovations Beyond Pathogen Sequences*

It is not necessary to patent underlying pathogenic sequences in order to protect novel and innovative technologies such as diagnostics, vaccines, therapeutics, and genetic modifications. There are, in fact, numerous innovative aspects of these technologies that can be and routinely are patented.[132]

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129. *But see* E. Richard Gold, *What the COVID-19 pandemic revealed about intellectual property*, 40 NATURE BIOTECHNOLOGY 1428, 1428 (2022) (challenging the need for patents to incentivize even vaccine or therapeutic development in the face of large government subsidies and procurement contracts during COVID-19); Sampat & Shadlen, *supra* note 126, at 406 ("rapid vaccine innovation has occurred despite considerable uncertainty about whether or when firms will be able to secure and enforce patents").

130. *See infra* notes 148–151, and accompanying text (discussing broad availability of genomic sequencing equipment).

131. And even with respect to vaccine development, significant work is often conducted by public agencies. *See* Matthew Herder et al., *From discovery to delivery: public sector development of the rVSV-ZEBOV Ebola vaccine*, 7 J.L. & BIOSCI. (Jan.–June 2020) at 1 ("The discovery and development of the Ebola rVSV-ZEBOV vaccine challenge the common assumption that the research and development for innovative therapeutic products and vaccines is best carried out by the private sector . . . The development of rVSV-ZEBOV, from sponsoring early stage research through to carrying out clinical trials during the epidemic, was instead the result of the combined efforts of the Canadian government, its researchers, and other publicly funded institutions"). *See also* RUTSCHMAN, *supra* note 9, at 48–55 (discussing public sector and military contributions to vaccine R&D).

132. There is significant debate regarding the benefits and drawbacks of patenting vaccine technologies. *See, e.g.*, Q. Claire Xue & Lisa Larrimore Ouellette, *Innovation Policy and the Market for Vaccines*, 7 J.L. & BIOSCI., Jan.–June 2020, at 1 (arguing that even given IP protection, the vaccine pipeline remains "anemic" due to vaccines' preventive rather than palliative nature and their tendency to be durable goods, making them less profitable than other treatments); Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZONA L. REV. 728, 731–733 (2019) (noting that the entry of new vaccines on the market each year remains low despite increasing rates of vaccine-related patent applications, and suggesting that reliance on the patent system has contributed to "inefficient transactional practices between vaccine manufacturers"); Ana Santos Rutschman, *IP Preparedness for Outbreak*

For example, the manufacture and delivery of vaccines involves multiple complex technologies and processes including active ingredients, adjuvants, delivery vectors and manufacturing, storage, and transport processes.[133] According to a 2012 WIPO study, there were more than 50,000 patents and published patent applications in fifty-seven countries that claimed the active ingredients of vaccines for pneumonia, typhoid and influenza alone.[134] Similar levels of variety and opportunities for innovation exist in the area of therapeutics.[135] For instance, Regeneron filed more than one hundred patent applications around the world for its Ebola drug Inmazeb,[136] even though the viral sequence was publicly available in GenBank.

The broad availability of patents protecting innovation directed toward the containment and prevention of pathogenic disease outbreaks was clearly demonstrated during the COVID-19 pandemic. While, as noted in Part III.B, there are no known patents claiming the SARS-CoV-2 genomic sequence or its variants, several diagnostics and vaccines for COVID-19 were developed, tested, and administered to the public in record time. Even without patents covering the viral genomic sequence, the governmental and private sector researchers that

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Diseases, 65 UCLA L. Rev. 1200, 1200 (2018) (arguing that current IP regimes are ineffective in developing innovative drugs, and proposing new mechanisms like a "dormant license" to support vaccine development during public health emergencies); Douglas Lichtman, *The Central Assumptions of Patent Law: A Response to Ana Santos Rutschman's IP Preparedness for Outbreak Diseases*, 65 UCLA L. Rev. 1268, 1268 (2018) (concurring with Rutschman on the "foundational" failure of the patent system but arguing that the "market-based patent regime" should be reformed more extensively). This essay takes no position on the merits of such patents, and simply observes that such patents are available.

133. *See* Rutschman, *supra* note 9, at 22–25 (discussing the range of vaccine technologies on the global market and the scientific processes employed to develop and administer them); *see also* Kane, *supra* note 71, at 1156–58 (discussing the range of patents that may be relevant to vaccine production).

134. *Patent Landscape Report on Vaccines for Selected Infectious Diseases*, WHO (2012) at 19, https://www.wipo.int/publications/en/details.jsp?id=264 [https://perma.cc/M92P-GAR6].

135. *See* Kane, *supra* note 71, at 1160–62 (discussing antiviral stockpiles and concerns about different viral strains).

136. Edward Hammond, *Ebola: Company Avoids Benefit-Sharing Obligations by Using Sequences*, Third World Network Briefing Paper (May 2019), https://wp.twnnews.net/wp-content/uploads/2019/05/TWN-BP99.pdf.

developed these technologies applied for large numbers of patents. For example, one 2020 study found that with respect to mRNA vaccine technology alone, fifty-six different entities ranging from large pharmaceutical companies such as Bayer, Bristol Myers Squibb, and GlaxoSmithKline to small and medium-sized firms including Moderna, CureVac, and BioNTech, controlled nearly 120 different patent families.[137] Several reports and studies describe the different patented vaccine technologies developed to address COVID-19, from novel spike proteins to lipid nanoparticle delivery mechanisms to specialized adjuvant excipients.[138] Perhaps the most convincing evidence that sizeable numbers of patents have been issued in this field is the patent litigation being waged by half a dozen vaccine manufacturers and technology developers, recently dubbed the "COVID-19 Patent Wars".[139] All of these examples demonstrate that COVID-19 technology innovations—and vaccines in particular—have been amply protected by patents and are extremely profitable, all without patents on pathogenic sequences.

5. *Pathogen Patents Will Advantage Other Countries Over the U.S.*

When Senator Thom Tillis introduced the proposed Patent Eligibility Restoration Act in the U.S. Senate in 2022, he explained that one of the bill's principal goals was to promote

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137. *See* Cecilia Martin & Drew Lowery, *mRNA vaccines: intellectual property landscape*, 19 NATURE BIOTECH. 578, 578 (2020) (describing patents and patent applications published from January 2010 to April 2020). *See also* Ehrich & Morton, *supra* note 6 (discussing recent trends in patented mRNA technology).

138. *See* Conti, *supra* note 3, at 39–42 (discussing a number of technologies patented in recent years that researchers have built on to respond to SARS-CoV-2); Working Paper, *Innovation and Patenting Activities of COVID-19 Vaccines in WTO Members: Analytical Review of Medicines Patent Pool (MPP) COVID-19 Vaccines Patent Landscape (Vaxpal)*, WTO Doc. WT/ERSD/W/1 (Jan. 18, 2022), at 13–16 (surveying ten COVID-19 vaccines and the four technology platforms used to develop them).

139. *See* Daniel L. Shores, *COVID-19 Patent Wars: mRNA and Lipid Nanoparticle Pioneers Clash over Vaccine Delivery Patents*, 15 LANDSLIDE, Sept.–Oct. 2022, https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2022-23/september-october/covid-19-patent-wars-mrna-lipid-nanoparticle-pioneers-clash-over-vaccine-delivery-patents/ [https://perma.cc/LLT8-5FJP].

"the economic and global competitiveness of the United States".[140] He and others faulted judicial decisions like *Myriad* for "undermining American innovation and allowing foreign adversaries like China to overtake [the United States] in key technology innovations."[141] Supporters of the bill have predicted that it will "rev the US innovation engine once again", warning that "[e]conomic growth, job creation, global competitiveness, public health and national security are all at risk until Congress repairs the law of patent eligibility that the Supreme Court has distorted."[142] Yet, ironically, at least in the case of pathogen genomic sequences, the benefits of the proposed legislation would accrue largely to institutions in China and elsewhere.

As discussed in Part III, most infectious disease outbreaks can be traced to the transmission of pathogenic agents from animals to humans.[143] A majority of these outbreaks originate in regions with extensive animal husbandry or live animal markets, where populations rely on hunting for sustenance or where habitat loss has resulted in the encroachment of wild animals into human settlements.[144] Across regions with these characteristics, the precise location of a future outbreak is impossible to predict. The earlier outbreaks described in Part III have been traced, respectively, to China (SARS and H5N1), Saudi Arabia (MERS), Zaire and Congo (Ebola), and Uganda

140. *Landmark Legislation, supra* note 56.

141. *Id.*

142. Paul Michel & David Kappos, *Tillis's 101 bill will rev the US innovation engine once again*, INTELLIGENT ASSET MGMT. (Aug. 6, 2022), https://www.iam-media.com/article/tilliss-101-bill-will-rev-the-us-innovation-engine-once-again [https://perma.cc/MBY8-HRBM].

143. *See* Rachel E. Baker, et al., *Infectious disease in an era of global change*, 20 NATURE REV. MICROBIOLOGY 193, 194–96 (2022) (discussing how changing human geography can contribute to spillover of pathogens from humans to animals); Brian L. Pike, et al., *The Origin and Prevention of Pandemics*, 50 CLINICAL INFECTIOUS DISEASES 1636, 1636 (2010) (discussing factors that contribute to human-animal transmission of pathogens); Nathan D. Wolfe, Claire Panosian Dunavan & Jared Diamond, *Origins of major human infectious diseases*, 447 NATURE 279, 279 (2007) (identifying five intermediate stages through which a pathogen exclusively infecting animals may become a pathogen exclusively infecting humans).

144. *See supra* note 143 (exploring the causes of transmission of pathogens from animals to humans).

and Brazil (Zika).[145] Once a pathogenic strain has infected a human population, the location(s) where its variants will emerge is also hard to predict. For example, *Table 1* illustrates the documented locations of the emergence of the major variants of SARS-CoV-2:

TABLE 1[146]

SARS-CoV-2 Variants of Concern	Earliest documented samples
Original strain	China
Alpha	United Kingdom
Beta	South Africa
Gamma	Brazil
Delta	India
Omicron	South Africa, Botswana[147]

The fact that some of these countries are low-income and do not possess large biopharmaceutical facilities does not prevent governmental and non-profit agencies in those countries from sequencing emergent pathogenic genomes. Today, genomic sequencing equipment is available around the world at a modest cost.[148] In 2021, the cost of sequencing a SARS-CoV-2

145. There is no clear origin site for the Hepatitis C virus (HCV). *See* Peter Simmonds, *The Origin of Hepatitis C Virus*, *in* HEPATITIS C VIRUS: FROM MOLECULAR VIROLOGY TO ANTIVIRAL THERAPY 1–16 (Ralf Bartenschlager ed., 2013) (discussing a number of ways to conceptualize the pathogen's origin, and pointing to areas of future research on the ultimate origin of HCV).

146. *Tracking SARS-CoV-2 variants*, WHO, https://www.who.int/activities/tracking-SARS-CoV-2-variants [https://perma.cc/NYF8-26YV] (last visited Nov. 5, 2022). See Frank Diamond, *Lambda Variant of COVID-19 Might Be Resistant to Vaccines*, INFECTION CONTROL TODAY (July 30, 2021), https://www.infectioncontroltoday.com/view/lambda-variant-of-covid-19-might-be-resistant-to-vaccines [https://perma.cc/M9CF-RGZV], for discussion of the "Lambda" variant, which emerged in Peru in 2020 and received significant media attention given its potential resistance to vaccines. This variant was not classified as a Variant of Concern by WHO.

147. Smriti Mallapaty, *Where did Omicron come from? Three key theories*, 602 NATURE 26, 26 (2021).

148. *See* Emily Mullin, *The Era of Fast, Cheap Genome Sequencing Is Here*, WIRED (Sept. 29, 2022), https://www.wired.com/story/the-era-of-fast-cheap-genome-sequencing-is-here/ [https://perma.cc/XZ8F-DXEE] (explaining

genome (only 1/100,000 the size of the human genome)[149] was estimated at approximately $120—well within the reach of researchers in most countries. As a result, by mid-2021, Gambia had sequenced more SARS-CoV-2 genomes than Germany.[150]

Furthermore, under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"),[151] signatory countries must extend "national treatment" to other signatory countries with regards to the protection of intellectual property.[152] This implies that applicants from any TRIPS country will be afforded the same rights to U.S. patents as applicants from the United States. Indeed, over the past several years, more U.S. patents have been issued to non-U.S. than U.S. applicants. In 2021, approximately 53% of all U.S. patents were issued to foreign applicants.[153] And of the top one hundred universities obtaining U.S. patents in 2021, forty-one were based outside of the United States (with twelve in China alone).[154] This situation is indicative of today's global economy, where national patents are readily available to any entity that wishes to exploit a national market.

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that ten years ago, it cost $10,000 for researchers to sequence a human genome, while today it's about $600).

149. *See supra* note 64, and accompanying text (comparing the number of nucleotide base pairs in the SARS-CoV-2 genome and the human genome).

150. Puja Changoiwala, *A Lack of COVID-19 Genomes Could Prolong the Pandemic*, QUANTA MAG. (June 28, 2021), https://www.quantamagazine.org/a-lack-of-covid-19-genomes-could-prolong-the-pandemic-20210628/# [https://perma.cc/3UF6-W3AG].

151. Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1869 U.N.T.S. 299 Annex 1C (Agreement on Trade-Related Aspects of Intellectual Property Rights) [hereinafter TRIPS Agreement].

152. *Id.* art. 3(1).

153. U.S. PAT. & TRADEMARK OFF., PERFORMANCE AND ACCOUNTABILITY REPORT—FISCAL YEAR 2021 205 tbl. 6, 215 tbl. 10 (2022) (including both utility and design patents).

154. NAT'L ACAD. INVENTORS & INTELL. PROP. OWNERS ASS'N, TOP 100 WORLDWIDE UNIVERSITIES GRANTED U.S. UTILITY PATENTS 2021, https://academyofinventors.org/publications/view-the-top-100-worldwide-universities-granted-u-s-utility-patents-for-2021/?utm_source=rss&utm_medium=rss&utm_campaign=view-the-top-100-worldwide-universities-granted-u-s-utility-patents-for-2021 [https://perma.cc/BH3P-WB8X].

The combination of pathogenic emergence in certain less developed countries, the availability of inexpensive genome sequencing, and national treatment of applicants under TRIPS suggests that if U.S. patents become available for pathogenic sequences, the applicants most likely to obtain these patents will be entities based outside the United States.

The SARS-CoV-2 genome was first sequenced by a team of researchers at institutions in China.[155] As noted above, these researchers immediately released the viral sequence to the public GenBank database. Had patenting been an option and had the Chinese researchers elected to file a patent application in the United States, the resulting U.S. patent on the baseline sequence of SARS-CoV-2 would most likely be owned by a group of Chinese state-owned institutions. Similar results would have occurred with respect to the major SARS-CoV-2 variants, each of which was first identified and sequenced outside of the United States (see Table 1). As a result, allowing pathogen patenting, as proposed by the draft Patent Eligibility Reform Act, would likely result in patents being issued to non-U.S. applicants. Consequently, American companies and others that wished to develop diagnostics, vaccines, and other technologies dependent on those patented sequences would either be excluded from the market, required to pay excessive prices, or make other onerous commitments in exchange for licenses to practice those patents.

Further, as discussed in Sections II.A and II.B, certain foreign governments have sought to delay international research on outbreaks and response efforts in order to gain concessions under the banner of "access and benefit sharing" (ABS).[156] The most prominent example of this approach occurred during 2006–07, when the government of Indonesia refused to share samples of the H5N1 influenza virus with the WHO.[157] Some countries adopted similar approaches during the MERS, Ebola and Zika outbreaks.[158] If countries are willing to delay international research and the response to a pandemic in order to secure ABS benefits for themselves, then they are also

155. Wu et al., *supra* note 2, at 265.

156. *See supra* note 86 (reviewing global debates around ABS rights).

157. *See supra* notes 84–86, and accompanying text (tracing Indonesia's 2006 refusal to share H5N1 samples with the WHO).

158. Rourke et al., *supra* note 10, at 717.

likely to use patents to extract further concessions from the international community. Demands for ABS concessions are not necessarily unjustified in view of past exploitation of local resources by foreign firms.[159] Yet, these barriers to the international response to emergent disease outbreaks can negatively impact global health. Reintroducing pathogen patenting will give countries where outbreaks emerge yet another tool to hold up critical international research and development to the detriment of all.

B. *Is this Really a Problem?*

While Section III.A above points to potential risks inherent in the issuance of pathogen patents, some might argue that these risks are mitigated by several factors, including patent holders' voluntary forbearance from enforcing their patents during a global health crisis, as well as built-in limitations on enforcement measures. These arguments are countered below.

1. *Informal Non-Enforcement Commitments Are Not Enough*

In the past, some entities that have patented pathogenic sequences have claimed to have done so with no intention of profiting from those patents or excluding others from conducting research or developing competing products. For example, the Erasmus researchers who patented the MERS virus insisted that their patent would not be used to inhibit research, and that they would continue to be open to collaboration.[160] Likewise, the U.S. CDC, which obtained patents covering the SARS, H5N1, and Ebola viruses,[161] has stated that such patents are "protective measure[s] to make sure access to the virus remains available to anyone."[162] Similar sentiments were

159. However, the appropriateness of ABS in international disease response remains contested. *See supra* note 86 (reviewing global debates around ABS rights).

160. *See* Arnold, *supra* note 62, at 496 (quoting Erasmus researcher and patent applicant Ab Osterhaus).

161. *See supra* notes 69, 79 and 99, and accompanying text (discussing the patent applications and grant of patents).

162. Antonio Regalado & David P. Hamilton, *CDC Seeks Patent on SARS To Keep Discovery Public*, WALL ST. J. (May 7, 2003), https://www.wsj.com/articles/SB105226807345954200 [https://perma.cc/9SM5-FA9R] (quoting CDC director Julie Gerberding with reference to SARS patent). With respect

expressed by the British Columbia Cancer Agency, which obtained patents claiming SARS-CoV.[163] One Canadian researcher suggested that the government participated in obtaining this patent only to prevent private companies from doing the same.[164]

Of course, not all holders of pathogen patents have made such assurances and there is no guarantee that future holders, even of the same patents, will do so.[165] It would be imprudent to rely on the goodwill of future (or current) holders of pathogen patents when assessing the threat posed by these patents. Additionally, it is not clear that much comfort can be derived even from those patent holders that have made such informal assurances regarding their intentions concerning enforcement. While patent holders' expressions of public-spirited intent may help defuse criticism, these statements taken alone are unlikely to result in legally binding commitments.[166] Even

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to Ebola, the CDC stated that it applied for patents on the 2008 EboBun strain (*see supra* note 99, and accompanying text) in order to "grant rights to use the virus strain for the commercialization of diagnostics, vaccines, and antibody/antigen testing, and make them more quickly and readily available to patients, doctors and research scientists" and "to ensure that another entity does not acquire a patent in a similar space and restrict the beneficial uses of the invention." REUTERS, *supra* note 162.

163. Regalado & Hamilton, *supra* note 162.

164. *Id.* Even taking at face value patent holders' assurances that they obtained patents only to prevent others from doing so, this strategy is a flawed one, at best. A more effective, and less costly, way to prevent patenting by others is to publish the discovery without restriction, as the HGP and other public-spirited genomic research projects have done. *See supra* notes 38–41, and accompanying text (discussing the impact of the Bermuda Principles on the availability of genome sequence data).

165. During the H1N1 swine flu pandemic, the WHO's Initiative for Vaccine Research (IVR) apparently took comfort from the fact that Medimmune, the exclusive licensee of patents covering important "reverse genetics" technology, committed to "act benevolently" with respect to the enforcement of those patents. Greene, *supra* note 75, at 1401. Yet questions were raised when Medimmune was acquired by Astra Zeneca, causing IVR to admit "[i]t is not yet known what effect, if any, this acquisition will have on the access to the reverse-genetics intellectual property." *Id.* at 1401 n. 11 (quoting IVR, Mapping of Intellectual Property Related to The Production of Pandemic Influenza Vaccines 18 (2007)).

166. Though unilateral commitments not to enforce patents (so-called "patent pledges") can become binding obligations under legal theories such as promissory estoppel, a greater degree of formality and certainty is usually required to bind the promisor. *See* Jorge L. Contreras, *The Open COVID Pledge: Design, Implementation and Preliminary Assessment of an Intellectual Prop-*

when public pledges are sufficiently robust to be legally binding, patentees have been known to violate these commitments, even during global health crises, thereby causing uncertainty in the market and requiring significant cost to enforce.[167]

Absent legally binding commitments—which no pathogen patent holder appears to have made yet—the public cannot rely on statements of goodwill by patent holders, even when they are government agencies and academic institutions. The NIH was partially responsible for enabling Myriad Genetics to corner the U.S. market for *BRCA* testing by granting the company full control over NIH's rights in the *BRCA* patents—patents that Myriad then asserted against other clinical test providers.[168] Governmental and academic institutions have increasingly engaged in patent assertion and litigation, both directly and through professional patent assertion entities, for the sole purpose of monetizing their patent assets.[169] The CDC is an aggressive enforcer of patents, as exemplified by its recent infringement action against one of its own researcher collaborators—an action held by a federal court to violate CDC's agreements with that collaborator.[170] For all of these reasons, informal assurances that patents will not be asserted or monetized should not be relied upon. While more formal

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erty Commons, 2021 UTAH L. REV. 833, 878 n.193 (2021) (discussing the "conservative approach" of establishing binding legal commitments through written licensing agreements). *See generally* Jorge L. Contreras, *A Market Reliance Theory for FRAND Commitments and Other Patent Pledges*, 2015 UTAH L. REV. 479 (2015) (discussing other arguments for the enforceability of IP pledges standing alone).

167. *See, e.g.*, Jorge L. Contreras, *No Take-Backs: Moderna's Attempt to Renege on its Vaccine Patent Pledge*, BILL OF HEALTH (Aug. 29, 2022), https://blog.petrieflom.law.harvard.edu/2022/08/29/no-take-backs-modernas-attempt-to-renege-on-its-vaccine-patent-pledge/ [https://perma.cc/6KZ3-C38B] (discussing Moderna's patent infringement litigation against Pfizer and BioNTech that seemingly violated its prior pledge not to assert its mRNA patents during the COVID-19 pandemic).

168. Contreras, *Association for Molecular Pathology*, *supra* note 45, at 45–46.

169. *See* Jorge L. Contreras, "*In the Public Interest*" *- University Technology Transfer and the Nine Points Document—An Empirical Assessment*, 12 U.C. IRVINE L. REV. 435, 481-84 (2023) (on file with author) (noting the increasing number of patents obtained by universities on a revenue-generating basis and citing literature which suggests increasing amounts of patent litigation).

170. Gilead Sci. Inc. v. United States, Opinion and Order, No. 20-499C (Ct. Fed. Cl., Nov. 30, 2022).

pledge mechanisms may be utilized by some patent holders,[171] a more reliable and comprehensive solution is to stop issuing pathogen patents at all.

2. *Legal Limitations on the Enforcement of Patents During Public Health Crises*

Some might argue that pathogen patents need not be limited because patent holders are already constrained from enforcing their patents, especially during global health crises. For example, in the United States, a patent holder cannot obtain a permanent injunction preventing an infringer from practicing a patented invention unless it demonstrates that the public interest would not be disserved by the entry of the injunction.[172] Likewise, the International Trade Commission, when assessing the appropriateness of an exclusion order barring the importation of infringing goods into the United States, must take into account "the effect of such exclusion upon the public health and welfare."[173] These limitations have significantly reduced the number of injunctions and exclusion orders that are issued with respect to medical and health-related technologies.[174] And under 28 U.S.C. § 1498, injunctions may not be obtained for patent infringement against the U.S. federal government or its contractors; the remedy for such infringement is limited to monetary damages as assessed by the Court of Federal Claims.[175]

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171. *See, e.g.*, RUTSCHMAN, *supra* note 9, at 127–29 (proposing a "formalized, permanent, and technology-specific patent pledge"); *see generally* Contreras, *Open Covid Pledge, supra* note 166 (discussing the "conservative approach" of establishing binding legal commitments through written licensing agreements).

172. eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006). *See also* Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7 (2008) (comparable test for preliminary injunctions).

173. 19 U.S.C. § 1337(d)(1).

174. *See* Christopher B. Seaman, *Permanent Injunctions in Patent Litigation after eBay: An Empirical Study*, 101 IOWA L. REV. 1949, 1999 (2016) (noting that injunctions are granted "at a significantly lower rate in cases involving medical device technology"). For proposed explanations for this situation, see Andrew Riley & Scott A. Allen, *The Public Interest Inquiry for Permanent Injunctions or Exclusion Orders: Shedding the Myopic Lens*, 17 VAND. J. ENT. & TECH. L. 751, 766-67 (2015).

175. 28 U.S.C. § 1498.

These limitations might suggest that, at least in the United States, the existence of patents claiming pathogenic sequences might not represent a significant threat. However, the existence of patents on these basic research tools, no matter the eventual litigation outcomes, can chill research, impose delays, and provide leverage for the demand of unwarranted fees.[176] Even meritless claims are costly to defend against and impose some level of risk to defendants, particularly in the United States, where fee shifting is rare. Despite the seeming assurance under § 1498 that firms operating under government contracts to produce vaccines and other biomedical supplies will be shielded from actions in district court, this has not always been the case.[177] Accordingly, while various litigation doctrines may tend to lessen the threat that pathogen patents will successfully be enforced in the United States, that threat is not entirely eliminated and may still impose a significant cost on firms that are engaged in research and development of pathogen-based biomedical products.

C. *Options for Avoiding Pathogen Patents*

As shown in Section III.A, above, the reintroduction of pathogen patenting could delay or impede research on new pathogen outbreaks with few offsetting benefits. Accordingly, this Section III.C outlines three policy options for avoiding pathogen patents in the future.

1. *Leave* Myriad *Intact under U.S. Law*

The U.S. Patent Act should not be amended to overturn the Supreme Court's *Myriad* decision and once again allow the patenting of naturally occurring genomic sequences, even if corresponding genomic material is "isolated, purified, enriched or otherwise altered by human activity".[178] Accordingly, the proposed clause of the Patent Eligibility Restoration Act

176. *See* Jorge L. Contreras, *Patent Reality Checks—Eliminating Patents on Fake, Impossible and Other Inoperative Inventions*, 102 J. PATENT & TRADEMARK OFF. SOC'Y 3, 8 (2021) (discussing economic and market effects of "bad" patents).

177. *See, e.g.*, Arbutus Biopharma Corp. v. Moderna, Inc., Case 1:22-cv-00252-MSG, 2022 WL 16635341 (D. Del. Nov. 2, 2022) (denying defendant's Motion to Dismiss based on § 1498).

178. *See supra* note 57, and accompanying text (reviewing the content of the proposed Patent Eligibility Restoration Act).

that expressly *allows* patenting of such sequences should be struck from the bill and excluded from any future legislative amendments to the Patent Act. Further, the Patent Act should be amended expressly to enshrine the *Myriad* holding in the law and to discourage future attempts to reverse it by legislative means. These revisions would preserve U.S. law as a model for other countries to follow and as a signal for norms in the scientific community.

2. *Ban Pathogen Patenting Under the WHO Pandemic Treaty*

Objections to patenting pathogenic sequence data have previously been made at the WHO, particularly in the context of sample sharing during the H5N1 influenza outbreak.[179] These efforts were largely subsumed by the 2011 PIP Framework that established a set of procedures for the international sharing of influenza samples.[180] The issues today are different. Though patenting of naturally occurring genomic sequences today has largely been eliminated, this situation could change. As noted in Part II.F above, legislative proposals have been made in the United States to overturn *Myriad*, and several countries, including Germany and the United Kingdom, still allow patenting of genomic sequences. For these reasons, an international ban on pathogen patenting is the best way to ensure that efforts at the national level to reintroduce this practice do not succeed. As such, the WHO should include in its pending Pandemic Treaty[181] a provision by which signatory states expressly agree to exclude from patentability naturally occurring genomic sequences, even if isolated and purified.[182]

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179. *See supra* note 89, and accompanying text (describing anti-patent proposal made by Bolivia).

180. *See supra* note 88, and accompanying text (discussing the PIP regulation process).

181. WHO Pandemic Treaty Draft, *supra* note 21.

182. Other international organizations that could conceivably sponsor such a treaty include the World Trade Organization (WTO), which recently enacted a COVID-19 IP Waiver, and the World Intellectual Property Organization (WIPO), which has collaborated with WHO on various outbreak and related patenting issues in the past. World Trade Organization, Ministerial Declaration on the TRIPS Agreement, WTO Doc. WT/MIN(22)/30 (2002); *see supra* notes 80–81 and 134 (discussing WIPO reports on patenting in the vaccines space).

(a) *Reversing the WHO's Accommodative Stance Toward Pathogen Patenting*

It is important that the WHO take a public stand against the patenting of pathogenic sequences. Recent statements by the WHO have been ambivalent at best, and accommodating at worst, with respect to the patenting of pathogenic genomes. Most notably, WHO's November 2022 *Guiding Principles for Pathogen Genome Data Sharing*,[183] a sweeping call for researchers around the world to share genomic data relating to pathogenic outbreaks, makes no mention whatsoever of patents or other intellectual property. Instead, the WHO seemingly concedes the right of researchers to secure intellectual property rights in pathogenic data, urging them to use "unrestricted open access models for sharing [data]" only when they "do not wish rights to be reserved."[184] The *Guiding Principles* go on to provide that

> [w]here submitters opt to retain certain protections related to pathogen genome data, platforms that preserve data generators' rights should be used. In this case, any user seeking access should be granted such access under agreed terms. Access should be free of charge for users.[185]

Statements like this urge researchers to make data freely available "under agreed terms," though not to charge for access. While at first blush this arrangement may seem to eliminate the impact that pathogenic patents could have on research collaboration, it does not. First, a requirement that users seeking access to data agree to unspecified terms opens the door to a range of restrictive conditions on data usage, including bans on commercial usage that could severely disrupt efforts at diagnostic, vaccine, and drug development. Second, free "access" does not imply that *usage* of sequence data would be free of charge, particularly in commercial applications, or that such usage would be permitted broadly, if at

183. WHO, *Guiding Principles for Pathogen Genome Data Sharing* (2022), https://apps.who.int/iris/bitstream/handle/10665/364222/9789240061743-eng.pdf [hereinafter WHO Pathogen Guiding Principles].

184. *Id.*, at 4.

185. *Id.*

all.[186] Only by eliminating patents on pathogen sequences entirely would the threat of these potential impediments be overcome.

(b) *Consistency with the TRIPS Agreement*

Some may question whether the proposed treaty ban on pathogen sequence patenting would be consistent with the minimum protections that countries are required to provide in their national laws under the WTO TRIPS Agreement.[187] Such a ban would, in fact, be entirely consistent with signatory states' obligations under TRIPS. Article 27 of the TRIPS Agreement includes the following provisions:

> 1. [P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application . . . without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
>
> 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health . . .

The proposed exclusion from patentability for pathogen genomes could be authorized under Article 27 under the following rationales: (a) a naturally occurring pathogen is not an "invention," (b) sequencing a naturally occurring pathogen is a routine activity that involves no inventive step, and (c) the exclusion is necessary to protect human health. And while the proposed exclusion relates to patent eligibility (Art. 27) rather than patent enforcement (Art. 28) or compulsory licensing (Art. 31), it is consistent with the intent and spirit of prior

186. The distinction between access and usage is fundamental under patent law. In most countries, a patent applicant is legally required to disclose its invention to the public at no charge. Yet even with this disclosure, usage of the invention is permitted during the term of the patent only with the authorization of the patent holder, which is often subject to charge or which may be withheld entirely for competitive reasons.

187. TRIPS Agreement, *supra* note 151.

WTO instruments addressing public health matters, namely, the 2022 Ministerial Decision creating the COVID-19 Vaccine IP Waiver[188] and the 2001 Doha Declaration on the TRIPS agreement and public health.[189]

Of course, patents are not the only legal mechanisms that have been used to enclose pathogenic data and samples from global research. As noted above, certain foreign governments have, in the past, sought to delay international research and responses in order to gain concessions under the banner of ABS.[190] The further recognition of ABS principles is currently under discussion as part of the WHO Pandemic Treaty negotiation, and clarifications should be introduced to ensure that individual states cannot use ABS demands to hold-up global public health research.[191]

3. *Policy Restrictions*

In addition to the legislative and treaty measures proposed above, the WHO, governmental public health agencies, and public and private research funders could deter the filing of patents on pathogenic sequences through express policies and restrictions placed in procurement and funding agreements.[192]

First, such policies could explicitly prohibit the patenting of pathogenic genomic sequences discovered by researchers supported by these bodies. Such prohibitions could be implemented along the lines of the contractual restrictions imposed

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188. COVID-19 IP Waiver, *supra* note 182.

189. World Trade Organization, *Declaration on the TRIPS Agreement and Public Health made at Doha*, Nov. 14, 2001, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2001).

190. *See supra* notes 86–87 and 156–59, and accompanying text (discussing Indonesian invocation of ABS and its influence on other countries).

191. WHO Pandemic Treaty Draft, *supra* note 21, at ch. 3, art. 10.

192. Major philanthropic funders of biomedical research such as the Bill & Melinda Gates Foundation and the Wellcome Trust routinely include grant conditions relating to intellectual property access and use. For an example of these efforts, see *Global Access*, BILL & MELINDA GATES FOUND., https://globalaccess.gatesfoundation.org [https://perma.cc/2X9G-78GC] (last visited Dec. 4, 2022); *Intellectual Property Policy*, WELLCOME TRUST, https://wellcome.org/grant-funding/guidance/intellectual-property-guidance/intellectual-property-policy [https://perma.cc/AG56-J7GE] (last visited Dec. 4, 2022).

on scientific discoveries by the HapMap Project.[193] Several commentators have observed that during the COVID-19 pandemic, government funding and procurement bodies around the world could have imposed conditions on funded entities relating to vaccine and drug pricing, access, production, and knowledge transfer;[194] such provisions could also be adapted to prohibit patenting of pathogen genomic sequences.

Less directly, and in cases where statutory or other requirements prevent governmental bodies from directly prohibiting the acquisition of patents by funded researchers,[195] funders can adopt rapid data release requirements modeled on the Bermuda Principles.[196] As discussed in Section I.C, the 24-hour data release requirement under the Bermuda Principles served to deter patenting of HGP sequence data both by HGP sequencing centers and third parties. A similar data release requirement could be imposed, for example, on researchers participating in a WHO pathogen sharing arrange-

193. *See* Contreras, *Genomic Data Sharing*, *supra* note 41, at 195 (discussing the HapMap Project and the affirmative steps taken, including contractual provisions, to prevent restrictions on access to its research data). *See also* Donna M. Gitter, *Resolving the open source paradox in biotechnology: A proposal for a revised open source policy for publicly funded genomic databases*, 24 COMPUTER L. & SECURITY REP. 529 (2008) (discussing HapMap data release strategy).

194. *See, e.g.*, Ana Santos Rutschman, *Vaccine Contracts in The Context of Pandemics and Epidemics*, NYU J. INT'L L. & POL. (forthcoming 2023) (identifying funder requirements in vaccine contracts); Gold, *supra* note 129, at 1429 (stating that government should "insist that companies follow existing policies that require broad licensing of IP to speed development"); Sapna Kumar & Ana Santos Rutschman, *Contractual solutions to overcome drug scarcity during pandemics and epidemics*, 40 NATURE BIOTECH. 301, 302 (2022) (arguing that governments should "extract guarantees on pricing and supply for low-income countries" when funding drug development among manufacturers); Jorge L. Contreras, *What Ever Happened to NIH's "Fair Pricing" Clause?*, BILL OF HEALTH (Aug. 4, 2020), https://blog.petrieflom.law.harvard.edu/2020/08/04/nih-fair-pricing-drugs-covid19/ (discussing historical fair pricing clauses in NIH cooperative R&D agreements); *see also* Contreras, *Association for Molecular Pathology*, *supra* note 45, at 46–51 (discussing similar approaches in the context of genetic diagnostics).

195. *See* Contreras, *Bermuda*, *supra* note 29, at 94, 121–22 (noting NIH's position that prohibiting patenting by its funded researchers could be at odds with the Bayh-Dole Act).

196. *See supra* notes 35–36, and accompanying text (summarizing the Bermuda Principles).

ment such as the PIP (which is limited to influenza)[197] or who are supported by public health agencies or other public or private funders. Given that the vast majority of pathogenic sequences have been identified by public agencies or publicly funded researchers, and not by corporate labs, such measures could effectively limit the emergence of patents on these global public resources.

Far from constituting a radical departure from current practice, genomics researchers routinely deposit genomic data into public databases around the world.[198] In fact, when SARS-CoV-2 was first sequenced by a research team in China,[199] it may have been these very norms of exchange that motivated the team to upload the viral sequence to GenBank within days of its identification. Though policy requirements such as this are less comprehensive than global treaty agreements and may have less legal force than national legislation, they can play a valuable role in deterring patenting behavior by most participants in the global pathogen research community.

The imposition by the WHO of policy requirements such as these would be far more useful than the accommodative posture that the WHO has adopted in its recent *Guiding Principles for Pathogen Genome Data Sharing*.[200] These *Guiding Principles* make the open release of pathogenic data optional when

197. *See* WHA *supra* note 88, and accompanying text (discussing the emergence of the PIP Framework). The WHO recognized the patent deterrent effect of open publication of viral genomes in 2007, but failed to require such publication through any binding instrument. WHO Director-General, Patent issues related to influenza viruses and their genes, WHO Doc. A/PIP/IGM/3, at 3 (Nov. 7, 2007) ("The early, open publication of a gene sequence of a newly-isolated strain of influenza virus would, in itself, preclude obtaining patent protection for those genes in the form as published.")

198. *See* Contreras & Knoppers, *supra* note 42 (acknowledging the "remarkable" success of genomic data sharing); Toronto International Data Release Workshop Authors, *Prepublication data sharing*, 461 NATURE 168 (2009) (discussing the rising growing tendency of data sharing prior to the release of scientific papers); Jane Kaye et al., *Data sharing in genomics—re-shaping scientific practice*, 10 NATURE REV. GENETICS 331, 332 (2009) (discussing then emergent trends of data-sharing policies in the United States and United Kingdom).

199. *See supra* notes 2–3, and accompanying text (tracing the early stages of elucidating and sharing the sequence of SARS-CoV-2).

200. WHO *Pathogen Guiding Principles*, *supra* note 183, at 4.

researchers wish to retain intellectual property rights.[201] Moreover, the "agreed terms" that the *Guiding Principles* contemplate could easily include requirements that users keep shared pathogen data confidential, thereby eliminating it as a prior publication that defeats patenting.[202] For all of these reasons, the WHO in particular should adopt more stringent data release and sharing requirements for pathogen sequence data that effectively deter patenting of that data by its discoverers and third parties.

V. Conclusion

Open, global research collaboration will be essential to address future pathogenic disease outbreaks, and measures should be taken to ensure that pathogenic sequence information is not appropriated by individual researchers, institutions, or states. A first step toward this goal is defeating legislative attempts in the United States that would overturn judicial precedents establishing that naturally occurring genomic sequences are ineligible subject matter for patent protection, while retaining ample opportunities to patent downstream innovations.

But given the fractured landscape of national patent laws and the inconsistent positions of different countries regarding genomic patenting, an international agreement that keeps the genomic sequences of pathogenic agents free from legal enclosure and appropriation is a preferred avenue for addressing this pressing global need.

At the same time, the WHO, national public health agencies and research funders should independently seek to limit researchers' ability to patent pathogenic sequences either directly or by imposing rapid data release requirements on researchers over which they have authority. Together, these measures can ensure that pathogen genomic sequences remain global public goods that are available to all researchers in the service of public health while interfering little with private incentives to develop innovative biomedical technologies.

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201. *See supra* Section III.C.2.a. (discussing options for avoiding pathogen patents).

202. *See supra* notes 39–41, and accompanying text (discussing the various implications that public disclosure of data may have on legal entitlement to patents).