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Smitha Gundavajhala
University of Washington School of Law

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Cover Page Footnote

Smitha Gundavajhala, University of Washington School of Law, Class of 2023; University of California, Berkeley, B.A. Public Health 2017. I would like to express my sincere gratitude to my advisor, Dr. Allyn Taylor, whose teachings on global health law helped this article take shape, and to my professor, Dr. Magali Eaton, whose guidance and expertise in international intellectual property helped sharpen my message. Finally, I would like to extend my gratitude to Kimberly Shely and the Editorial Team of the Washington, Journal of Law, Technology & Arts for sculpting this article into its final form.

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Smitha Gundavajhala[1]

ABSTRACT

Genetic technologies range in scope from agricultural to medical applications. Most recently, during the COVID-19 pandemic, companies like Moderna developed and patented genetic technologies for diagnostic and therapeutic purposes, like the mRNA vaccine. However, patent protection provides these companies with a monopoly that ultimately limits domestic production of generic versions, thus limiting access to life-saving diagnostics and therapeutics. When a company located in one country files a patent for recognition in another country, it effectively places a hold on production of any technologies covered by that patent's reach, whether that patent is enforced or not. However, the TRIPS Agreement, the Convention on Biological Diversity and Nagoya Protocol, and other instruments create obligations for countries to transfer technology to other countries. TRIPS and the Nagoya Protocol permit countries to exempt genetic technologies from patentability. However, some countries have formed "TRIPS-Plus" agreements that are superimposed upon, and prevent countries from taking advantage of, these exceptions in TRIPS.

This article will cover current patent law governing genetic technologies, and how these laws, along with intellectual property rights and anti-competitive practices, often hinder access to genetic technologies. It will also provide recommendations on how to facilitate access, including via a duty to transfer.

[1] Smitha Gundavajhala, University of Washington School of Law, Class of 2023; University of California, Berkeley, B.A. Public Health 2017. I would like to express my sincere gratitude to my advisor, Dr. Allyn Taylor, whose teachings on global health law helped this article take shape, and to my professor, Dr. Magali Eaton, whose guidance and expertise in international intellectual property helped sharpen my message. Finally, I would like to extend my gratitude to Kimberly Shely and the Editorial Team of the *Washington, Journal of Law, Technology & Arts* for sculpting this article into its final form.

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INTRODUCTION

The sequencing of the Human Genome has facilitated the development of a wide range of applications across industries. Technologies derived from genetic material have had implications for agriculture, biofuels, medicine, and more. Gene technologies have taken center stage in public awareness in recent years, especially during the COVID-19 pandemic, when companies used genetic technologies to develop vaccines and diagnostic kits. Scientists finished sequencing the remainder of the human genome in 2022. The newly discovered sequences appear to have implications for human evolution and adaptation, including immune response genes enabling humans to adapt to and survive infections, plagues, and viruses.[2] The recently discovered sequence also sheds light on the rest of the genome, making for the perfect conditions for further innovation in genetic technologies.[3]

However, because genetic technologies are currently patentable, countries that are not home to patent-holding companies do not have as much access to the products of this new wave of innovation. The disparity in access to innovative genetic technologies has economic consequences, as well as consequences for global health. During the COVID-19 pandemic, charities that sought to independently produce the COVID-19 vaccine expressed concern that Moderna's filing of a patent effectively placed a hold on production of any technologies covered by that patent's reach, whether the patent would be enforced or not.[4] Countries that are not home to patent-holding companies will be prevented from manufacturing their own diagnostic and therapeutic technologies cheaply and affordably.[5] As a result, these countries may become dependent upon the patent-holders to supply these technologies, and these countries may have to pay steep prices they cannot afford to pay. Furthermore, countries barred from producing genetic technologies may suffer worse health outcomes, as the dependence upon external supply could result in inconsistent access for patients. The prices these countries have to pay to obtain these technologies may also impact the quantity of a certain product (e.g. a vaccine) available to members of the public.

However, international laws concerning technology transfers can help address the restrictions on access that patents create. At international law, the TRIPS Agreement, the Convention on Biological Diversity, the accompanying Nagoya Protocol, and other instruments create obligations on countries to transfer technology to other countries, especially where diagnostic and therapeutic applications of genetic technologies are concerned. This "duty to transfer" can help mitigate production disparities, and by extension, health disparities. For countries with limited access to essential genetic technologies, the duty to transfer serves an important equity function. In fact, the Convention on Biological Diversity and Nagoya Protocol

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[2] David Lumb, *Scientists Finally Sequence the Entire Human Genome*, CNET (Apr. 1, 2022, 9:45 AM), https://www.cnet.com/science/biology/scientists-finally-fully-sequence-the-human-genome/#:~:text=While%2092%25%20of%20the%20human,Until%20now.

[3] *Id*.

[4] Wendell Roelf and Julie Steenhuysen, *Charities say Moderna patents could hit Africa COVID vaccine hub*, REUTERS (Feb. 17, 2022, 2:26 PM), https://www.reuters.com/business/healthcare-pharmaceuticals/charities-say-moderna-patents-could-hit-africa-covid-vaccine-hub-2022-02-17.

[5] *Id*.

discuss fair and equitable benefit-sharing and require parties to promote research on the sustainable use of biological diversity in "developing countries."[6]

This paper will cover current patent law governing genetic technologies. It will then discuss how patents and patent law work together to hinder access to genetic technologies, especially considering anti-competitive practices by pharmaceutical companies. It will discuss policy reasons for facilitating access to genetic technologies and provide recommendations as to what can be done in patent law to facilitate access. This paper will also discuss the current laws governing technology transfer between countries and whether there is a duty to transfer genetic technologies between countries. The paper will then address how duties to transfer technology can be squared with private intellectual property rights. Finally, the paper will provide some avenues by which the duty to transfer can be strengthened.

I. SIGNIFICANCE OF GLOBAL GENOME HEALTH

The human genome's discovery has had a wide range of impacts on health and medicine for all. The international Human Genome Project launched in 1990, publishing a paper on the initial sequencing and analysis of the human genome in 2001. Since then, insights from the human genome have advanced research on treatments for cancer, chronic health conditions like obesity, developmental and behavioral health conditions, and more. Broadly, the discovery of the human genome has allowed scientists to link biological structure with physiological function. This has allowed researchers to understand the genes and cellular pathways associated with diseases, and to monitor the ways in which external conditions can alter the genome over the course of one's lifetime. A wide range of therapeutic applications of genetic technologies has arisen in the last decade, including CRISPR-Cas9 gene editing and vaccines based on messenger RNA (an analog to DNA). While the uses of genetic technologies span a wide range of industries, the diagnostic and therapeutic applications of genetic technologies are the subject of this paper.

A. GENETIC MATERIALS ARE AT THE CUTTING EDGE OF INNOVATION

The Human Genome was 92% sequenced as of 2003.[7] 100 scientists from the Telomere-to-Telomere (T2T) Consortium collaborated on the project to map the entire human genome.[8] The sequencing of the remainder was recently completed, and on March 31, 2022, T2T published the complete sequence in the journal *Science*.[9] This sequence (T2T-CHM13) adds 200 million base pairs and corrects thousands of structural errors in the previous version of the Human Genome (GRCh38).[10] It improves our understanding, not only of the newly sequenced portion, but also of

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[6] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, Tenth Meeting of the Parties to the Convention on Biological Diversity, U.N. Doc. UNEP/CBD/COP/DEC/X/1, art. 5, art. 8, (Oct. 29, 2010)[hereinafter "Nagoya Protocol"]..

[7] Lumb, *supra* note 2, at paragraph 1.

[8] Lumb, *supra* note 2, at paragraph 2

[9] Nurk et al., *The complete sequence of a human genome*, 376 SCIENCE 44-53 (2022)(publishing the entire sequence of the human genome).

[10] University of California, Santa Cruz, *First complete, gapless sequence of a human genome reveals hidden regions: Parts of the human genome now available to study for the first time are important for understanding genetic diseases, human diversity, and evolution,* SCIENCEDAILY (31 March 2022), https://www.sciencedaily.com/releases/2022/03/220331151524.htm.

the entire genome.[11] That means that the T2T-CHM13 sequence opens the door for further research and innovation in this space. According to Evan Eichler, professor of genome sciences at University of Washington & one of the major contributors to the main paper on the research, the additional genes are very important for adaptation.[12] The new sequence includes immune response genes enabling humans to adapt to and survive infections, plagues, and viruses, as well as that enable human brains to grow larger than those of other primates.[13] Thus, the sequencing of this remaining portion of the human genome will have important implications for future pandemics, as well as for the story of human evolution going forward.

B. GENETIC TECHNOLOGIES HAVE MANY APPLICATIONS, ESPECIALLY IN HEALTHCARE

Genetic technologies are utilized in healthcare, agriculture, food science, biofuels and bioplastics, and many other areas. Among the applications of genetics, healthcare applications are of increasing importance. Genetic technologies are useful in research. For instance, research using T2T-CHM13 to identify links between certain genetic patterns and cancers has already begun. The portion of the human genome that had been sequenced before this year contained valuable information on how biological functions mapped to genes, and how our environments could alter our genes by the expression of protein markets sitting on top of the genome (called the ”epigenome”). Gene sequences obtained from early efforts have advanced research on treatments for autism, Alzheimer's, ovarian cancer, schizophrenia, obesity, and a host of other genetically linked disorders. One promising treatment purports to permanently lower patients' cholesterol via an injection that would alter their DNA.[14] Genetic technologies are useful not only in developing treatments, but also in screening & diagnosis. Adam Phillippy, Head of Gene Informatics at the National Human Genome Research Institute, said that the goal of the Human Genome Project was for sequencing one's genome to become an affordable, routine medical test.[15] Genetic technologies are especially useful in immunization and treatment**.** The T2T-CHM13 sequence contains key information on genes that may contain the key to humans' adaptation and survival in future pandemics.

During the COVID-19 pandemic, genetic technologies have been essential in protecting the population from, and mitigating the impacts of, COVID-19. Pfizer, Moderna, and other companies utilized mRNA technology in their vaccines. This technology "teaches" cells to produce a protein that will the appropriate immune response.[16] Vaccines utilizing mRNA technology are not new; mRNA technology has been studied for use in combating flu, Zika virus, rabies, and more.[17] CRISPR-Cas9 gene editing technology has also been used to develop COVID-

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[11] Sergey Aganezov et al., *A complete reference genome improves analysis of human genetic variation*, 376 SCIENCE 1, 4 (2022)(describing the new insights made possible the recently completed gene sequence).
[12] Lumb, *supra* note 1, at 3.
[13] *Id*.
[14] Michael Le Page, *Injection could permanently lower cholesterol by changing DNA*, NEWSCIENTIST (Feb. 6, 2017), https://www.newscientist.com/article/2120369-injection-could-permanently-lower-cholesterol-by-changing-dna/#ixzz7VHi3XwJE.
[15] Tasnim Ahmed, *Scientists sequence the complete human genome for the first time*, CNN (Mar. 31, 2022, 5:40 PM), https://www.cnn.com/2022/03/31/health/first-complete-human-genome-sequence/index.html.
[16] *Understanding How COVID-19 Vaccines Work*, CENTERS FOR DISEASE CONTROL (May 12, 2023), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html.
[17] *Id.*

19 diagnostic kits during the pandemic.[18] These diagnostic kits contain enzymes that target the genomic site to be diagnosed, as well as RNA sequences that guide the enzymes to the genomic site.[19] The patentability and transfer obligations surrounding genetic technologies will have global health implications for the treatment of heritable conditions and the mitigation of future pandemics.

II. PATENT LAW IMPLICATIONS

As genetic technologies become more widely used and relied upon, it is important to consider whether patent laws hinder access to genetic technology, and by extension, life-saving diagnostic and therapeutic technologies. Patents can create anti-competitive results by imposing barriers to production and creating dependence upon the countries that are home to patent-holding companies. In addition, patent laws can facilitate anti-competitive behavior by biotechnology companies. Currently, few binding instruments at international law address the patentability of genetic material. One likely source of regulation can be found in the Trade-Related Aspects of Intellectual Property Agreement, or TRIPS.

A. LAWS GOVERNING PATENTING OF GENETIC TECHNOLOGY

TRIPS was first adopted on April 15, 1994, as Annex 1C to the Marrakesh Agreement Establishing the World Trade Organization. The purpose of TRIPS is to "promot[e] technological innovation and to… transfer and disseminat[e] technology.[20] TRIPS describes, among other things, the patentability of diagnostic, therapeutic, and surgical methods and "essentially biological processes."[21] However, TRIPS does not explicitly address genetic material, which critics suggest leaves room for inconsistencies in the patentability of genetic material between WTO member states.[22] Article 27 currently allows Member States to decide whether to exclude genetic material. Section Five of TRIPS provides for the patentability of products or processes, "provided that they are new, involve an inventive step, and are capable of an industrial application."[23] Genetic material itself has often not involved an inventive step such that it is patentable, but genetic technologies can be patented. The language of Section 5 remained the same after its amendment in 2017, but the current definition in Article 27 around the excludability of "diagnostic, therapeutic, and surgical methods" and "biological processes" may change when the TRIPS Council meets to amend it in 2023.[24]

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[18] Hossein Rahimi et al., *CRISPR Systems for COVID-19 Diagnosis*, 6 ACS SENSORS 1430, 1431 (2021).
[19] *Id.*
[20] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 7, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 869 U.N.T.S. 299 [hereinafter "TRIPS"] (identifying the objectives of the TRIPS Agreement as to "promot[e] technological innovation and to . . . transfer and disseminat[e] . . . technology").
[21] TRIPS, art. 27.
[22] Cydney A. Fowler, *Ending Genetic Monopolies: How the Trips Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide*, 25 AM. U. INT'L L. REV. 1093 - 96 (2010) (discussing the room that TRIPS leaves for inconsistencies in national laws).
[23] TRIPS, art. 27(3).
[24] *Amendment of the TRIPS Agreement – Eighth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, WORLD TRADE ORGANIZATION (Nov. 22, 2021), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/L/1122.pdf&Open=True.

Providing additional color to the TRIPS Agreement is the Declaration on the TRIPS Agreement and Public Health, also known as the Doha Declaration. The Doha Declaration affirms that intellectual property protections under TRIPS should not prevent members from taking measures to protect public health, and that member states are free to take steps to facilitate access to existing medicines and the creation of new medicines.[25] Article 4 of the Doha Declaration states that the "[TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[26] The Doha Declaration restates member states' right to use TRIPS flexibilities.[27] However, it does not impose any additional obligations that would facilitate the use of those flexibilities — those decisions are still left to member states.

While there is no one international patent system, United Nations member states have signed on to the Patent Cooperation Treaty (PCT) under the auspices of the World Intellectual Property Organization, a subsidiary organization of the UN. The treaty, which entered into force on June 19, 1970, and was amended on October 3, 2001, allows companies to file an "international" patent application to obtain patent protection for an invention simultaneously across all 156 contracting states.[28] Most of the world's corporations, research institutions and universities utilize PCT to seek international patent protection. Regulations to the PCT do not conflict with the requirements laid out in TRIPS, but rather support the implementation of TRIPS.[29] Specifically, the Regulations to the PCT provide the steps required to obtain patent protection across contracting countries.[30] It is important to consider the ability of companies to obtain widespread patent protection under TRIPS by following the protocols laid out in the Regulations to the PCT. A single application could have a variety of impacts on domestic production around the world. A country's entry into the Patent Cooperation Treaty could open the floodgates for patent applications, limiting opportunities for generic medicines to enter the market, as discussed further below.

B. TRIPS FLEXIBILITIES AND TRIPS-PLUS OBLIGATIONS

Global regulation of intellectual property rights is a relatively recent concept. Prior to TRIPS' entry into force, countries had the ability to regulate their own regimes freely. TRIPS took that freedom away by imposing a uniform set of standards around intellectual property protections and trade. In order to compensate for the loss of freedom, TRIPS provided for certain flexibilities that would allow member states to comply, while allowing states to implement TRIPS in accordance with their own priorities. These flexibilities were intended to mitigate the negative impacts of the heightened standards of intellectual property protection under TRIPS. Some of these flexibilities included transitional periods for the Least Developed Countries (LDCs) to comply with TRIPS, compulsory licensing to allow countries to obtain access to patented technologies,

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[25] *The Doha Declaration Explained*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm#trips (last visited Jun. 4, 2022).
[26] Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002).
[27] The Doha Declaration Explained, *supra* note 25.
[28] *PCT FAQs*, WORLD INTELLECTUAL PROPERTY ORGANIZATION (April 2020), https://www.wipo.int/pct/en/faqs/faqs.html.
[29] Council for Trade-Related Aspects of Intellectual Property Rights, *Note by the Secretariat: The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity*, WTO Doc. IP/C/W/368 (February 8, 2006).
[30] *Id.*

certain government use exceptions, increased patentability standards, and parallel importations that would allow countries to obtain a parallel technology, patented in another country, for a lower price.[31]

However, use of these flexibilities has been limited overall. While these flexibilities continue to be available, they have little effect if not adopted by member states. Many countries have entered into agreements (referred to as TRIPS-Plus) that limit the applicability of TRIPS flexibilities and impose additional intellectual property protections via bilateral and regional Free Trade Agreements (FTAs).[32] In states that have formed these FTAs, TRIPS-Plus has strengthened monopolies by expanding the scope of current biotechnology patents, extending patent terms beyond the 20 years required under TRIPS, and blocking the registration and marketing of generic versions of patented pharmaceuticals.[33] While the impacts of TRIPS-Plus vary based on a wide range of factors, including market dynamics, production capacity, and domestic policy, the impacts have been overwhelmingly negative for many countries.[34] The United States, in particular, has taken an aggressive approach in forming FTAs with developing countries and imposing higher levels of intellectual property protection, which in turn has negatively impacted access to essential medicines in those countries.[35]

The Free Trade Agreement between the U.S. and Jordan is a prime example of the harmful impacts of TRIPS-Plus. The United States-Jordan FTA was signed in 2001.[36] In the five years after its adoption, it drove up prices of essential medicines by over 20 percent.[37] The data exclusivity provisions of TRIPS-Plus rules also solidify the monopoly power of biotechnology companies by preventing generic medicines from relying on the originators' safety & efficacy data.[38] Data exclusivity in Jordan delayed generics for 79 percent of medicines within five years after the adoption of the FTA.[39] In addition, Jordan has spent almost $22 million on medicines with no generic competitors.[40] Another negative impact of the FTA in Jordan is that patients pay two to ten times more than its neighbor Egypt, where new medicines are manufactured locally.[41] Jordan also entered the PCT in 2017, which has facilitated the filing of patent applications and posed further barriers to the entry of generic equivalents of patented therapeutics into the market.[42]

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[31] MOHAMMED EL SAID, THE IMPACT OF 'TRIPS-PLUS' RULES ON THE USE OF TRIPS FLEXIBILITIES: DEALING WITH THE IMPLEMENTATION CHALLENGES, at 307 (2021)(eBook).
[32] *Id.*
[33] *Id.*
[34] *Id.* at 316.
[35] Rohit Malpani, ALL COSTS, NO BENEFITS: HOW TRIPS-PLUS INTELLECTUAL PROPERTY RULES IN THE US-JORDAN FTA AFFECT ACCESS TO MEDICINES, OXFAM (2007).
[36] *Jordan Free Trade Agreement*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE (last visited Jun. 5, 2022).
[37] Malpani, *supra* note 35.
[38] WORLD HEALTH ORG., IMPACT ASSESSMENT OF TRIPS PLUS PROVISIONS ON HEALTH EXPENDITURE AND ACCESS TO MEDICINES 2 (2006).
[39] *Id.*
[40] *Id.*
[41] *Id.*
[42] OXFAM, *supra* note 35; *see also WORLD INTELLECTUAL PROPERTY ORGANIZATION, The PCT now has 156 Contracting States,* https://www.wipo.int/pct/en/pct_contracting_states.html (last visited Jun. 5, 2022).

C. HOW PATENTS AND PATENT LAW HINDER ACCESS TO GENETIC TECHNOLOGIES

Patents can deprive countries of access to genetic technologies, which can have detrimental consequences during a pandemic or similar global health crisis. The filing of a patent, whether enforced or not, can in and of itself have anti-competitive effects on domestic production of genetic technologies. The very existence of a patent poses a threat of enforcement and can harm investments into local production of essential diagnostics and therapeutics. One salient example of this is the impact of Moderna's patents on vaccine production in Africa. WHO backed an African vaccine hub pilot to address poor domestic manufacturing capacity in African countries, which currently forces Africa to import 99% of its vaccine needs.[43] However, African charities fear that Moderna's applications for patents in South Africa could prevent a new African vaccine hub from manufacturing the mRNA vaccine.[44] Afrigen Biologics, located in South Africa, has already used the publicly available sequence of Moderna's vaccine to make its own version of the vaccine.[45] Enforcing the patents would halt Afrigen's progress towards all applications of this mRNA technology, including treatments for diabetes, cancer, and insulin. Moderna pledged in 2020 not to enforce patents against other manufacturers of vaccines. As of 2022, Moderna has issued an updated pledge in which it declared that vaccine supply is no longer an issue, and stated that it expects all countries — but for 92 low- and middle- income countries — to "respect its intellectual property."[46] While Afrigen's hub has not been met with patent enforcement, Moderna has already begun to enforce its patent rights against fellow vaccine manufacturers Pfizer and BioNTech, where it previously promised not to do so.[47] Enforcing patents would have economic and public health consequences for vaccine production in all countries in which Moderna has filed patent applications. Afrigen representatives said that unless Moderna's patents are revoked, voluntary licenses are awarded, or Moderna agrees to waive its patent in those countries, these patents limit the ability of local vaccine hubs to operate.[48] In practice, this means that the patent holders might behave monopolistically and drive up pricing, and make it unaffordable to procure sufficient vaccine units for members of the public.[49]

Another battleground in genetic intellectual property is the battle for recognition of CRISPR-Cas9 patents. As mentioned above, CRISPR-Cas9 is a piece of DNA that facilitates the finding and editing of gene sequences in a living being.[50] The technologies have been used in COVID-19 diagnostic kits, bioenergy, agriculture, and therapeutics for a range of genetic diseases,

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[43] Wendell Roelf and Julie Steenhuysen, *Charities say Moderna patents could hit Africa COVID vaccine hub*, REUTERS (Feb. 17, 2022, 2:26 PM), https://www.reuters.com/business/healthcare-pharmaceuticals/charities-say-moderna-patents-could-hit-africa-covid-vaccine-hub-2022-02-17.
[44] *Id.*
[45] *Id.*
[46] Andrew Alexander, *Did Moderna Sink its Own Ship by Making a Patent Pledge?* JDSUPRA (Oct. 24, 2022), https://www.jdsupra.com/legalnews/did-moderna-sink-its-own-ship-by-making-5067968/.
[47] Hannah Kuchler, *Patent wars: Moderna's battle for the spoils of Covid vaccines*, FINANCIAL TIMES (Nov. 7, 2022), https://www.ft.com/content/5769f077-641e-4d37-adc6-7634c59b6d5d.
[48] Roelf, *supra* note 43.
[49] Vaccine production aside, vaccine hesitancy is also rampant in Africa, and poses a barrier to deployment of vaccines once produced. Production of vaccines is only half the battle. Polydor N. Mutombo et al., *COVID-19 vaccine hesitancy in Africa: a call to action*, THE LANCET (Mar. 1, 2022), https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(21)00563-5/fulltext.
[50] Aparna Vidyasagar & Nicoletta Lanese, *What is CRISPR?*, LIVESCIENCE (Mar. 13, 2023), https://www.livescience.com/58790-crispr-explained.html.

from Alzheimer's to ovarian cancer.[51] The Broad Institute recently won the interference raised by UC Berkeley's Jennifer Doudna, and as a result, has priority of recognition for CRISPR-Cas9 use in humans, plants, and animals in the United States.[52] Now, ToolGen in South Korea and Sigma Aldrich in Germany contest the Broad Institute's patents in those countries.[53] Patent battles have consequences not only for the economic success of the company that gains patent recognition, but also for the health of the world. Here, the countries in which the patent holders are headquartered have an advantage in development and distribution of CRISPR-related diagnostics and therapeutics. The countries that are not home to patent holders face significant barriers in producing vaccines affordably and locally. Thus, patenting can place these non-patent holders' countries at the mercy of the companies that do hold the patents.

The barriers that patents and patent enforcement pose are exacerbated by biotechnology companies' anti-competitive practices. While it is important to acknowledge the role of intellectual property in encouraging biotechnology companies to innovate, anti-competitive practices run counter to competition and innovation. For instance, the existence of patents alone has delayed the entry of generic drugs into the U.S. healthcare system, costing the U.S. over $55 billion over the next 15 years.[54] Some companies take these practices further, using "pay-to-delay" tactics to pay manufacturers of generics to stay off the market. Another harmful process called "evergreening" involves obtaining patents that make only marginal changes to existing patents. By extending the duration and scope of patents, pharmaceutical companies expand their monopolies, prevent competitors from entering the market, and drive up prices — all while contributing little in the way of true innovation.

D. POLICY AND RATIONALE

Given the wide range of health applications for genetic technologies, it is important for genetic technologies to be widely available. Genetic technologies, as a product of the human genome, should not be hindered by patents.

The Universal Declaration on the Human Genome and Human Rights articulates this principle in Article 12(a): "Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual."[55] Article 19(a) also provides that states "should seek to encourage measures enabling … the capacity of developing countries to carry out research on human biology and genetics … developing countries to benefit from the achievements of scientific and technological research … and the free exchange of scientific knowledge and information in the areas of biology, genetics and medicine."[56]

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[51] Allen Caobi et al., *The Impact of CRISPR-Cas9 on Age-related Disorders: From Pathology to Therapy*, INT'L SOC'Y ON AGING & DISEASE (Aug. 1, 2020), http://www.aginganddisease.org/EN/10.14336/AD.2019.0927.
[52] Catherine Shaffer, *Broad defeats Berkeley CRISPR patent*, NATURE (Mar. 14, 2022), https://www.nature.com/articles/d41587-022-00004-2.
[53] *The Broad Institute, Inc., Massachusetts Institute of Technology, and President and Fellow of Harvard College v. Toolgen, Inc.*, No. 106,126 (P.T.A.B. May 28, 2021); *see also* Kevin Noonan, *Sigma-Aldrich and Broad Propose Preliminary Motions in Recent CRISPR Interference, No. 106,133*, JDSUPRA (December 16, 2021), https://www.jdsupra.com/legalnews/sigma-aldrich-and-broad-propose-6553124.
[54] El Said, *supra* note 31.
[55] Universal Declaration on the Human Genome and Human Rights art. 12, Nov. 11, 1997 [hereinafter UDHGHR].
[56] UDHGHR art. 19.

Proponents of patent protections argue that having intellectual property protections motivates investment into research and development, and as a result, boosts innovation. These proponents assert excluding genetic technologies from patentability would deal a blow to global health because biotechnology companies would hesitate to invest in research. Fewer diagnostics and therapeutics would become available, running counter to the objective of the TRIPS agreement to promote widespread access to technology. But the enforcement of patents can have anti-competitive results, which are exacerbated by TRIPS-Plus obligations. Even when companies experience favorable conditions for innovation, as Moderna did when developing the COVID-19 vaccine, other countries may not see the benefits from this innovation. TRIPS-Plus rules do not necessarily increase innovation, as they expand the scope of patentability to technologies that provide only marginal improvements on existing patents. As a result, technologies that are neither "new" nor include an "inventive step" can be patented under Article 27 of TRIPS. When weighing the benefits that countries experience against the disparities in access to these innovative technologies, it appears that the promise of innovation falls flat in practice.

E. WHAT CAN BE DONE IN PATENT LAW TO FACILITATE ACCESS?

TRIPS can be amended to strengthen its existing compulsory licensing and benefit-sharing provisions.[57] Under Article 31 of TRIPS, states may order compulsory licensing when "the public interest requires that others than the patent owner exploit the invention or as a remedy against the utilization of the patent rights in an abusive manner."[58] Article 31(b) contains an obligation to obtain authorization that may be waived in the event of a "national emergency" or in cases of "public non-commercial use."[59] Gene-based diagnostic and therapeutic technologies are a perfect example of a public non-commercial use, as advances in biomedical technologies benefit humankind. Requesting countries should not have to obtain authorization when it comes to genetic technologies.

The obligation to obtain authorization creates barriers to exercising the right to compulsory license provisions in TRIPS. In "Waiver of IP Protections for COVID-19 Vaccines Still Under Consideration at WTO," Casey Donahoe highlights some of the challenges posed by the current process for obtaining compulsory licenses: "existing processes … can require country-by-country and case-by-case negotiations and litigation with the vaccine developers and may be limited to public uses, are too time-consuming and inconvenient to mount an effective response, particularly where thickets of IP protection cover single vaccines."[60] The process of obtaining a compulsory license is so expensive, time-consuming, and subject to uneven bargaining power between countries that it ceases to be an effective redistribution measure.

Other measures to prevent patent abuse include introducing exceptions to data exclusivity for generic medicines, raising patentability standards, limiting patent term extensions, and expanding grounds for patent opposition. In its report on the US-Jordan FTA, Oxfam

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[57] Fowler, *supra* note 22.

[58] NUNO PIRES DE CARVALHO, *THE TRIPS REGIME OF ANTITRUST AND UNDISCLOSED INFORMATION* 139, 141 (2008)(explaining the role and purpose of compulsory licenses and their requirement in order to benefit the public good or provide redress against abuses).

[59] TRIPS, at Art. 31(b).

[60] Casey D. Donahoe, *Waiver of IP Protections for COVID-19 Vaccines Still Under Consideration at WTO,* WOMBLE BOND DICKINSON (August 23, 2021), https://www.womblebonddickinson.com/us/insights/articles-and-briefings/waiver-ip-protections-covid-19-vaccines-still-under-consideration.

recommended that Jordan introduce exceptions to data exclusivity that permit generic medicines to enter the market and restrict the scope of patentability by raising patentability standards.[61] Australia implemented similar measures in response to the negative impacts of the U.S.-Australia FTA. Australia's 2013 Patent Law reform mitigated the impacts of "evergreening" practices by raising patentability standards so that companies could not accumulate patents that made only marginal improvements.[62] It did so by raising the "inventive step" standard for patentability, and made it so that patent term extensions could only be obtained for specific products or where the patent involved new active ingredients or formulations.[63] Australia also expanded grounds for opposition against patent term extensions and prevented companies from marketing products during the patent approval process.[64] All of these measures can be imported into a TRIPS amendment that would impose higher standards for patentability and limit patent term extensions where diagnostic and therapeutic applications of genetics are concerned. This amendment would also create specific carve-outs preventing member states from invoking data exclusivity for diagnostic and therapeutic applications of genetic technologies, which would enable generics to enter the market and lower prices.

At least in the United States, the "last-in-time rule" of treaty interpretation provides that statutes and treaties must be read to give effect to both if possible, but in the event a statute and treaty conflict, the most recent instrument governs.[65] The "last-in-time rule" would allow this proposed amendment to TRIPS supersede any previously passed implementing legislation at the national level. However, this is only true for states that agree to become parties to the amending agreement; under Article 40 of the Vienna Convention on the Law of Treaties, states that do not agree to the amendment will still be bound by the unamended version.[66] The need for states to adopt to the amending agreement may limit reach of protections under the proposed amendment, as some countries (like the U.S.) may benefit from TRIPS Plus and be unwilling to give up their leverage. Here, it is important to involve stakeholders, like pharmaceutical companies and research institutions in domestic and international negotiations to secure wider buy-in for the amended agreement.

III. TECHNOLOGY TRANSFER IMPLICATIONS

Laws governing technology transfer also have implications for global health. Technology transfer allows for the exchange of scientific findings, knowledge and intellectual property; in this context, it refers to the transfer of intellectual property from creators, like universities and biotechnology companies, to users in other countries.[67] Patent laws and agreements that restrain competition may have adverse effects on the transfer of technology, and in turn, adverse effects on the public health and economy of transferee states. Thus, it is important to understand the obligations to transfer, and to determine how those duties can be strengthened under current

[61] OXFAM, *supra* note 35.
[62] El Said, *supra* note 31.
[63] *Id*.
[64] *Id*. at 317.
[65] EMILY S. BREMER, 22 IND. INT'L & COMP. L. REV. 27-28 (2012).
[66] Vienna Convention on the Law of Treaties art. 40, May 23, 1969, 1155 U.N.T.S. 331.
[67] *Intellectual Property and Technology Transfer*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, https://www.wipo.int/technology-transfer/en/index.html (last visited Jun. 5, 2022).

international law. Where genetic technologies are patentable, strengthening duties of technology transfer can help counterbalance the anti-competitive effects of intellectual property protections.

A. LAWS GOVERNING TRANSFER OF GENETIC TECHNOLOGY

Here, two binding instruments have implications for the technology transfer: TRIPS and the Convention on Biological Diversity (operationalized in the Nagoya Protocol). TRIPS and CBD are the products of different international bodies: while TRIPS binds WTO member states, the CBD is a binding document on the UN member states that have ratified it. The Convention on Biological Diversity was adopted by the United Nations on December 29, 1993.[68] It provides a more equity-focused approach to sharing genetic technologies, with specific provisions and financing mechanisms that make it easier for developing countries to participate in technological exchange. This approach allows the benefits of technologies to be shared widely.

i. TRIPS Articles 40(3) and 40(4)

TRIPS provides for the transfer of technology through Articles 40(3) and 40(4), which impose on member states a duty of consultation and information exchange. These articles address restraints on cross-border competition in license agreements. Article 40(3) says, "The Member … shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available nonconfidential information of relevance to the matter in question … subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member". This provision obligates intellectual property holders to be open to information exchange, which in practice undermines the competitive advantage of having intellectual property protections in place. However, the last two conditions render these technology transfer provisions vulnerable to conflicting interpretations. These conditions mean that the duty of information exchange is subject to the laws of the member states, as well as to the formation of agreements between the requesting and addressed members. Different member states may have different laws surrounding the duty to share information and technology. In addition, the ability to modify the duty of information exchange through agreement allows disparities in bargaining power to impact the rights of transferee countries. The states with less bargaining power may also be the states requesting the technology. Modifying the duties of exchange outlined in TRIPS by agreement creates a risk of deepening disparities between countries.

ii. Convention on Biological Diversity and Nagoya Protocol

The Convention on Biological Diversity (CBD) and the accompanying Nagoya Protocol also contain provisions regarding technology transfer duties. Articles 16 and 19 of CBD, in particular, provide guidelines for technology transfer between state parties. Paragraph 2 of Article 16 says, "Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most [favorable] terms, including on

[68] *Convention on Biological Diversity,* UNITED NATIONS TREATY COLLECTION, https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-8&chapter=27 (last visit Jun. 5, 2022).

concessional and preferential terms where mutually agreed."[69] Paragraphs 3 and 4 operationalize this obligation. Paragraph 3 says that each contracting party shall take legislative, administrative, or policy measures such that developing countries providing genetic resources "are provided access to and transfer of technology which makes use of those resources".[70] Paragraph 4 builds on the requirement to take "legislative, administrative, or policy measures" by framing it through the aim that the private sector facilitates access to, joint development and transfer of technology.[71] Article 19 ("Handling of Biotechnology and Distribution of its Benefits") says, "Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties.[72] Such access shall be on mutually agreed terms.[73]

The principles laid out in CBD are operationalized by the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. The Nagoya Protocol entered into force on October 12, 2014 — eleven years after CBD entered into force.[74] Genetic resources have been considered the "shared heritage of humankind," and the Nagoya Protocol accordingly requires signatory states to establish domestic legislation promoting equitable access to the benefits of genetic resources.[75] Article 1 of the Protocol ("Objectives") states, "The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies…".[76] The Nagoya Protocol's equity lens helps shift some of the existing power dynamics surrounding technology transfer. Article 23 ("Technology Transfer, Collaboration and Cooperation"), in particular, concerns the limitation of state efforts in sharing privately owned technology, particularly when protected by intellectual property rights.[77] Article 23 states that "Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition…".[78] The duty outlined in Article 23 is weakened by the language "undertake to," but this language provides a valuable roadmap to making TRIPS provisions surrounding technology transfer more equitable.

Despite its objective of promoting access and benefit-sharing, the Nagoya Protocol has faced criticism for obstructing innovators' access to genetic resources. The pharmaceutical industry has criticized the Nagoya Protocol for being too weak. The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) claims that the Nagoya Protocol allows

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[69] Convention on Biological Diversity art. 16, June 5, 1992, 1760 U.N.T.S. 69.
[70] *Id*.
[71] *Id*.
[72] Convention on Biological Diversity art. 19, June 5, 1992, 1760 U.N.T.S. 69.
[73] *Id*.
[74] *The Nagoya Protocol on Access and Benefit-sharing*, CONVENTION ON BIOLOGICAL DIVERSITY, https://www.cbd.int/abs (last visited Jun. 5, 2022).
[75] Kevin McCluskey et al., *The U.S. Culture Collection Network Responding to the Requirements of the Nagoya Protocol on Access and Benefit Sharing*, 8 AM. SOC'Y FOR MICROBIOLOGY 1, 2 (2017).
[76] Nagoya Protocol art 1.
[77] Elisa Morgera et al., Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access & Benefit-Sharing to the Convention on Biological Diversity 314 (2014).
[78] Nagoya Protocol, art. 23, Oct 12, 2014.

countries to "withhold access to… pathogens needed for research."[79] In particular, IFPMA is opposed to the inclusion of genetic resource sequence data in the Nagoya Protocol, believing that the Protocol's aim of preserving biological diversity works counter to public health objectives of information-sharing.[80] Others echo this concern: the tradeoff for the legal certainty and transparency that the Protocol provides is the "increased cost and complexity of obtaining genetic resources."[81] This is due to a requirement to obtain the Prior Informed Consent (PIC) of the providing party contained in Article 6 of the Protocol.[82] While the Nagoya Protocol provides for access and benefit-sharing on paper, it has had mixed results with respect to information sharing in practice. Part of the ambiguity surrounding the Nagoya Protocol lies in the fragmentation of its implementation. The Nagoya Protocol requires implementation at the national level, and given the room left to states for interpretation, the Protocol has given rise to a wide range of implementing rules.[83] It is important to note that the United States did not ratify the CBD and is not a signatory of the Nagoya Protocol.[84] However, these instruments still impact scientists in the U.S. For instance, the U.S. maintains collections of cultures and other biological specimens, including the genetic material of those specimens, in Nagoya Protocol signatory states.[85] U.S. scientists are required to follow the "Access and Benefit Sharing" (ABS) regulations of the signatory state in which its microbe collections are located.[86] Should they not follow these requirements, U.S. scientists stand to lose access to genetic resources, grant support, and respect in the eyes of the international scientific community.[87]

B. POLICY AND RATIONALE

Genetic technologies are only useful for global health if states can access the technologies. Technology transfer laws are important because they mitigate anti-competitive behavior by holders of intellectual property rights, and because they allow states to provide technology to their citizens. Reforming existing technology transfer provisions in TRIPS, CBD, and the Nagoya Protocol will make it easier for states to license technology from holders of intellectual property rights, and thus, to provide these technologies to their own citizens.

Articles 7 and 8 of TRIPS affirm this rationale for facilitating the transfer of genetic technologies. Article 7 ("Objectives") of the TRIPS Agreement states that the protection and enforcement of intellectual property rights should "contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[88] Article 8 ("Principles") also provides that

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[79] *Public Health Implications of the Implementation of the Nagoya Protocol*, INT'L FED'N OF PHARMACEUTICAL MANUFACTURERS & ASS'NS (May 12, 2021), https://www.ifpma.org/subtopics/public-health-implications-of-the-implementation-of-the-nagoya-protocol.
[80] *Id*.
[81] Kyung-Nam Kang et al., *The Nagoya Protocol and the Biotechnology Industry*, 4 INTL. J. OF PHARMA MED. AND BIOLOGICAL SCI. 209 (2015)(describing the barriers that the Nagoya Protocol poses to obtaining genetic resources).
[82] *Id*. at 210.
[83] Emily Marden et al., The Nagoya Protocal's Impact on Research & Development 2 (2020).
[84] McCluskey et al, *supra* note 74.
[85] *Id*. at 1.
[86] *Id*. at 3.
[87] *Id*.
[88] TRIPS art. 7.

"Appropriate measures … may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."[89]

C. HOW DO DUTIES OF TRANSFER SQUARE WITH PRIVATE INTELLECTUAL PROPERTY RIGHTS?

While the text of the Nagoya Protocol does not explicitly mention the interaction of technology transfer duties with private intellectual property rights, there is one reference to intellectual property rights, "buried" in the Annex.[90] The Annex lists "joint ownership of relevant intellectual property rights" among the possible monetary and non-monetary benefits of genetic resources.[91] Unlike the Nagoya Protocol, the CBD explicitly acknowledges private ownership of genetic resources. Article 16(4) of CBD requires parties to pass domestic legislation promoting the joint development of technologies between governmental institutions and the private sector.[92] Article 16(3) also requires parties' domestic legislation to provide access to technologies when these technologies are protected by intellectual property rights.[93] The CBD further requires parties to balance the need for transfer with the "adequate and effective protection" of intellectual property in ensuring access to technologies.[94] Thus, the CBD and Nagoya Protocol, read together, require that states facilitate access to technologies, even when private actors hold the intellectual property rights to said technologies.

Despite the provisions in both CBD and the Nagoya Protocol that reinforce the duty to transfer, even in light of private intellectual property rights, several significant weaknesses prevents these instruments from having a meaningful impact on the duty to transfer. One such weakness is the lack of a deadline for compliance. The Nagoya Protocol does not provide a date by which signatory states are expected to comply with their obligations; it only requires that states comply within a reasonable time.[95] The practical impact of this is that signatory states can drag their feet on compliance indefinitely. Another significant weakness is the lack of tangible guidelines and consequences for states that do not comply in a timely manner. As such, few states have implemented domestic legislation or other measures supporting equitable access and benefit sharing.[96] Both CBD and the Nagoya Protocol afford states considerable discretion in defining and carrying out their obligations. For instance, Article 16(3) of CBD requires parties to "balance" the need for transfer with intellectual property rights; the balance struck by a given party may weigh preservation of intellectual property rights above the duty to transfer. Similarly, the requirement to pass domestic legislation to provide access to technologies protected by intellectual property

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[89] TRIPS art. 8.
[90] Morgera et al. *supra* note 319.
[91] Nagoya Protocol, Annex, October 12, 2014.
[92] Morgera et al., *supra* note 76.
[93] *Id*. at 320.
[94] The reference to "adequate and effective protection" implicitly refers to protection under TRIPS. Lyle Glowka et al. *Guide to the Convention on Biological Diversity* 86-87 (1994).
[95] Giovani Tomasoni & Luiza Ramos, *Biodiversity: the Nagoya Protocol and its impacts in Brazil*, International Bar Association https://www.ibanet.org/article/1F3022E3-142D-4BDA-A05D-6D6BA9C67802#:~:text=To%20reinforce%20the%20legal%20security,addition%20to%20the%20conservation%20of (last visited Jun. 5, 2022).
[96] Morgera et al. 17.

rights under CBD Article 16(4) is weakened by the discretion afforded to states in determining what providing sufficient access means. Strengthening the duty to transfer will require addressing these ambiguities. Specific recommendations on how to strengthen this duty are included below.

D. WHAT CAN BE DONE TO STRENGTHEN DUTY OF TRANSFER?

The duty to transfer can be strengthened by adding provisions that provide a deadline, as well as concrete consequences, for failure to comply with CBD and the Nagoya Protocol. Such provisions would catalyze the passage of domestic legislation in compliance with duties of technology transfer under both instruments. In particular, Article 10 of the Nagoya Protocol, referring to the possible creation of a global benefit-sharing mechanism, would be strengthened. The benefit-sharing mechanism would be multilateral in nature, which would be helpful in situations where jurisdiction is unclear. The African Group first proposed one such mechanism during negotiations, a "trust fund" that would facilitate benefit-sharing where specimens were acquired outside of national jurisdiction. Article 10 as drafted only requires parties to 'consider the need for and modalities' of this benefit-sharing mechanism; it does not mandate that parties establish such a mechanism, nor does it provide a deadline. Thus, refining the language of Article 10 to make establishment of benefit-sharing mechanisms mandatory and adding a deadline to comply would make it easier to realize the promise of technology transfer under the Nagoya Protocol. The UN Environment Programme recently invited peer review of a draft study exploring the kinds of resources that would be covered by Article 10.[97] The results of that study may help move signatories towards tangible implementation of a benefit-sharing mechanism.

CONCLUSION

The complete sequencing of the human genome will usher in a new wave of medical innovation, especially given the implications of the T2T-CHM13 sequences for evolution and adaptation. Genetic technologies have had significant impacts upon global health, not only in mapping the sources of chronic health conditions, but also in diagnosing and vaccinating populations during the COVID-19 pandemic.

Given the importance of access to genetic technologies, it is important to consider the consequences of patent protections. Patent protections can inhibit countries from producing diagnostics and therapeutics affordably and locally, creating reliance upon patent holders. Furthermore, current patent laws (TRIPS) and bilateral agreements (TRIPS-Plus) permit anti-competitive practices by biotechnology companies, which further inhibit access to and drive up prices of diagnostic and therapeutic applications of genetic technologies. An amendment to TRIPS would permit developing countries to defend against the negative impacts of such anti-competitive practices and promote access to generic versions of patented therapeutics.

There is a duty of technology transfer outlined in both TRIPS and the Convention on Biological Diversity. Under CBD and the accompanying Nagoya Protocol on Access & Benefit Sharing, this duty to transfer is to be balanced with private intellectual property protections. Despite their provisions on equitable access and technology transfer, both the CBD and Nagoya Protocol have few concrete deadlines and leave states substantial room for interpretation. Incorporating

[97] Secretariat of the Convention on Biological Diversity, Notification of Extension of deadline: Peer review of a study related to Article 10 of the Nagoya Protocol, U.N. Doc. SCBD/NPU/DC/WY/BG/RKi/88737 (Mar. 19, 2020).

deadlines, as well as consequences for failure to comply with those deadlines, can motivate countries to pass domestic legislation promoting technology transfer, and can allow developing countries to realize the benefits of technology transfer via a benefit-sharing mechanism.