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# Balancing Intellectual Property Rights and Public Health to Cope with the COVID-19 Pandemic

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**BALANCING INTELLECTUAL PROPERTY RIGHTS AND PUBLIC HEALTH TO COPE WITH THE COVID-19 PANDEMIC**

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## Abstract

Over the past several months, the COVID-19 pandemic has devastated both industrialized and developing countries all over the world. By early late November 2020, the World Health Organization (WHO) reported a total of 56,261,952 confirmed cases and 1,349,506 deaths in 214 countries.[1] The COVID-19 pandemic represents the most serious public health crisis the United States has faced in decades.[2] With millions of lives hanging in the balance due to lack of effective vaccines and medical treatments, governments and pharmaceutical companies across the globe are taking unprecedented measures to spur the development of vaccines and treatments for combating COVID-19. According to ClinicalTrials.gov, there are 3507 studies currently registered to investigate COVID-19.[3] However, monopolies created by intellectual property (IP) protection and regulatory exclusivities can pose barriers to competition and impede market entry and scale-up of more affordable generic and biosimilar products critical for saving millions of lives. Given the magnitude of devastation caused by COVID-19 worldwide, this paper argues that there is a pressing need to adapt the present IP policy by reducing the barriers to ensure equitable and affordable access to essential COVID-19 vaccines and treatments for people in need.

[1] WHO, https://covid19.who.int/ (visited November 20, 2020).
[2] Brian Dean Abramson, *Brief Insight: Preparing Health Care Providers for a COVID-19 Vaccine*, J. Health & Life Sci. L., Vol. 13, No. 3, Pg. 2.
[3] ClinicalTrials.gov, https://clinicaltrials.gov/ct2/who_table (visited November 20, 2020).

## I. Introduction

The right to health is a fundamental and universal human right.[4;5] One key component of the right to health is access to medicines and health technologies.[6] As stated in the Human Rights Council's Resolution adopted in June 2011, "access to medicine is one of the fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." [7]

The monopoly rights granted under patent laws and regulatory exclusivities have adverse impacts on access to essential medicines, especially for underprivileged patients in low-income countries. Prior to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, pharmaceuticals were not patentable in national laws of about fifty countries.[8] In 1995, intellectual property protection started to be coupled with the trade because a prerequisite to become a member of the World Trade Organization (WTO) is signing the TRIPS Agreement. Under TRIPS, patent protection to inventions in all fields of technology, including pharmaceuticals, is mandatory for a 20-year period.[9]

The outbreak of the HIV/AIDS pandemic in the 1990s, which resulted in an estimated 65 million infections and 32.7 million deaths[10], highlighted the problems of access to life-saving

[4] The Charter of the United Nations, 1945, Articles 55-56, signed June 26, 1945.
[5] Muhammad Zaheer Abbas, *Treatment of the novel COVID-19: why Costa Rica's proposal for the creation of a global pooling mechanism deserves serious consideration?,* J Law Biosci (June 2020) 7 (1): 1-10.
[6] Human Rights Council, *Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, *A/HRC/23/L.10/Rev*.1. (2013) paras 5-10.
[7] Human Right Council, *Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development- The right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, UN General Assembly 2 (2011).
[8] *See* F.M. Scherer and Jayashree Watal, *Post-Trips Options for Access to Patented Medicines in Developing Countries*, Commission on Macroeconomics and Health ,(2001) 4, doi: *http://www.icrier.org/pdf/jayawatal%20.pdf*.
[9] *TRIPS Agreement*, Articles 27(1) and 33.
[10] UNAIDS, Global HIV & AIDS statistics — 2020 fact sheet, https://www.unaids.org/en/resources/fact-sheet

medicines in developing and low-income countries and drew global attention to the conflicts between intellectual property rights (IPRs) and the fundamental right to health.[11;12]

The present COVID-19 pandemic, which has taken 1.35 million lives as of late November 2020, has once again highlighted the need to address the tension between the right to health and IPRs.[13] Due to its "winner-take-all" principle, patent law presents significant barriers to the rapid development of much-needed health technologies by disincentivizing the sharing of pre-patenting or unpatentable knowledge that could be valuable for drug discovery and development.

In addition, exclusive rights lead to competitive pricing and restrict large-scale manufacturing across the globe, thus negatively impacting equitable and affordable access to innovative health technologies. For example, in the past decades, high prices for patented treatments have undermined countries' capacity to supply treatments for tuberculosis (TB), HIV/AIDS, hepatitis C, and cancer to patients in need. Also, it has been argued that unmerited patents on key technologies that block follow-on producers had delayed the availability of more affordable vaccines and treatments in low- and middle-income countries (LIMCs).[14] Moreover, due to the global economic downturn resulting from the COVID-19 pandemic, combined with reduced health budgets, the ability of governments to subsidize COVID-19 medicines and vaccines and the ability of patients to pay out-of-pocket has been significantly eroded.[15] Thus, reducing

[11] Wolfgang Hein and Suerie Moon, *Informal Norms in Global Governance: Human Rights, Intellectual Property Rules and Access to Medicines*(2016) 45.
[12] MMWR, The Global HIV/AIDS Pandemic, 2006, CDC, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5531a1.htm.
[13] Muhammad Zaheer Abbas, *Treatment of the novel COVID-19: why Costa Rica's proposal for the creation of a global pooling mechanism deserves serious consideration?,* J Law Biosci (June 2020) 7 (1): 1-10.
[14] MSF Access Campaign, A fair shot for vaccine affordability: understanding and addressing the effects of patents on access to new vaccines. 2017 Sep https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf.
[15] Nuffield Council on Bioethics, https://www.nuffieldbioethics.org/assets/pdfs/Fair-and-equitable-access-to-COVID-19-treatments-and-vaccines.pdf.

market monopolies and ensuring earlier competition will help to increase affordable and fair access to COVID-19 medicines and vaccines.

However, the problems of access to life-saving medicines cannot be fully addressed by solely relying on voluntary commitments by phartmaceutical companies. In response to a petition by South Africa and India to the WTO calling for waiver or suspension on the granting or enforcement of any patents and other IP related to COVID-19 drugs, vaccines, and diagnostics for the duration of the pandemic,[16] on October 8, 2020, US-based pharmaceutical corporation Moderna, developer of one of the four front-running COVID-19 vaccine candidates, announced its decision to not enforce its patents on COVID-19 vaccine technologies throughout the duration of the pandemic and issue open licenses for the post-pandemic period. However, currently, Moderna is the only company that pledged to openly share its patents for the COVID-19 drugs and vaccines. In addition, Member States of the WTO have failed to reach an agreement that would have temporarily waived intellectual property rights for vaccines and treatments related to COVID-19 as the pandemic continues worldwide.[17]

To achieve a better balance between private IPRs and public health, and to increase access to essential medicines to combat the COVID-19 pandemic, this paper proposes an integrated approach that utilizes various policy instruments, including the flexibilities within the TRIPS Agreement. Part II provides a brief introduction to the IP system and the global IP framework as defined by the international treaties, *e.g.*, TRIPS, and discusses how some of the IP practices and regulatory exclusivities become barriers to access to essential health technologies for fighting the COVID-19 pandemic. Part III discusses several policy instruments that can be taken at national,

[16] *Raisa Santos & Elaine Ruth Fletcher, Moderna Makes Milestone Pledge To "Not Enforce Our Patents" On COVID-19 Vaccine Technologies During Pandemic & Issue Open Licenses Afterward, Health Policy Watch, https://healthpolicy-watch.news/77521-2/.*
[17] *Id.*

regional, and international levels, including: (i) restricting the grant of patent evergreening by applying stricter patentability criteria; (ii) restricting patenting of repurposed or combination drugs; (iii) reducing or suspending regulatory exclusivities (*i.e.*, data exclusivity, market exclusivity) to facilitate rapid regulatory approval of COVID-19-related generic and biosimilar products; (iv) reducing or suspending patent linkage; (v) suspending enforcement of COVID-19 related IPRs; (vi) issuing compulsory licenses; (vii) invoking Article 73 security exceptions of the TRIPS Agreement; and (viii) participating in medicine patent pool and the Open COVID Pledge.

It should be noted that each of the above policy instruments has its advantages and disadvantages. Thus, there is no one-size-fits-all solution, and countries should tailor these policy instruments in accordance with their particular circumstances and needs.

## II. The IP Systems and Barriers to Access to Health Technologies

The IPRs granted through the IP systems and the global IP framework, as defined by the WIPO treaties, the TRIPS Agreement, free trade agreements (FTAs), regulatory exclusivities, and patent linkage, are the primary schemes that give rise to monopolies of health technologies. Although such monopolies are believed to be important for driving innovations[18], in many cases, they also constitute barriers to competition and delay market entry of more affordable generic drugs. A good understanding of the current IP systems and the underlying factors of the barriers is a prerequisite for formulating solutions to reduce or eliminate the barriers to ensure broad access to COVID-19 vaccines and treatments.

[18] WIPO Magazine, *Intellectual property, innovation, access and COVID-19*, https://www.wipo.int/wipo_magazine/en/2020/02/article_0002.html

### 3.1. IP systems

IP refers to a category of property, including intangible creations of the human mind,[19] such as copyrights, patents, trademarks, and trade secrets. The fundamental goal of the patent system is to offer a mechanism to encourage the dissemination of technical knowledge.[20] The patent system achieves this goal through a *quid pro quo*—in exchange for the exclusive right, the applicant is obligated to fully disclose the technical details of the invention to enable society to make and/or use the invention.[21]

By providing rights to exclude third-party use of protected inventions, IP protection strengthens market-based incentives to invest resources for development and marketing of new technologies.[22] Such incentives are critical for research and development of new medical technologies due to the requirement of substantial investment of financial and technical resources, the high risk of failure associated with product development, and issues related to product liability. Generally, it is very costly to develop new medical technologies but relatively cheaper to reproduce or reverse engineer. Thus, it would be unsustainable for companies to invest resources and assume a significant risk of failure in product development and regulatory approval if their competitors are allowed to take a free ride.

On the other hand, IP protection can be a barrier to competition by preventing entry of generic products. In addition, it can also impede further innovation by hindering access to new technologies. Further, the use of the exclusive right can contribute to market distortion and lead to

[19] *See* WIPO, *What is Intellectual Property?*, https://www.wipo.int/about-ip/en/.
[20] Sean B. Seymore, *Symposium: The Disclosure Function of the Patent System*, 69 *Vanderbilt Law Review* 1455 (2016).
[21] *Id*.
[22] WTO/WHO/WIPO, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (second edition), July 2020, https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.

high prices of goods and market inefficiencies.[23] Thus, IP policy needs to accommodate and balance various legitimate interests, including public and private interests, in a delicate way to promote public health.[24]

## 3.2. International IP framework established by international treaties and free trade agreements

### 3.2.1. TRIPS Agreement

The global IP framework is mainly defined by the treaties (*e.g.*, the Paris Convention) administered by the World Intellectual Property Organization (WIPO) and the TRIPS Agreement. Most countries in the world, including all the Member States of the WTO, are parties to the TRIPS Agreement. TRIPS, with the objectives of "the promotion of technological innovation and "the transfer and dissemination of technology," mandates implementation of international standards that require IP protection to be available for inventions in all areas of technology (*e.g.*, medical technologies) and protection against unfair commercial use for undisclosed test data submitted for obtaining marketing approval.[25;26] Note that the global, multilateral IP framework, established by the WIPO treaties and the TRIPS Agreement, only sets minimum standards for the Member States. The Member States are free to implement more extensive protections based on their own national priorities and needs.

In 2001, the Doha Declaration—a landmark declaration adopted by the WTO—reaffirmed the objectives and principles of TRIPS as guidance for implementing the TRIPS provisions in line

[23] WTO/WHO/WIPO, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (second edition), July 2020, https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf

[24] *Id*.

[25] *Id*.

[26] Article 7, the TRIPS Agreement

with public health policy. The Doha Declaration provides a set of flexibilities within the TRIPS legal framework. One of such flexibilities is compulsory licensing. Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself.[27] Specific situations in which compulsory licenses may be issued are set out in the legislation of each patent system and vary between systems. The situations in which a compulsory license may be granted include lack of working over an extended period in the territory of the patent, inventions funded by the government, failure or inability of a patentee to meet a demand for a patented product and where the refusal to grant a license leads to the inability to exploit an important technological advance, or to exploit a further patent.[28] TRIPs also provides that the requirements for a compulsory license may be waived in certain situations, in particular cases of national emergency or extreme urgency or in cases of public non-commercial use.[29] Article 31.f of TRIPS requires that compulsory licenses be used "predominantly" for local markets, a requirement that complicates the ability of countries to import drugs manufactured overseas.[30]

### 3.2.2. Free Trade Agreements (FTAs)

Certain IP provisions in FTAs are of particular relevance to the health technologies sector.[31] Those IP provisions in FTAs affecting the pharmaceutical sector include definitions of patentability criteria; patent term extensions (PTE) and other similar instruments; regulatory exclusivities; patent linkage with regulatory approval; and IPRs enforcement such as border

[27] WTO, *Compulsory licensing of pharmaceuticals and TRIPS*, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm
[28] Article 31, the TRIPS Agreement, *Other Use Without Authorization of the Right Holder*.
[29] *Id*.
[30] *Id*.
[31] WTO/WHO/WIPO, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (second edition), July 2020, https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.

measures. In the past decade, many FTAs have also reaffirmed the Doha Declaration, including the right to take measures to protect public health.[32]

When the TRIPS Agreement went into effect in 1995, there were 44 FTAs in force. By December 2019, the number of FTAs had surpassed 300, most of which contain IP provisions.[33] About twenty percent of the FTAs contain provisions requiring the parties to implement higher standards for protection and enforcement of IPRs than those in the TRIPS Agreement.[34] Such provisions are generally referred to as "TRIPS-plus." For example, some FTAs specify how to apply patentability criteria and disclosure requirements.[35] Some FTAs contain provisions allowing the patent term to extend beyond 20 years to compensate for the time patent owners spend in obtaining marketing approval.[36] While the TRIPS Agreement does not provide an exhaustive list of grounds for granting compulsory licenses, some FTAs, such as the United States-Australia FTA, limit grounds to situations of extreme urgency and public non-commercial use.[37]

### 3.3. Barriers created by patent evergreening and second medical use patents

A patent will be granted to an inventor if the invention is novel, non-obvious, and useful to a person skilled in the art. Article 27 of the TRIPS Agreement states that "patents should be available for any inventions, provided that they are new, involve an inventive step, and are capable of industrial application." [38] Under the TRIPS Agreement, countries have flexibilities in determining how to apply the patentability criteria.

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[32] *Id*.
[33] WTO, Regional Trade Agreements Database, http://rtais.wto.org/UI/PublicMaintainRTAHome.aspx
[34] WTO/WHO/WIPO, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (second edition), July 2020, https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.
[35] *Id*. at 71.
[36] *Id*.
[37] See https://ustr.gov/trade-agreements/free-trade-agreements/australian-fta
[38] Article 27, TRIPS Agreement

Companies often employ patenting strategies to seek new monopolies or prolong market exclusivity through, for example, applying for secondary patents on known medicines. Such patenting practice is known as "patent evergreening." Evergreening, as defined by the 2003 WHO Commission on IP, Innovation and Public Health (CIPIH), is a term popularly used to describe patent holders' use of various strategies to extend the period of exclusivity beyond the 20-year patent term, even absent apparent additional benefits.[39] The commercial benefits of evergreening patents are significant. A study by Kapczynski *et al.* of the 1,304 patents on new molecular entities listed in the FDA's Orange Book shows that secondary patent claims extended patent protection by an average of 6 to 7 years.[40]

When a known substance previously used for a certain non-medical purpose is found effective in the treatment of disease, a patent application may be filed to claim the "first medical indication," also called "new use" or "second use" of the known substance.[41] If the known substance previously used for a certain medical purpose is found effective for another medical use, such medical use is called "second medical indication."[42] Article 27.3 of the TRIPS Agreement permits countries to exclude diagnostic, therapeutic, and surgical methods for the treatment of humans or animals from patenting.[43] However, the TRIPS agreement does not address the patentability of the first and second medical indications, and national patent laws differ on this

[39] WHO, *Public health, innovation and intellectual property rights*, Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), ISBN 9241563230, Geneva, Switzerland 2006, p.131, http://www.who.int/intellectualproperty/report/en/.
[40] Amy Kapczynski, Chan Park, and Bhaven Sampat, *Polymorphs and prodrugs and salts: an empirical analysis of "secondary" pharmaceutical patents*, PLOS One 7, no. 12 (2012): e49470, doi: 10.1371/journal.pone.0049470.
[41] WHO, *Public health, innovation and intellectual property rights*, Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), ISBN 9241563230, Geneva, Switzerland 2006, p.131, http://www.who.int/intellectualproperty/report/en/.
[42] *Id*.
[43] Article 27.3(a), TRIPS Agreement

point.[44] Some jurisdictions (*e.g.*, Argentina, Philippines) specifically rule out patenting the first or second medical indication inventions. Some other jurisdictions allow both the first and second medical indication inventions. For example, Article 54(4) and (5) of the European Patent Convention (EPC), as revised in 2000 (referred to as EPC 2000), state that the novelty requirement does not exclude the patentability of a known substance used for a new method for treatment or diagnosis.[45]

The patentability of first and second medical indications is still a subject of debate, exemplifying the continuing challenge in patent law of balancing access against innovation. Opponents of medical indication patents express concerns that such patents can restrict access to medicines and reward uninventive activities and unjustly extend patent protection for medicines.

### 3.4. Barriers created by regulatory exclusivities

Regulatory exclusivities are conferred by national or regional law, which provide another mechanism of protection independent of IP protection. The period of protection through regulatory exclusivity may overlap with or be additional to the term of patent protection.

Regulatory exclusivities include data exclusivity (*i.e.*, protection of test data) and market exclusivity. Data exclusivity prevents regulatory authorities, such as the Food and Drug Administration (FDA), from relying on the test data previously submitted by an originator (*e.g.*, for a brand name drug) as reference data for approval of a generic medicine for a certain period of time.[46] Market exclusivity, on the other hand, prevents regulatory authorities from granting market approval for a certain period of time. Unlike data exclusivity, market exclusivity prevents a

[44] WTO/WHO/WIPO, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (second edition), July 2020, https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.
[45] The European Patent Convention, https://www.epo.org/law-practice/legal-texts/epc.html.
[46] Gene Quinn, *Data exclusivity is not the same as market exclusivity*, January 26, 2020, http://www.gabionline.net/Policies-Legislation/Data-exclusivity-is-not-the-same-as-market-exclusivity.

competitor from obtaining regulatory approval, even without referring to the test data from the originator.[47]

Member States of the WTO generally grant exclusivity rights for a fixed period of between five and eight years, which can be further extended in some cases. The US provides a wide range of regulatory exclusivities, including five years' data exclusivity for new chemical entities (NCEs).[48] As for new biological entities (NBEs) (*e.g.*, antibody drugs), the Biologics Price Competition and Innovation Act provides twelve years' data exclusivity and four years' market exclusivity. In other words, a biosimilar product cannot obtain approval for four years after the date of the approval of its reference product, nor can it be approved until twelve years after the reference product's approval date if it relies upon the test data of the reference product. In addition, to encourage firms to develop drugs to treat rare diseases and conditions (*i.e.*, diseases affecting fewer than 200,000 people in the US), the US provides seven years' exclusivity to orphan drugs, called orphan drug exclusivity. Gilead was caught in the controversy after it applied for and obtained the orphan drug designation from the US FDA in March 2020. Under the US Orphan Drugs Act, the orphan drug designation provides a seven-year market exclusivity in addition to tax and other incentives. Gilead was reprimanded for applying for such designation in seeking additional exclusivity "despite calls for solidarity" to fight the COVID-19 pandemic.[49] After facing sharp criticism, Gilead announced that it had rescinded the orphan drug designation.[50]

[47] Thomas, J. R. (2014), *The Role of Patents and Regulatory Exclusivities in Pharmaceutical Innovation*, Washington, DC: Congressional Research Service.
[48] Thomas, J. R. (2015), *Pharmaceutical Patent Law*, 3rd Edition, Arlington (VA): Bloomberg BNA.
[49] DP Mancini, *Gilead Criticised Over 'Orphan Status' for Potential Virus Treatment*, Financial Times, 24 March 2020, https://www.ft.com/content/9fea4f1c-6dba-11ea-89df-41bea055720b
[50] Gilead Sciences, Press release, Mar 24, 2020, https://www.gilead.com/-/media/gilead-corporate/files/pdfs/company-statements/remdesivir-orphan-drug-designation.pdf?la=en&hash=ED14BC7B26E2FEAA2E31E7741A8C9692

In comparison, the European Union (EU) uses a system of exclusivity called the "8+2+1" system.[51] The EU's system grants originator drugs eight years of data protection and ten years of marketing protection, both starting at marketing approval of the originator drugs.[52] This means marketing approval for a prospective generic competitor can only be granted at the end of the ten-year marketing protection period, which is extendable to eleven years.

The granting of regulatory exclusivities, including data exclusivities, generally increases the expectation of revenues of bringing a product to market. Thus, in theory, it incentivizes development of new products at the expense of delaying the entry of generic products.

### 3.5. Barriers created by patent linkage

Normally, IP protection and regulatory exclusivities are two separate mechanisms of protection granted by different agencies independent of each other. Nevertheless, some countries, including the US, link regulatory approval (based on safety, efficacy, and quality) of a new medicine to its patenting status, which is generally referred to as "patent linkage." In the US, patent linkage is statutorily recognized by the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch Waxman Act.[53] Under the Act, a manufacturer seeking marketing approval for a generic drug must submit certification to the FDA that its marketing approval will not infringe any patents of the originator on the reference drug listed in the FDA "Orange Book." [54] A stronger patent linkage prohibits market entry of generic drugs until the

[51] WHA, *Resolution WHA65.19*: Substandard/spurious/falselylabelled/falsified/counterfeit medical products, https://www.who.int/medicines/regulation/ssffc/mechanism/WHA65.19_English.pdf?ua=1.
[52] WHA, *WHO member state mechanism on substandard*, medical products, https://www.who.int/medicines/regulation/ssffc/mechanism/A70_23-en33-36.pdf?ua=1.
[53] Kyung-Bok Son *et al.*, *Moderating the impact of patent linkage on access to medicines*, Global Health. 2018; 14: 101. doi: 10.1186/s12992-018-0423-0.
[54] FDA, *The Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)*, https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book#:~:text=The%20publication%20Approved%20Drug%20Products,Act)%20and%20related%20patent%20and

expiry of the patent.[55] An even stronger version of patent linkage prohibits consideration of the marketing approval of a generic drug before the expiry of the patent. Since TRIPS, the US has negotiated a series of bilateral and plurilateral trade agreements having "TRIPS-Plus" IP provisions requiring trading partners to establish patent linkage mechanisms.[56]

Not surprisingly, patent linkage has been found to have an adverse effect on access to medicines, by delaying market entry of generic drugs and enabling high prices of originator drugs by shielding them from generic competition.[57; 58] It has also been argued that patent linkage places regulatory agencies in the role of enforcers of patents.[59] Notably, some patent linkage provisions make no exception for generic medicines produced under compulsory licenses. Thus, such patent linkage provisions can unjustifiably extend exclusivity of originator drugs in the market since the regulatory agencies are unable to consider market approval of generic drugs during the patent period.

On the other hand, originator companies and proponents of patent linkage argue that patent linkage is a reasonable means to ensure that the regulatory authorities do not promote infringement and that it increases transparency and predictability by identifying patents associated with each pharmaceutical product as part of the market approval process.[60; 61] However, such arguments are

[55] WTO/WHO/WIPO, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (second edition), July 2020, https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.
[56] Kyung-Bok Son *et al.*, *Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States*, Globalization and Health (2018) 14:101, https://doi.org/10.1186/s12992-018-0423-0.
[57] Code of Federal Regulations Title 21, Sec 314.53 (d) *When and where to submit patent information*.
[58] Code of Federal Regulations Title 21, Sec 314.53 (b) *Patents for which information must be submitted and patents for which information must not be submitted*.
[59] Kyung-Bok Son *et al.*, *Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States*, Globalization and Health (2018) 14:101, https://doi.org/10.1186/s12992-018-0423-0.
[60] Ho Cynthia M. The Globalization of Health Care. 2013. Beyond Patents; pp. 302–317.
[61] WIPO, Promoting Access to Medical Technologies and Innovation - Second Edition, page 62.

not well-founded because adequate IP protection can be achieved through private enforcement of IPRs via the judicial system even if patent linkage is not available.[62]

## III. Increasing Access to COVID-19 Related Vaccines and Treatments

Over the past few months, the COVID-19 pandemic has devastated industrialized countries and developing countries all over the world. While several of the therapeutic candidates under clinical investigation as COVID-19 treatments are now off patent, other drugs being studied are under patent protection.[63] With IPRs and regulatory exclusivities, pharmaceutical companies can control who can produce medicines and where they can be supplied. Furthermore, the lack of access to IP, data, and technical know-how impedes market entry and scale-up of more affordable generic and biosimilar products.

To overcome the barriers of market dominance and access to patented health technologies and products needed for COVID-19 treatment, diagnosis, and prevention, countries can make use of a range of public health safeguards, including the built-in flexibilities of the TRIPS Agreements and the Doha Declaration on TRIPS. To this end, this paper proposes an integrated approach featuring several policy instruments that can be employed at national, regional, and international levels, such as: (i) restricting the grant of patent evergreening by applying stricter patentability criteria; (ii) restricting patenting of repurposed or combo drugs; (iii) reducing or suspending regulatory exclusivities (*i.e.*, data exclusivity, market exclusivity) to facilitate rapid regulatory approval of COVID-19-related generic and biosimilar products; (iv) reducing or suspending patent

[62] Kyung-Bok Son *et al.*, *Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States*, Globalization and Health (2018) 14:101, https://doi.org/10.1186/s12992-018-0423-0.
[62] Ho Cynthia M. *A New Approach to Compulsory License Conundrum, in Patent Law in Global Perspective*, The Globalization of Health Care. 2013. Beyond Patents; pp. 302–317.
[63] MedsPal: the medicines patents and licenses database, *Patent status of selected COVID-19 candidate drugs in low-and-middle-income countries*. https://www.medspal.org/?disease_areas%5B%5D=COVID-19+(drug+candidate)&page=1.

linkage; (v) suspending enforcement of COVID-19 related IPRs; (vi) issuing compulsory licenses; (vii) invoking Article 73 security exceptions of the TRIPS Agreement; and (viii) participating in medicine patent pools and the Open COVID Pledge. It should be emphasized, however, that each individual instrument has advantages and disadvantages. If needed, countries should undertake these policy instruments in concert and adapt them according to nations' priorities and needs.

### 4.1. Restricting patent evergreening by applying stricter patentability criteria

Patent evergreening is a patenting strategy pharmaceutical companies often employ to seek new monopolies or prolong market exclusivity. It is in the public interest of all nations to refrain from allowing "patent evergreening" through secondary patents derived from a parent patent by applying stricter patentability criteria. While excluding entire fields of technology (*e.g.*, medicines, food) is no longer permitted under the TRIPS Agreement, countries can set more stringent patenting standards to meet the domestic needs of public health and economy. This will help to limit granting secondary and new use patents—a practice that often leads to patent evergreening.

Under the present IP systems, whether to grant or refuse a secondary patent is judged based on its merits. It is important to determine if the secondary patent is separately patent-eligible. The mere fact that an innovation is incremental is not a ground for refusing a secondary patent claim. In fact, most innovation is incremental by nature. Some health policy-makers argue that therapeutic efficacy should be included as an additional criterion to restrict evergreening and that secondary patents should be granted only if the embodied incremental innovation provides sufficient therapeutic benefits.[64] Although the therapeutic value of a product is not a patentability criterion

[64] *Id*.

in most jurisdictions, superior therapeutic advantages over the prior art may be considered when evaluating nonobviousness (or inventive step) of the product. [65]

In limiting patent evergreening, some countries have revised their legislation to adopt narrower patentability criteria. Section 3(d) of India's Patents Act 1970 and Section 26.2 of the Philippines' Intellectual Property Code are two examples of a narrow definition of patentability criteria.[66] Other countries apply different approaches. For example, many patent offices, such as Argentina, Brazil, China, Germany, the UK, the US, and EPO patent offices, have established examination guidelines for pharmaceutical inventions.[67] The examination guidelines for patent examiners adopted by Argentina are along similar lines as Section 3(d) of India's Patents Act 1970.[68] Thus, the goal of limiting patent evergreening can be achieved at both legislative and administrative levels.

### 4.2. Restricting patenting of repurposed or combination drugs

Second medical use patents are permitted for repurposed medicines and combination therapies in some jurisdictions, including the US. The patentability of medical indications is relevant to our fight against the COVID-19 pandemic considering many of the ongoing clinical trials are based on either repurposing or combining known drugs. Drug repurposing (also known as drug repositioning or therapeutic switching) is re-tasking an approved drug for the treatment of a different disease or medical condition than its original purpose of development. [69] Drug

[65] WTO/WHO/WIPO, *Promoting Access to Medical Technologies and Innovation: Intersections between public health*, intellectual property and trade (second edition), July 2020, https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.
[66] WTO/WHO/WIPO, *Promoting Access to Medical Technologies and Innovation: Intersections between public health*, intellectual property and trade (second edition), July 2020.
[67] *See* WIPO document SCP/30/4, *Further Study on Inventive Step (Part III)*, available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_4.pdf.
[68] Joint Resolution 118/2012, 546/2012 and 107/2012 (Ministry of Industry, Ministry of Health and National Industrial Property Institute) of 5 May 2012, published in Official Gazette of 8 May 2012.
[69] Wikipedia, *COVID-19 drug repurposing research*, https://en.wikipedia.org/wiki/COVID-19_drug_repurposing_research

repurposing has been pursued to develop safe and effective COVID-19 treatments.[70; 71] Several existing antiviral medications, previously developed for treating severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), HIV/AIDS, and malaria, have been investigated as potential COVID-19 treatments, some of which are currently being tested in clinical trials.[72; 73; 74] For example, the world's largest COVID-19 clinical trial was launched by the United Kingdom (UK) to test repurposed drugs.[75] In particular, drugs included in the trial protocol are all existing medicines repurposed for COVID-19, such as AbbVie's Kaletra (lopinavir/ritonavir), commonly used to treat HIV infection; dexamethasone, an anti-inflammatory steroid; hydroxychloroquine, an antimalarial drug; and the antibiotic azithromycin.[76]

Currently, there are eleven registered COVID-19 clinical trials for remdesivir alone. Remdesivir is an antiviral drug, which was originally developed by Gilead Sciences to treat Hepatitis C and was then tested against Ebola virus disease and Marburg virus disease, but was ineffective for all of these viral infections.[77; 78; 79] It is thought that remdesivir may be beneficial for treating patients with COVID-19, and the FDA recently granted emergency use of remdesivir

[70] Harrison C., *Coronavirus puts drug repurposing on the fast track. Nature Biotechnology*. 38 (4): 379-381(2020). doi:10.1038/d41587-020-00003-1.
[71] Sleigh SH, Barton CL. *Repurposing Strategies for Therapeutics*. Pharmaceutical Medicine. 24 (3): 151-159 (2010). doi:10.1007/BF03256811.
[72] Li G, De Clercq E. *Therapeutic options for the 2019 novel coronavirus (2019-nCoV).* Nature Reviews. Drug Discovery. 19 (3): 149–150 (2020). doi:10.1038/d41573-020-00016-0.
[73] Milken Institute. *COVID-19 treatment and vaccines tracker* 2 June 2020, https://covid-19tracker.milkeninstitute.org/.
[74] Sanders JM, Monogue ML, Jodlowski TZ, Cutrell JB. *Pharmacologic Treatments for Coronavirus Disease 2019 (COVID-19): A Review*. JAMA. 323 (18): 1824–1836 (2020).
[75] *Biggest COVID-19 trial tests repurposed drugs first*. Nat Biotechnol 38, 510 (2020). https://doi.org/10.1038/s41587-020-0528-x.
[76] *Biggest COVID-19 trial tests repurposed drugs first*. Nat Biotechnol 38, 510 (2020). https://doi.org/10.1038/s41587-020-0528-x.
[77] Scavone C, *et al.* (April 2020). *Current pharmacological treatments for COVID-19: What's next?. British Journal of Pharmacology*. https://doi.org/10.1111/bph.15072.
[78] Stephens B (18 April 2020). *The Story of Remdesivir*. The New York Times. p. A23.
[79] Warren, T., Jordan, R., Lo, M. *et al. Therapeutic efficacy of the small molecule GS-5734 against Ebola virus in rhesus monkeys*. *Nature* 531, 381–385 (2016). https://doi.org/10.1038/nature17180

during the pandemic.[80] In January 2020, the Wuhan Institute of Virology applied for a patent covering the use of remdesivir as a treatment for COVID-19. However, such a move to claim patent rights over unproven use of the treatment, made in the midst of a rapidly worsening public health crisis, was heavily criticized.[81] The need for claiming such patent rights was also questioned, since the national law implementing the TRIPS Agreement explicitly permits compulsory licensing.

Given the fact that the candidate therapeutics of many (if not most) of the ongoing clinical trials are repurposed drugs, this paper calls on all countries to refrain from granting COVID-19-related second medical use patents based on repurposed medicines and combination therapies.

### 4.3. Reducing or suspending regulatory exclusivities

Even if the patent on the original version of a drug has expired, it still may not be possible to bring a generic drug to the market if regulatory exclusivities apply. As discussed in the previous section, both data exclusivity and market exclusivity provide additional monopoly power alongside patent rights and can thus represent a significant barrier to equitable and affordable access to COVID-19 vaccines and treatments. Hence, regulatory exclusivities can hinder global efforts to address the urgent need for COVID-19 vaccines and treatments in a timely and accessible way.

Thus, regulatory exclusivities represent another area requiring quick action to facilitate the introduction of generic competition and to bring down drug prices. It is also high time for pharmaceutical companies, research institutes, and universities to share data and transfer technologies to treat COVID-19. Applications of generic drugs for marketing approval should be

[80] Nicholas J DeVito, *et al*. *COVID-19 Clinical Trials Report Card: Remdesivir*, https://www.cebm.net/covid-19/covid-19-clinical-trials-report-card-remdesivir/.
[81] W Haiyun, *China to Begin Testing Ebola Drug on Coronavirus Patients*, *Sixth Tone*, 3 February 2020, http://www.sixthtone.com/news/1005155/china-to-begin-testing-ebola-drug-on-coronavirus-patients

encouraged even if they are based on the reference data submitted by originator drug producers. The present COVID-19 public health emergency should justify reducing or suspending data and/or market exclusivity, at least for the duration of the COVID-19 pandemic. This is also consistent with the Open COVID Pledge, discussed further below, which states, "The Pledger will not assert any regulatory exclusivity against any entity for the use of the Licensed IP in accordance with the license granted in Section 1, and we will not seek injunctive or regulatory relief to prevent any entity from doing so."[82]

### 4.4. Reducing or suspending patent linkage

Patent linkage is perhaps one of the most debated aspects of patent policy around the world. Thus, it is a highly effective strategy for patent owners to shield their products from competition, delay entry of generic drugs, and extend market monopolies beyond the protection granted by the patents of the original product.[83]

Considering the detrimental effects of patent linkage on access to medicines by delaying marketing approval of generics drugs and biosimilars and enabling the maintenance of high prices of originator products, there has been significant concern about its effects in LMICs.[84] In particular, patent linkage also impedes the use of compulsory licensing, despite being recognized as a flexibility within the TRIPS Agreement.[85] Thus, patent linkage mechanisms should be avoided where possible.

Since many bilateral and plurilateral trade agreements (*e.g.*, FTAs) have "TRIPS-Plus" IP provisions requiring trading partners to establish patent linkage mechanisms, it is recommended

[82] Open COVID Pledge, https://www.unifiedpatents.com/open-covid-pledge (visited October 10, 2020)
[83] *Id*.
[84] *Id*.
[85] Kyung-Bok Son *et al.*, *Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States*, Globalization and Health (2018) 14:101, https://doi.org/10.1186/s12992-018-0423-0.

that countries, especially LMICs, should ensure that exemptions of essential medicines to patent linkage are enabled for in domestic legislation.[86;87] At the minimum, any patent linkage mechanism should be in harmony with other domestic medicines policies.[88] In particular, there should be an exception to patent linkage such that it does not hinder the use of compulsory licensing.

### 4.5. Suspending enforcement of COVID-19 related IPRs

As noted in the Introduction section, Moderna pledged to suspend enforcement of its COVID-19-related patents until the pandemic ends. However, some commentators argue such a pledge is not enough to ensure broad access for everyone in need.[89] First, pharmaceutical companies are free to determine when the pandemic ends.[90] Second, it is also argued that the non-enforcement of IPRs is not sufficient without a commitment to share data, technical know-how, and biological resources needed for other manufacturers to produce the vaccine and to scale up to meet global needs.[91] Finally, it is also reasonable to demand suspension of IP enforcement, especially considering many pharmaceutical companies had received a massive amount of public funds from the government without any strings attached. For example, Moderna has received more than $2.48 billion from the US government by far.[92]

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[86] *Kyung-Bok Son et al., Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States, Globalization and Health (2018) 14:101, https://doi.org/10.1186/s12992-018-0423-0.*
[87] *Id*. at 4.
[88] *Id*. at 8.
[89] Raisa Santos & Elaine Ruth Fletcher, *Moderna Makes Milestone Pledge To "Not Enforce Our Patents" On COVID-19 Vaccine Technologies During Pandemic & Issue Open Licenses Afterward*, Health Policy Watch, https://healthpolicy-watch.news/77521-2/.
[90] *Id.*
[91] *Raisa Santos & Elaine Ruth Fletcher, Moderna Makes Milestone Pledge To "Not Enforce Our Patents" On COVID-19 Vaccine Technologies During Pandemic & Issue Open Licenses Afterward, Health Policy Watch, https://healthpolicy-watch.news/77521-2/.*
[92] *Id*.

Nevertheless, the pledge made by Moderna is an important step to eliminate IP barriers to vaccine development during the COVID-19 pandemic. Accordingly, this paper calls on more pharmaceutical companies to make pledges to suspend or waive enforcement of IPRs on COVID-19-related technologies, including drugs, vaccines, and diagnostics, at least for the duration of this pandemic.

### 4.6. Issuing compulsory licenses in the time of the COVID-19 pandemic

The TRIPS Agreement has various built-in flexibilities that allow governments to take measures to allow use by third parties of otherwise protected rights.[93] The main flexibilities related to battling the COVID-19 pandemic include the compulsory patent licensing under Article 31 and 31*bis* of the TRIPS Agreement and some exceptions (*e.g.*, research exception, regulatory exception or "Bolar" provision, patent eligibility exceptions, *e.g.*, excluding diagnostic, therapeutic and surgical methods for treating humans or animals) for patents under Articles 27 and 30.[94; 95]

Compulsory patent licensing allows governments to authorize the making, use, sale or importation of patented products and technologies by third parties without the consent of the patent owners. In some cases, the third party can be the government itself, which is referred to as "government use." Compulsory licensing is an important attempt by the TRIPS Agreement to strike a balance between promoting access to existing drugs while promoting research and development of new drugs.[96]

Compulsory licensing and government use of patents can only be employed under conditions aimed at protecting the legitimate interests of the patent owners. Generally, a

[93] Frederick M. Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, FSU College of Law, Public Law Research Paper No. 930, 28 Aug 2020, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3682260.
[94] Articles 31 and 31*bis*, TRIPS Agreement.
[95] Articles 27 and 30, TRIPS Agreement.
[96] WTO, *Under TRIPS, what are member governments' obligations on pharmaceutical patents?*, https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.

compulsory license cannot be issued unless attempts to obtain a voluntary license from the patent owner on reasonable commercial terms have been unsuccessful. [97; 98] However, voluntary licensing has several issues, such as lack of transparency and limitations in geographic coverage, which can impact access to medicines, although the step of obtaining a voluntary license can be waived for "national emergencies" or "other circumstances of extreme urgency." [99; 100] The Doha Declaration states that Member States maintain "the right to determine what constitutes a national emergency or other circumstances of extreme urgency," and that a public health crisis can be an emergency under this provision.[101] The COVID-19 pandemic a public health crisis that has devastated many Member States across the globe, which should trigger the special accommodation of the flexibilities under Article 31 of the TRIPS Agreement, including compulsory licensing without the need for seeking a voluntary license on reasonable terms.[102]

It has been shown that compulsory licenses, where they have been granted, have led to a significant reduction of drug prices.[103] For example, in 2012, the generic drug manufacturer Natco in India was granted a compulsory license for sorafenib, an anti-cancer drug and required to pay 6% royalties to Bayer AG, sorafenib's patent right holder and a German company. With this

[97] Article 31b, TRIPS Agreement.
[98] Article 31h, TRIPS Agreement.
[99] MSF Access Campaign, *Voluntary licenses and access to medicines*, https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf
[100] Article 31b, TRIPS Agreement.
[101] WTO, *The Doha Declaration On The TRIPS Agreement and Public Health*, https://www.who.int/medicines/areas/policy/doha_declaration/en/.
[102] Frederick M. Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, FSU College of Law, Public Law Research Paper No. 930, 28 Aug 2020, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3682260.
[103] BONADIO, E., & BALDINI, A. (2020). *COVID-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health*. European Journal of Risk Regulation, 1-6. https://doi.org/10.1017/err.2020.24

compulsory license, the price of the generic version of sorafenib was reduced by 97% as compared to Bayer's price.[104]

Further, the threat of compulsory licensing can often lead to a positive outcome, such as voluntary licensing. A study by Beall and Kuhn identified 24 grants of compulsory licensing in 17 countries for 22 drugs, only half of which actually resulted in compulsory licenses.[105] This is because when countries signaled their intention to grant compulsory licenses, patent rights holders generally conceded with price reductions through, for example, voluntary licensing or discounts.[106]

Several countries have announced consideration of compulsory licensing as part of their response to the COVID-19 pandemic.[107] For example, on March 19, 2020, Israel issued compulsory patent licenses allowing generic versions of AbbVie Inc.'s HIV drug lopinavir/ritonavir (brand name Kaletra) to be imported to treat COVID-19 patients.[108] Under the pressure of invoking compulsory licensing provisions citing "national emergency" by the Member States of the WTO, Gilead recently signed non-exclusive voluntary licensing agreements with five generic pharmaceutical manufacturers to manufacture remdesivir for distribution in 127 countries.[109]

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[104] Bonadio E, *Compulsory Licensing of Patents: The Bayer/Natco Case* (2012) 10 European Intellectual Property Review 719

[105] Beall R, Kuhn R (2012) *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*. PLoS Med 9(1): e1001154. https://doi.org/10.1371/journal.pmed.1001154

[106] Ellen 't Hoen, *Private Patents and Public Health: Changing intellectual property rules for access to medicines*, Health Action International (HAI), https://haiweb.org/wp-content/uploads/2016/07/Private-Patents-Public-Health.pdf.

[107] Wong H. *The case for compulsory licensing during COVID-19*. J Glob Health. 2020 Jun;10(1):010358. doi: 10.7189/jogh.10.010358.

[108] Ellen 't Hoen, *Private Patents and Public Health: Changing intellectual property rules for access to medicines*, Health Action International (HAI), https://haiweb.org/wp-content/uploads/2016/07/Private-Patents-Public-Health.pdf.

[109] Gilead Sciences, *Voluntary Licensing Agreements for Remdesivir*, May 12, 2020, https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir

However, compulsory licensing also has its limitations. First, the use of the patent is limited to the purpose for which it is issued.[110] A government must make an attempt to obtain consent (*e.g.*, voluntary licensing) of the patent owner unless there is a national emergency or other extreme urgencies, such as COVID-19. Also, if the compulsory license is issued based on a national emergency, it will be terminated when the national emergency is under control. In addition, the patent owner has the right to receive payment for use under the compulsory license depending on the circumstances of each case. However, determining the fair and reasonable payment (*e.g.*, patent royalty) that the patent owner should receive will likely be a subject of dispute and delay. Further, if companies know that all their COVID-19 medications will be subject to compulsory licensing, they might have less of an incentive to develop the drugs or to enter into particular markets.[111]

Nevertheless, compulsory licensing is a powerful public health tool, which can be instrumental in mitigating insufficient supplies of essential COVID-19 vaccines and treatments and reducing prohibitively expensive drug prices.[112] While currently there is no approved treatment for COVID-19, governments are legally entitled under the TRIPS Agreement to issue compulsory licenses for treatments authorized for emergency use. In particular, governments of LMICs should prepare to issue compulsory licenses of any effective COVID-19 treatments in anticipation of the needs of their most vulnerable populations.[113]

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[110] Nafsika Karavida, *et al.*, *Patent Rights and Wrongs in the COVID-19 Pandemic: EU and U.S. Approaches to Compulsory Licensing*, May 19, 2020, https://www.ipwatchdog.com/2020/05/19/patent-rights-wrongs-covid-19-pandemic-eu-u-s-approaches-compulsory-licensing/id=121709/

[111] Urias E, Ramani SV. Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence (2020). *Journal of International Business Policy*. 2020;1-18. doi:10.1057/s42214-020-00068-4

[112] Hilary Wong, *The case for compulsory licensing during COVID-19*, Vol 10(1), doi: 10.7189/jogh.10.010358

[113] Hilary Wong, *The case for compulsory licensing during COVID-19*, Vol 10(1), doi: 10.7189/jogh.10.010358

### 4.7. Participating in medicine patent pool and Open COVID Pledge

The patent pooling mechanism can be an effective tool to spur drug discovery and development for control and treatment of the COVID-19 pandemic. It acts as an intermediary or a clearinghouse to pool inbound licenses on a broad array of medical IPRs and research data from IPRs owners across the globe.[114] The pooled licenses can be sublicensed on a royalty-free basis or on equitable terms to qualified developers or manufacturers.[115] Through the patent pooling mechanism, various IPRs owned by different owners are combined, which serves as a one-stop-shop for all parties.[116] Hence, transaction costs and risks will be substantially reduced. In addition, the patent pooling mechanism will facilitate the access to research data and collaborative innovation of relevant health technologies, thus accelerating response to the COVID-19 pandemic. The pooling mechanism can potentially increase equitable and affordable access to health technologies in these desperate times. Recently, a proposal for a global intellectual property pooling mechanism was proposed by Costa Rica, which received prompt support from the WHO.[117; 118]

One of the important advantages of patent pooling is that it negotiates licenses from a public health perspective.[119] In addition, the licenses under the patent pooling mechanism are

[114] Muhammad Zaheer Abbas, *Treatment of the novel COVID-19: why Costa Rica's proposal for the creation of a global pooling mechanism deserves serious consideration?,* J Law Biosci (June 2020) 7 (1): 1-10.
[115] Brook Baker, *Rationale for Supporting Costa Rica's Proposal for Emergency Covid-19 Technology Ip Pool for All Countries*, INFOJUSTICE, Mar. 25, 2020, *http://infojustice.org/archives/42137* (accessed Apr. 16, 2020).
[116] Muhammad Zaheer Abbas, *Treatment of the novel COVID-19: why Costa Rica's proposal for the creation of a global pooling mechanism deserves serious consideration?,* J Law Biosci (June 2020) 7 (1): 1-10.
[117] Muhammad Zaheer Abbas, *Treatment of the novel COVID-19: why Costa Rica's proposal for the creation of a global pooling mechanism deserves serious consideration?,* J Law Biosci (June 2020) 7 (1): 1-10.
[118] Elaine Ruth Fletcher, *WHO Director General 'Welcomes' Costa Rica Call for Pooled Rights to COVID-19 Treatments; G-20 Pledges Broad Support to Emergency Response,* Health Policy Watch (Mar. 26, 2020) https://healthpolicy-watch.org/whodirector-general-welcomes-co sta-rica-presidents-call-for-pooledrights-to-covid-19-treatments/.
[119] Elaine Ruth Fletcher, *WHO Director General 'Welcomes' Costa Rica Call for Pooled Rights to COVID-19 Treatments; G-20 Pledges Broad Support to Emergency Response,* Health Policy Watch (Mar. 26, 2020) https://healthpolicy-watch.org/whodirector-general-welcomes-co sta-rica-presidents-call-for-pooledrights-to-covid-19-treatments/.

transparent and predictable. All agreements are made available to the public on the organization's website. This is an improvement over voluntary licenses, the terms of which are generally kept secret.

As the COVID-19 pandemic continues to negatively impact the world, a number of initiatives, such as "Open COVID Pledge," have been launched to address the challenges associated with the sharing of IP and knowledge in the fight against the COVID-19 pandemic.[120] The Open COVID Pledge was developed by a group of scientists, lawyers, and entrepreneurs to encourage businesses and research facilities to make their intellectual property available for use in the fight against COVID-19.[121] The Open COVID Pledge is aimed to encourage sharing of IP and technologies to combat and end the pandemic without the need for timely and costly licenses or royalty agreements.[122]

The main concern for patent pooling and the Open COVID Pledge is the degree of participation by IPRs owners. IPRs owners devote a substantial sum of capital to develop their IP, with the expectation of recouping their investments through IPRs. Thus, it remains unclear how IPRs owners balance data sharing and open access to technologies against financial stability and potential legal issues that may arise from participating in patent pooling or the Open COVID Pledge due to IPRs owners' legal obligations to their sponsors and other IP stakeholders.

### 4.8. Invoking Article 73 security exceptions of the TRIPS Agreement

To facilitate production and distribution of medical products to combat the COVID-19 pandemic, governments across the globe are taking steps to bypass or override patents and other IPRs. The recent paper by Abbott *et al.* explores the possibility to invoke Article 73 ("Security

[120] Open COVID Pledge, https://opencovidpledge.org/.
[121] Theresa Rakocy, *The Open COVID Pledge: What Is It and Is It Right for You?*, National Law Review, Volume X, Number 105, https://www.natlawreview.com/print/article/open-covid-pledge-what-it-and-it-right-you
[122] *Id*.

Exceptions") of the TRIPS Agreement as the legal basis to override IPRs by classifying the COVID-19 as an "emergency in international relations."[123] Abbott *et al.* concluded that the COVID-19 pandemic can be considered an emergency in international relations under Article 73(b)(iii), which permits governments to take necessary measures to protect essential security interests.[124]

In supporting invocation of Article 73 security expectations, it is first determined the COVID-19 constitutes an emergency in international relations. Article 73 provides "Nothing in this [TRIPS] Agreement shall be construed … to prevent a member from taking any action which it considers necessary for the protection of its essential security interests … taken in time of war or other emergency in international relations …." [125] One of the major issues in combating and ending the pandemic involves allocating medical products such as vaccines, medicines, personal protection equipment (PPE) among nations as COVID-19 is transmitted across national borders and affects people in many geographic regions. Under the present pandemic, the needs of LMICs for medical devices and medicines will not be met in a timely way. Thus, the allocation of scarce resources can be an issue of "international relations," and a viable mechanism should be established to ensure equitable and affordable access to these resources.[126] In addition to the allocation issue of scarce resources, other pandemic-related issues can lead to an emergency in international relations, including a significant slowdown of international trade and a deeply contracted economy.[127]

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[123] Frederick M. Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, FSU College of Law, Public Law Research Paper No. 930, 28 Aug 2020, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3682260.
[124] *Id*.
[125] Article 73(b)(iii), the TRIPS Agreement
[126] Frederick M. Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, FSU College of Law, Public Law Research Paper No. 930, 28 Aug 2020, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3682260.
[127] *Id*.

Abbott *et al.* concluded that overriding IPRs is among the actions considered necessary "for the protection of its essential security interests" under Article 73(b).[128] Use of Article 73 by a WTO member to override IPRs or market exclusivity interests in medical devices or medicines will allow its domestic manufacturers or importers to use protected technologies of foreign IPR owners that are critical for fighting the COVID-19 pandemic. Such use of Article 73 to override IPRs is reasonably and directly related to addressing the national security interest.[129]

However, as with many other policy measures, overriding IPRs may face challenges based on national laws. Article 73 only addresses the challenges from another member in the WTO but not potential domestic law problems.[130]

## IV. Conclusion

While IP laws and policy are crucial in incentivizing research and development of vital health technologies, they are far from perfect and may very well require further adjustment or reform to meet overarching public interests, especially when it comes to facing unprecedented global health emergencies such as the COVID-19 pandemic. The monopolies established by IP protection and regulatory exclusivities have led to barriers to equitable and affordable access to essential drugs, vaccines, and diagnostics for combating the COVID-19 pandemic. Multiple policy instruments can be employed in concert to reduce or eliminate these barriers to ensure broad access to COVID-19 vaccines or treatments for people in need.

[128] Article 73(b), the TRIPS Agreement
[129] Frederick M. Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, FSU College of Law, Public Law Research Paper No. 930, 28 Aug 2020, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3682260.
[130] *Id*. at 19.