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Non-Patent Intellectual Property Barriers to COVID-19 Vaccines, Treatment and Containment

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NON-PATENT INTELLECTUAL PROPERTY BARRIERS TO COVID-19 VACCINES, TREATMENT AND CONTAINMENT

*Sean Flynn, Erica Nkrumah and Luca Schirru*¹

ABSTRACT

As the World Trade Organization considers a proposal to waive or otherwise address intellectual property barriers to the global response to the COVID-19 pandemic, most of the attention given by scholars and policy makers has been focused on patents. The original proposals by South Africa and India, as well as the groundbreaking support of the United States, however, explicitly applied to all forms of intellectual property. This paper documents many instances where non-patent forms of intellectual property create barriers to the global scale up of access to vaccines, treatments, and the ability to contain the virus through social distancing. Addressing the full scope of such barriers would assist the global efforts to combat COVID-19.

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INTRODUCTION

Intellectual property is a two-way street. In the general case, the protection of exclusive rights to practice inventions and use information may benefit social welfare through incentives to create information goods, even where some access to those goods is curtailed.² But enforcement of exclusive rights can also cut the other way, reducing innovation and causing undue social harm through lack of access to end products.³ Promoting access to intellectual property, including through compulsory licenses or limitations and exceptions to rights, becomes economically and morally justifiable in fields where the costs of exclusion clearly outweigh its benefits.⁴ There is a growing understanding that COVID-19 vaccine patents – largely invented through public funding and advance purchase commitments by government – should be opened to competition in the public interest under this logic.⁵ This understanding has been most prominently expressed in a proposal by India and South Africa that the World Trade Organization suspend its

² An “information good” is an end product “whose value is in important part constituted by their information content.” Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. 970, 995 (2012) (citing textbooks, newspapers, medicines, art, literature and music as examples).

³ See Giovanni Dosi & Joseph Stiglitz, *The Role of Intellectual Property Rights in the Development Process, with Some Lessons from Developed Countries: An Introduction* 22 (LEM Working Paper Series, No. 2013/23, Scuola Superior Sant’Anna, Laboratory of Economics and Management, 2013), <https://www.econstor.eu/bitstream/10419/89516/1/771928769.pdf> (on the “relations between the regimes of IPR protection and rates of innovations”, the authors conclude that “either the relation is not there, or if it is there that it might be a perverse one, with strong IPR enforcement actually deterring innovative efforts.”).

⁴ See Sean Flynn, Aidan Hollis, & Michael Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*. 37 JOURNAL OF LAW, MEDICINE AND ETHICS (2009) (explaining the economic case and concluding that markets for essential medicines in developing countries is a field where IP systematically produces far higher social costs from reduced access than benefits from incentives to produce new treatments); Thomas W. Pogge, *Human Rights and Global Health: A Research Program*, 36 (1-2) METAPHILOSOPHY 182 (2005) (explaining the moral case). Cf. Jessica Litman, *The Public Domain*, 39 EMORY L. J. 965, 968 (1990) (describing the public domain of unprotected information resources as best “understood not as the realm of material that is undeserving of protection, but as a device that permits the rest of the system to work by leaving the raw material of authorship available for authors to use”).

⁵ See, e.g., Dr. Tedros Adhanom Ghebreyesus, *Waive Covid vaccine patents to put world on war footing*, WORLD HEALTH ORGANIZATION (Mar. 7, 2021), <https://www.who.int/news-room/commentaries/detail/waive-covid-vaccine-patents-to-put-world-on-war-footing>; Stephen Buranyi, *The world is desperate for more Covid vaccines - patents shouldn’t get in the way*, THE GUARDIAN (Apr. 24, 2021, 06:00 EDT), <https://www.theguardian.com/commentisfree/2021/apr/24/covid-vaccines-patents-pharmaceutical-companies-secrecy>;

intellectual property rules for COVID-19 measures.⁶

The TRIPS waiver proposal is not limited to patents on vaccines. The proposal called for a suspension of WTO rules on all forms of intellectual property needed for a broad range of COVID-19 response measures, including for “vaccination,” “treatment,” and “containment.”⁷ Some commentators and WTO negotiators have proposed limiting the scope of the instrument to vaccine patents.⁸ There is little published research examining the non-patent barriers to COVID-19 to the full range of responses addressed by the original TRIPS waiver proposal.⁹ This paper fills that gap by summarizing literature in news and other sources describing potential non-patent intellectual property barriers to public health responses to the COVID-19 pandemic.

We conclude that non-patent barriers to COVID-19 responses are myriad and important. Access to copyrighted works, including software, is essential for COVID-19 related research, manufacture and repair of medical devices and equipment, manufacture of mRNA vaccines, and for the social distancing in education and other spheres required to contain outbreaks. Access to trade secrets and undisclosed “know how” are essential to achieving distributed production of vaccines, medicines and devices, even when patent protection is absent. International intellectual property law contains flexibilities that can be interpreted to permit emergency action by countries to overcome these barriers. We suggest ways that international organizations, including but not limited to the WTO, could clarify, and promote these flexibilities to aid COVID-19 responses.

This article progresses in three parts. In Parts I and II, we describe

⁶ Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True> [hereinafter “Revised TRIPS Waiver Proposal”].

⁷ Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/W/669 (Oct. 2, 2020) <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>

⁸ See Gary Winslett, *A Compromise Moratorium*, R STREET (March 2, 2021), <https://www.rstreet.org/2021/03/02/a-compromise-moratorium/>. The popular press often assumes this narrowing even where it has not occurred, referring to the WTO proposal as a “patent waiver.” See, Editorial, *A patent waiver on COVID vaccines is right and fair*, NATURE (May 25, 2021); Emma Farge, *Even after U.S. shift, opponents resist COVID-19 vaccine patent waiver*, REUTERS (May 31, 2021, 5:48 PM), <https://www.reuters.com/business/healthcare-pharmaceuticals/even-after-us-shift-opponents-resist-covid-19-vaccine-patent-waiver-2021-05-31/>

⁹ For a useful exception, see Doris Estelle Long, *The Overlooked Role of Copyright in Securing Vaccine Distribution Equity*, TRADERX REPORT (Sept. 6, 2021), <https://www.traderxreport.com/covid-19/the-overlooked-role-of-copyright-in-securing-vaccine-distribution-equity/>

evidence that access to copyrights and trade secrets, respectively, are needed to respond to the COVID pandemic.¹⁰ Part III defines opportunities for international action – including opportunities beyond the current TRIPS waiver discussion – that could clarify the international policy flexibility needed to address these barriers. This information may be useful to international policy makers in the WTO, WIPO and other multilateral agencies exploring avenues for international intellectual property policy to contribute to the response to the COVID pandemic.

I. THE NEED FOR USES OF COPYRIGHTED WORKS TO COMBAT COVID

Access to copyrighted works, including software, is essential for COVID-19 related research, for the provision of vaccines and treatment, and for containing the spread of the virus through social distancing.

A. Research

Advanced research methodologies using text and data mining has been instrumental in identifying and tracking COVID-19 as well as in identifying candidates for vaccines and other treatments.

1. Access to Scientific Literature

Researchers cannot contribute to COVID-19 responses if they cannot access the scientific literature they need to conduct their work. A global survey recently found that about 20% of researchers globally, and over 30% of researchers in South America (where copyright exceptions are the most limited), report that COVID has “completely” altered or halted their work.¹¹

Researchers and governments have called for voluntary efforts by publishers to release access to research materials and data to aid the global fight against the pandemic.¹² Many publishers have responded by making

¹⁰ The obligations to “promote” and “provide” access to medicines are part of the duties of states and international organizations to fulfil the international right to health. See U.N. Committee on Economic, Social and Cultural Rights, *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the International Covenant on Economic, Social and Cultural Rights)*, adopted at the 22nd Session of the Committee on Economic, Social and Cultural Rights, U.N. Doc. E/C.12/2000/4 (Geneva, Aug. 11, 2000).

¹¹ Chantelle Rijs & Frederick Fenter, *The Academic Response To Covid-19*, FRONTIERS, 7 (Oct. 28, 2020) (summarizing the results of a two month long survey of academics from several countries).

¹² See Letter by National Science and Technology Advisors in select Countries to the Members of the Scholarly Publishing Community (Mar. 13, 2020), <https://wellcome.org/sites/default/files/covid19-open-access-letter.pdf> (calling for action to help scientists “keep up with the rapidly growing body of literature and identify trends and relevant information in efforts to characterize this novel virus and address the associated global health crisis”); European Commission, *European Commission signs letter to scholarly publishing community in the fight against coronavirus* (Mar. 31, 2020), https://ec.europa.eu/info/news/european-commission-signs-letter-scholarly-publishing-community-fight-against-coronavirus-2020-mar-30_en; White House Office of Science and

publications relevant to COVID-19 freely available.¹³ The number of articles being made available through open licensed platforms is diminishing over time, however, indicating a potential need for further action to ensure that researchers have access to literature and data.¹⁴

2. Text and Data Mining (TDM)

Text and data mining – in which computational processes are used to derive data from or about a corpus of works¹⁵ -- has been central to many research breakthroughs regarding COVID-19. The outbreak was discovered by a Canadian text and datamining company, BlueDot, which tracks emerging health threats by analyzing “a variety of information sources, including chomping through 100,000 news reports in 65 languages a day.”¹⁶ TDM projects also mine scientific publications and other forms of data about the coronavirus family to aid vaccine research and development.¹⁷

Many of the materials used for COVID-related data mining projects are covered by copyright, including the news articles mined by BlueDot and the scientific articles mined by vaccine researchers. Less than 25% of the world’s copyright laws fully permit even non-commercial text and datamining research.¹⁸ The lack of copyright permission for such uses can block research

Technology Policy, *Call to Action to the Tech Community on New Machine Readable COVID-19 Dataset*, Trump White House Archives (Mar. 16, 2020), <https://trumpwhitehouse.archives.gov/briefings-statements/call-action-tech-community-new-machine-readable-covid-19-dataset/>.

¹³ Press Release, *Publishers make coronavirus (COVID-19) content freely available and reusable*, WELLCOME (Mar. 15, 2020), <https://wellcome.org/press-release/publishers-make-coronavirus-covid-19-content-freely-available-and-reusable>.

¹⁴ See Jeffrey Brainard, *No revolution: COVID-19 boosted open access, but preprints are only a fraction of pandemic papers*, SCIENCE (Sep. 8, 2021, 2:45 PM), <https://www.science.org/content/article/no-revolution-covid-19-boosted-open-access-preprints-are-only-fraction-pandemic-papers> (reporting that 77% of COVID-19 papers were free to read in early September 2021 – down from a high of 85% in May 2020).

¹⁵ Sean Flynn et al., *Implementing User Rights for Research in the Field of Artificial Intelligence: A Call for International Action* 42 (7) EIPR 393 (2020).

¹⁶ Mark Prosser, *How AI Helped Predict the Coronavirus Outbreak Before it Happened*, SINGULARITY HUB (Feb. 05, 2020), <https://singularityhub.com/2020/02/05/how-ai-helped-predict-the-coronavirus-outbreak-before-it-happened/>; Corey Stieg, *How this Canadian Start-Up Spotted Coronavirus Before Everyone Else Knew About it*, CNBC: MAKE IT (Mar. 6, 2020, 1:40 PM), <https://www.cnbc.com/2020/03/03/bluedot-used-artificial-intelligence-to-predict-coronavirus-spread.html>.

¹⁷ See Will Knight, *Researchers Will Deploy AI to Better Understand Coronavirus*, WIRED, (Mar. 17, 2020, 08:00 AM), <https://www.wired.com/story/researchers-deploy-ai-better-understand-coronavirus/>; Carrie Arnold, *How Computational Immunology Changed the Face of COVID-19 Vaccine Development*, NATURE: NATURE MEDICINE (Jul. 15, 2020), <https://www.nature.com/articles/d41591-020-00027-9>; Emily Waltz, *What AI Can and Can’t Do in the Race for a Coronavirus Vaccine*, IEEE: IEEE SPECTRUM (Sep. 29, 2020) (describing how “[m]achine-learning systems and computational analyses have played an important role in the vaccine quest,” including “helping researchers understand the virus and its structure, and predict which of its components will provoke an immune response”).

¹⁸ Sean Flynn, et. al., *Comparative Law on Copyright Exceptions for Research* (PIJIP

and publication.¹⁹ In July 2021, for example, a group of researchers in Canada and India were forced to retract a paper on vaccine hesitancy and Covid-19 because they lacked a license to mine a database of news articles used in the study.²⁰

B. Treatment

Access to copyrighted materials is necessary to create and repair many medical devices needed to treat COVID-19. Manufacturers have used copyright claims to prevent such repair and replacement of critical equipment.

I. Algorithms for mRNA Vaccines

Patents are not the only intellectual property barrier to the production of the leading mRNA vaccines. The creation of mRNA vaccines requires identification of “MicroRNAs (miRNAs)” – “small non-coding RNA that target gene expression at post-transcriptional level.”²¹ “To understand the molecular basis of miRNA regulation, it is essential to identify reliable miRNA target mRNAs and miRNA–mRNA functional networks,” which relies on several widely used computational algorithms and tools.²² Such tools may be subject to copyright or other forms of data protection in many countries.²³

Working Paper) (forthcoming 2021). See also Part III, below.

¹⁹ On the lawfulness of text and data mining under U.S. copyright law, see Michael W. Carroll, *Copyright and the Progress of Science: Why Text and Data Mining is Lawful*, 53 U.C. DAVIS L. REV. 893 (2019)

²⁰ ‘A very unfortunate event’: Paper on COVID-19 vaccine hesitancy retracted, RETRACTION WATCH, <https://retractionwatch.com/2021/07/30/a-very-unfortunate-event-paper-on-covid-19-vaccine-hesitancy-retracted/> (last visited, Oct. 6, 2021)

²¹ Rishav Ray & Priyanka Pandey, *Surveying computational algorithms for identification of miRNA–mRNA regulatory modules*, 60 THE NUCLEUS 165 (2017)

²² *Id.*

²³ See Clark D. Asay, *Artificial Stupidity* 61 WILLIAM & MARY L. REV. 1187, 1241 (BYU Law Research Paper No. 20-03. 2020) (“Finally, the fact remains that for many AI innovations, patenting remains a suboptimal intellectual property strategy because of patent law’s disclosure requirements.³³⁴ Trade secrecy, in contrast, provides some legal protections without the need to share with the world a party’s AI details.³³⁵ And though trade secrecy may provide such advantages, it is also typically associated with higher transaction costs as parties undertake extensive, costly measures to guard that secrecy.³³⁶”) (footnotes omitted); Guido Noto La Diega, *Against the Dehumanisation of Decision-Making – Algorithmic Decisions at the Crossroads of Intellectual Property, Data Protection, and Freedom of Information*, 9 JIPITEC 3, 12 (2018) (“Even though there are many open-source machine learning frameworks (e.g. Apache Singa, Shogun, and TensorFlow), most AI algorithms are proprietary... i.e. covered primarily by trade secrets,⁹⁷ ... Under the new Trade Secrets Directive,⁹⁹ algorithms can be covered by trade secrets because they are not generally known or easily accessible and they have commercial value.¹⁰⁰ This is true as long as the person who has control of the algorithm takes steps to keep it secret.¹⁰¹”) (footnotes omitted); See also FIVEIPOFFICES (IP5). *Report from the IP5 expert round table on artificial intelligence 2* (Oct. 31, 2018) (“Algorithms as such may not be eligible for patent protection. However, if the underlying algorithm is claimed as a series of concrete procedural

2. *Marketing Labels and Inserts*

Even if a competing vaccine or treatment is lawfully produced with respect to patent law, there are opportunities for companies to use copyrights to halt or delay generic marketing. The issue arises because labels and package inserts – which convey information often required by regulators – may be considered protected by copyright in some countries. There is a history of pharmaceutical companies making such claims (ultimately ineffectively) in the U.S.²⁴ A recent report by WTO and WIPO explained that the practice of using copyrights to block generic production continues in other countries.²⁵

3. *Repair Manuals*

Copyright is frequently used to block competition in the repair of medical devices.²⁶ One tool companies use to block unlicensed repairs is to prohibit the use and sharing of copyrighted repair manuals. In a recent example reported by the Electronic Frontier Foundation (EFF), the maker of sterilization-related devices demanded that their products' documentation be taken down from an open access repository of repair information based on

steps solving a technical problem or is incorporated into a practical application, it can be eligible for patent protection.”) https://www.fiveipoffices.org/wcm/connect/fiveipoffices/5e2c753c-54ff-4c38-861c-9c7b896b2d44/IP5+roundtable+on+AI_report_22052019.pdf?MOD=AJPERES&CVID=IP5 (2018, p. 2). *But see* Andrew C. Michaels, *Abstract Innovation, Virtual Ideas, and Artificial Legal Thought*, 14 JOURNAL OF BUSINESS & TECHNOLOGY LAW 1, 11 (2018) “A pure algorithm for example, even if inventive or “newly discovered,” is an abstract idea ineligible for patent protection.⁴⁸” (footnote omitted).

²⁴ See Zvi S. Rosen, *Product Labels and the Origins of Copyright Examination*, (MOSTLY) IP HISTORY (May 23, 2017) <http://www.zvirosen.com/2017/05/23/product-labels-and-the-origins-of-copyright-examination/> (describing the U.S. history of manufactures attempting to use copyright claims to gain marketing exclusivity); Roseann B. Termini & Amy Miele, *Copyright and Trademark Issues in the Pharmaceutical Industry: Generic Compliance or Brand Drug Imitating: 'Copycat or Compliance'*, PENNSYLVANIA BAR ASSOCIATION QUARTERLY (Jan. 2013)(same). See e.g. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm, Inc.*, 211 F.3d 21 (2d Cir. 2000), cert. denied, 531 U.S. 872 (2000) (rejecting copyright claims to label information as grounds for restricting marketing of generic).

²⁵ WHO/WIPO/WTO, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade*, 87 (2nd ed. 2020) (explaining that “courts have sometimes found that generic pharmaceutical producers cannot reproduce for their own products direct copies of the original expressions contained in package inserts of the first producer of the product,” citing litigation brought by pharmaceutical companies South Africa and Australia).

²⁶ Jason Koebler, *Hospitals Need to Repair Ventilators. Manufacturers Are Making That Impossible*, VICE: MOTHERBOARD (Mar. 18, 2020, 11:15 PM), <https://www.vice.com/en/article/wxekgx/hospitals-need-to-repair-ventilators-manufacturers-are-making-that-impossible> (describing how manufacturers have cemented a “repair monopoly ... by lobbying against legislation that would make it easier to repair machines, keeping access to repair guides out of the hands of independent repair professionals, and using software controls to limit who can perform repairs”).

copyright claims over that documentation.²⁷

4. 3D Printing

Copyright is complicating the use of 3D printing technology to print replacement parts for ventilators and other devices. Copyright can cover the 3D digital file needed to print objects, and copyright or design rights may cover the form and shape of the printed object.²⁸ In one recent example, copyrighted files and manuals needed to print ventilator valves were denied by their manufactures to Italian researchers attempting to use 3D printing to fill critical parts shortages during the height of that country's initial outbreak.²⁹

5. Software Enabled Devices

Ventilators and other medical devices have copyrighted software integrated into their operation.³⁰ Accordingly, to repair such equipment copyright permission to access the software and bypass technological protection measures may be required.³¹

The right to access software to make repairs to ventilators and other devices was a core request of 326 hospital repair experts in a letter to the U.S. Congress.³² The advocacy led to the introduction of the Critical Medical

²⁷ Kit Walsh, *Medical Device Repair Again Threatened With Copyright Claims*, ELECTRONIC FRONTIER FOUNDATION (June 11, 2020), <https://www.eff.org/deeplinks/2020/06/medical-device-repair-again-threatened-copyright-claims>; (describing EFF's defense of the contributions of manuals to the open access Medical Device Repair Database posted to the website iFixit); Letter from Russell S. Wheatley, Steris Corp. Chief IP Counsel to Kyle, Wiens, iFixit, CEO, ELECTRONIC FRONTIER FOUNDATION (May 26, 2020), <https://www.eff.org/document/letter-steris-ifixit-5-16-2020>.

²⁸ Elsa Malaty & Guilda Rostama, *3D Printing and IP Law*, WIPO MAGAZINE (Feb. 2017), https://www.wipo.int/wipo_magazine/en/2017/01/article_0006.html

²⁹ See Urian B., *3D Printer Saves Lives of Italian Coronavirus Patients As Hospitals Run Out of Ventilators! Here's How*, TECH TIMES (Mar. 16, 2020, 11:03 PM), <https://www.techtimes.com/articles/248085/20200316/3d-printer-saves-lives-italian-coronavirus-patients-hospitals-run-out-ventilators.htm>; Faye Brown, *Firm 'refuses to give blueprint' for coronavirus equipment that could save lives*, METRO NEWS (Mar. 16, 2020, 12:06 PM), <https://metro.co.uk/2020/03/16/firm-refuses-give-blueprint-coronavirus-equipment-save-lives-12403815/>; Urian B., *Maker of \$11,000 Ventilator Valves Threatens to Sue Volunteers Using \$1 3D-Printed Replicas That Just Saved 10 Coronavirus Patients!*, TECH TIMES (Mar. 17, 2020, 10:03 PM), <https://www.techtimes.com/articles/248121/20200317/maker-ventilator-valves-threatens-sue-volunteers-using-3d-printed-coronavirus.htm>

³⁰ Example of software used in ventilator, see *Puritan Bennett Ventilator Software*, MEDTRONIC, <https://www.medtronic.com/covidien/en-us/products/mechanical-ventilation/software.html> (last visited Oct. 06, 2021)

³¹ See generally Leah Chan Grinvald & Ofer Tur-Sinai, *Intellectual Property Law and the Right to Repair*, 88 FORDHAM L. REV. 63, 104 (2019) (noting that under US law “[c]onsumers cannot disable the digital lock without being liable . . . , even if the purpose for such hack was to diagnose, maintain, or repair the product”).

³² Nathan Proctor, *Hospital Repair Professionals: Just Let Us Fix Life-saving Devices Including Ventilators*, U.S. PIRG (May 18, 2020), <https://uspirg.org/news/usp/hospital->

Infrastructure Right to Repair Act of 2020, eliminating “liability under federal copyright law for creating an incidental copy of service materials or for breaking a digital lock during the course of equipment repair in response to COVID-19”.³³ That law has not passed, however, leaving care-givers in the U.S., as in many other countries, without the legal tools they need to repair software enabled devices.³⁴

6. *Personal Protective Equipment (PPE) Standards*

To address shortages of personal protective equipment (PPE), the European Committee for Standardization and the European Committee for Electrotechnical Standardization opened access to its copyrighted standards for production of PPEs.³⁵ Ordinarily, the standards need to be licensed from the standard setting organizations due to copyright.³⁶ The European Commission explained that “the derogation from this business model is a strong European response, based on a sense of social responsibility and solidarity, to address the shortage problem of protective equipment deriving from the Covid-19 epidemics.”³⁷

C. *Containment*

The final and perhaps most obvious example of the need for access to copyright to battle the COVID-19 pandemic is in promoting social distancing.³⁸ For the majority of the world’s population, the only way to

repair-professionals-just-let-us-fix-life-saving-devices-including-ventilators;

³³ Press Release, *Wyden and Clarke Introduce Bill to Eliminate Barriers to Fixing Critical Medical Equipment During the Pandemic*, RON WYDEN U.S. SENATOR FOR OREGON (Aug. 6, 2020), <https://www.wyden.senate.gov/news/press-releases/wyden-and-clarke-introduce-bill-to-eliminate-barriers-to-fixing-critical-medical-equipment-during-the-pandemic-> (quoting Senator Wyden that “it is just common sense to say that qualified technicians should be allowed to make emergency repairs or do preventative maintenance, and not have their hands tied by overly restrictive contracts and copyright laws, until this crisis is over”),

³⁴ There are a small number of voluntary measures that seek to overcome copyright barriers to the use of software. The government of Singapore publicly shared copyrighted software relating to its contact-tracing app to assist contact-tracing strategies by public health authorities worldwide. See Hariz Baharudin, *Coronavirus: S’pore Government to make its contact-tracing app freely available to developers worldwide*, THE STRAITS TIMES (Mar. 23, 2020, 5:58 PM SGT), <https://www.straitstimes.com/singapore/coronavirus-spore-government-to-make-its-contact-tracing-app-freely-available-to->; BLUETRACE PROTOCOL, <https://bluetrace.io/> (last visited Oct. 6, 2021). Some software providers have included their products within the Open COVID Pledge. OPEN COVID PLEDGE, <https://opencovidpledge.org/partner-ip/> (last visited Oct. 06 2021)

³⁵ Press Release, European Commission, *Coronavirus: European standards for medical supplies made freely available to facilitate increase of production* (Mar. 20, 2020), https://ec.europa.eu/commission/presscorner/detail/en/ip_20_502

³⁶ *Id.*

³⁷ *Id.*

³⁸ See *Coronavirus disease (COVID-19) advice for the public*, World Health Organization, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public> (last visited Sep 30, 2021)

prevent the virus is through social distancing. Promoting such distancing while protecting needed access to educational, research and cultural heritage materials requires rights to communicate copyrighted works over the internet.

1. *Institutional closures*

To promote social distancing, essential public institutions – including schools, universities, libraries, archives, and museums – have closed in countries across the world. UNESCO reports that COVID-19 has “created the largest disruption of education systems in history,” “affecting nearly 1.6 billion learners in more than 190 countries,” “94 per cent of the world’s student population,” and “up to 99 per cent” of students in low and lower-middle income countries.³⁹

Copyright laws often separately protect a right of “communication” or “making available” of works through digital platforms that is required to share materials over computer networks. Most education and research exceptions to copyright only cover the right of reproduction, and many are limited to specific uses such as “in the classroom” or “on the premises” of a library.⁴⁰

2. *The Inadequacy of Voluntary Licensing*

There have not been wide-scale voluntary measures to permit digital uses of educational or research materials as there has been with respect to COVID-related scientific articles. For example, only a small number of publishers have permitted uses of any of their works to conduct children’s story-time readings online.⁴¹ Many publishers and collective management organizations

³⁹ U.N., *Policy Brief: Education during COVID-19 and beyond*, 2 (Aug. 2020). See also *1.3 Billion Learners are Still Affected by School or University Closures, as Educational Institutions Start Reopening Around the World, Says UNESCO*, UNESCO (Apr. 29, 2020), <https://en.unesco.org/news/13-billion-learners-are-still-affected-school-university-closures-educational-institutions>; *COVID-19 Impact on Education*, UNESCO (last visited Oct. 06, 2021) <https://en.unesco.org/covid19/educationresponse> (global monitoring of school closures caused by COVID-19).

⁴⁰ See part III, below.

⁴¹ See *Access Copyright, Read Aloud Canadian Books Guidelines of Use*, accesscopyright.ca/media/1438/read-aloud-canadian-books-program-guidelines-of-use.pdf (last visited Oct. 06, 2021) (announcing a special license for their “Read Aloud Canadian Books Program” that covers only select books from participating publishers); Carys J. Craig & Bob Tarantino, “*An Hundred Stories in Ten Days*”: *COVID-19 Lessons for Culture, Learning and Copyright Law* 62 (Joint PIJIP/TLS Research Paper Series No. 10-2020) (reviewing voluntary pledges for educational uses and finding it “quickly evident that many titles in their catalogues are unavailable, certain publishers have made nothing newly available, and access to free volumes is stringently limited to particular audiences and for a specified time”); *Virtual Storytimes Aotearoa*, LIANZA, <https://lianza.org.nz/covid-19/virtual-storytimes/> (last visited Oct. 06, 2021) (listing “Public libraries [that] hosted nearly 750 virtual storytimes during the COVID-19 pandemic lockdown in late March”); Denise R. Nicholson, *How SA’s Copyright Bill Would Benefit Citizens During COVID*, EIFL (Nov. 13, 2020) (reporting that few temporary waivers or reductions in copying fees were offered by CMOs in South Africa for COVID-related uses), <https://www.eifl.net/blogs/how->

are working in the opposite direction, explicitly demanding additional licenses for online uses of works.⁴²

In sum, many essential activities needed to combat COVID-19, including research, vaccines and treatments, and promoting social distancing, require access to copyrighted works. But the non-patent barriers to COVID-19 responses do not end there. As the next section shows, access to trade secrets and know how are also essential to the production of vaccines and treatments.

II. THE NEED FOR ACCESS TO TRADE SECRETS AND KNOW HOW

Access to patents provides only a part of what a local producer needs to produce a vaccine, medicine or treatment device. Patents require the recipient to disclose the invention being protected. But patentees are not required to disclose everything they know to most efficiently reproduce their invention.⁴³ If the world is going to achieve a rapid scale up of production capacity, the sharing of trade secrets and know how must be accomplished.

A. *Trade Secrets on Medicines and Vaccines*

Undisclosed knowledge can be a significant barrier to entry for new firms, even where authorizations to use patented technology exists.⁴⁴ Thus,

sas-copyright-bill-would-benefit-citizens-during-covid

⁴² For example, Access Copyright, a reproduction rights collective in Canada, published an article warning organizations: “your co-workers are probably sharing content without permission from the copyright owners,” threatening “legal action for copyright infringement” without an extended license form the organization including online uses. *Working from home and copyright*, ACCESS COPYRIGHT, <https://www.accesscopyright.ca/businesses/working-from-home-and-copyright/> (last visited Jan. 15, 2021) (“During this pandemic and at any other time, our team is ready to meet your needs and offer you a range of solutions tailored to how you work”). See also Nicholson, *supra* note 38 (describing a university lecturer in South Africa who was denied permission from a publisher and the local collective management organization to place sections of an e-book version of a textbook on her institution’s password-protected e-learning platform for the specific class for a period of 6 weeks).

⁴³ See Christopher Garrison, *What is the ‘know-how gap’ problem and how might it impact scaling up production of Covid-19 related diagnostics, therapies and vaccines?*, MEDICINES LAW & POLICY (Dec. 16, 2020) (describing that, even in countries that require disclosure of the best mode for producing an invention, much of the practical information required to efficiently compete with the original producer may be protected by trade secret or otherwise withheld), <https://medicineslawandpolicy.org/2020/12/what-is-the-know-how-gap-problem-and-how-might-it-impact-scaling-up-production-of-covid-19-related-diagnostics-therapies-and-vaccines/>.

⁴⁴ Karl F. Jorda, *Trade Secrets and Trade-Secret Licensing*, in INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES Chapter 1043, 1051 (A. Krattiger, R.T. Mahoney, L. Nelsen, et. al. eds. 2007) MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. (explaining that “as a practical matter, licenses under patents without access to associated or collateral know-how are often not enough for taking advantage of the patented technology commercially ... because patents rarely disclose the ultimate scaled-up commercial embodiments”), <http://www.iphandbook.org/handbook/ch11/p05/>.

Moderna, the maker of one mRNA COVID-19 vaccine, explained to its investors that it anticipates ongoing market exclusivity even in the face of its public pledge not to enforce its patents.⁴⁵ “We also rely to a certain extent on trade secrets, know-how, and technology, which are not protected by patents, to maintain our competitive position,” it explained in 2020 Quarterly Report in 2020.⁴⁶ Similarly, access to medicine advocates have criticized Roche for releasing patents to the medicine Tocilizumab,⁴⁷ which is recommended by the World Health Organization (WHO) for treating severe COVID-19,⁴⁸ in part because Roche did not include “open, transparent and unrestricted transfer of ... its regulatory dossier and any other manufacturing information, which is critical for immediate scale-up of production by other manufacturers.”⁴⁹

B. Trade Secrets on Tests and Devices

Lack of access to trade secrets has impeded access to COVID testing in several countries. For example, laboratories in South Africa were cut off from a supply of needed reagents for a COVID test, and were prevented from making the materials themselves because of a refusal of the manufacturer to share its trade secret recipes.⁵⁰ A refusal to license trade secrets to another

⁴⁵ Press Release. *Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic*, MODERNA (Oct. 8, 2020, 6:39 AM) (explaining that its public pledge does not extend to know how), <https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19>.

⁴⁶ Moderna, Inc., Quarterly Report for the quarterly period ended June 30, 2020 (Form 10-Q) at 93 (Aug. 06, 2020) (noting that “[i]f any trade secret, know-how, or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected”). <https://www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm>

⁴⁷ Kerry Cullinan, *Roche Suspends Patents on Tocilizumab in LMICs after WHO Recommends it as Treatment for Severe COVID-19*, HEALTH POLICY WATCH (July 8, 2021), <https://healthpolicy-watch.news/roche-suspends-patents-on-tocilizumab-for-lmics-after-who-recommends-it-as-treatment-for-severe-covid/>.

⁴⁸ WHO recommends life-saving interleukin-6 receptor blockers for COVID-19 and urges producers to join efforts to rapidly increase access, WORLD HEALTH ORGANIZATION (July 6, 2021), <https://www.who.int/news/item/06-07-2021-who-recommends-life-saving-interleukin-6-receptor-blockers-for-covid-19-and-urges-producers-to-join-efforts-to-rapidly-increase-access>.

⁴⁹ Press Release, *MSF Response to Roche’s statement on access to tocilizumab*, MEDICINS SANS FRONTIERES ACCESS CAMPAIGN (July 9, 2021), <https://msfaccess.org/msf-response-roches-statement-access-tocilizumab>.

⁵⁰ Catherine Tomlinson, *COVID-19: Behind SA’s shortages of test materials*, SPOTLIGHT (May 5, 2020), <https://www.spotlightnsp.co.za/2020/05/05/covid-19-behind-sas-shortages-of-test-materials/>. It was only after threats of investigation for anti-competitive conduct by the European Commission that Roche eventually took steps to release its recipe. See Eelke Van Ark & Jan-Hein Strop, *Roche releases recipe after European Commission considers intervention due to lack of coronavirus tests*, FOLLOW THE MONEY (March 27, 2020), <https://www.ftm.nl/artikelen/roche-releases-recipe-after-public-pressure-while-european-commission-considers-intervention-due-to-coronavirus-test>; Ed Silverman, *Roche backpedals and agrees to provide a solution for COVID-19 tests in the Netherlands*, STAT

COVID-19 test used frequently in developing countries has been blamed by access to medicine advocates for perceived price gauging and supply constraints.⁵¹

Ultimately, it is clear that addressing patent rights alone will not solve the full range of intellectual property barriers to vaccines, treatments and containment measures needed to defeat COVID-19. International action to clarify flexibilities in the international system to respond to non-patent barriers are also needed. Some of the targets for such clarification are described in the next Part.

III. CLARIFICATIONS NEEDED IN INTERNATIONAL LAW

International intellectual property law, including that contained in the WTO TRIPS Agreement, could be usefully clarified in its application to non-patent barriers responses to the COVID-19 pandemic. The TRIPS waiver proposal, which would constitute a subsequent agreement between the same parties of the most important treaty mandating minimum standards for copyrights and trade secrets, is one key opportunity for such clarification.⁵² This part discusses the role of other agencies, including the World Intellectual Property Organization, as well.

A. *Emergency Uses of Copyrighted Works*

As described below, most countries do not provide copyright exceptions for emergency uses during COVID. There is accordingly a need to clarify the authority under international law to take emergency action to authorize certain uses of protected works during COVID, at least in an interim period where laws are amended to provide more adequate exceptions.

1. *Lack of Adequate Exceptions for COVID-19 Uses*

Copyright laws around the world fail to provide the limitations and exceptions needed to permit critical research, learning and health related measures needed to respond to COVID. As shown in the figures below, research by American University's Program on Information Justice and

(Mar. 27, 2020), <https://www.statnews.com/pharmalot/2020/03/27/roche-covid19-coronavirus-netherlands/>.

⁵¹ See *Local Diagnostics to meet Local Health Needs*, MEDECINS SANS FRONTIERES ACCESS CAMPAIGN, at 7, 9 (Jul. 08, 2021), <https://msfaccess.org/improve-local-production-diagnostics> (describing access to know-how as "especially important for complicated closed diagnostics systems like Cepheid's automated, cartridge-based GeneXpert tests," only 15% of which are dedicated to supply of developing countries); Press Release, *Diagnostic company Cepheid charging four times more than it should for COVID-19 tests*, MEDECINS SANS FRONTIERES (Jul. 28, 2020), <https://www.msf.org/diagnostic-company-cepheid-charging-more-it-should-covid-19-tests> (describing price gauging).

⁵² See United Nations Vienna Convention on the Law of Treaties, art. 31, May 23, 1969, I-18232, 1155 UNTS 331 (providing rules of interpretation of treaties and the role of subsequent agreements and practices).

Intellectual Property has categorized the world's copyright exceptions for research into three categories. Only the countries labeled green in the figures have sufficiently broad copyright exceptions to permit TDM research (Figure 1) or online education (Figure 2). While there are several U.S. state bills under discussion, there is not as much notice from other countries about the enactment of legislation on explicit rights to use works for the purpose of device repair.⁵³ On the contrary, several intellectual property regimes may impose significant obstacles to the right to repair.⁵⁴ Our review did not find a single copyright law with an express exception for uses needed to protect public health.

⁵³ See Daniel Moore, *You Gotta Fight for Your Right to Repair: The Digital Millennium Copyright Act's Effect on Right-to-Repair Legislation*, 6 TEX. A&M L. REV. 509, 515 (2019) (“Since 2015, states have responded to consumers' lack of freedom to choose how to fix their devices by trying to enact right-to-repair laws. These laws require manufacturers to offer repair instructions and parts to independent repair technicians. During the legislative sessions following the 2016 elections, almost half of the country's state legislatures considered right-to-repair laws.”)(footnotes omitted). See also S. Kyle Montello, *The Right to Repair and the Corporate Stranglehold over the Consumer: Profits over People*, 22 TUL. J. TECH. & INTELL. PROP. 165 (2020) (commenting that “Right to repair bills are also being considered in Canada and the European Union (EU).”)(footnote omitted)

⁵⁴ Aaron Perzanowski, *Consumer Perceptions of the Right to Repair*, 96 IND. L.J. 361, 377-378, 394 (2021) (commenting on the obstacles for the enactment of bills on right to repair imposed by “anti-repair” lobby, which uses IPR-based arguments and goes against costumers expectations on their rights); Leah Chan Grinvald & Ofer Tur-Sinai, *Intellectual Property Law and the Right to Repair*, 88 FORDHAM L. REV. 63, 128 (2019) (“from a doctrinal point of view, this Article's analysis points out that the concept of a right to repair and the proposed state legislation that seeks to secure it are not accommodated by the United States' far-reaching intellectual property regime.”). See also Nicholas A. Mirr, *Defending the Right to Repair: An Argument for Federal Legislation Guaranteeing the Right to Repair*, 105 IOWA L. REV. 2393, 2415 (2020) (arguing that “[t]he existing framework of copyright law is thus insufficient to properly address the demands of the right to repair movement.135”) (footnote omitted)

Figure 1

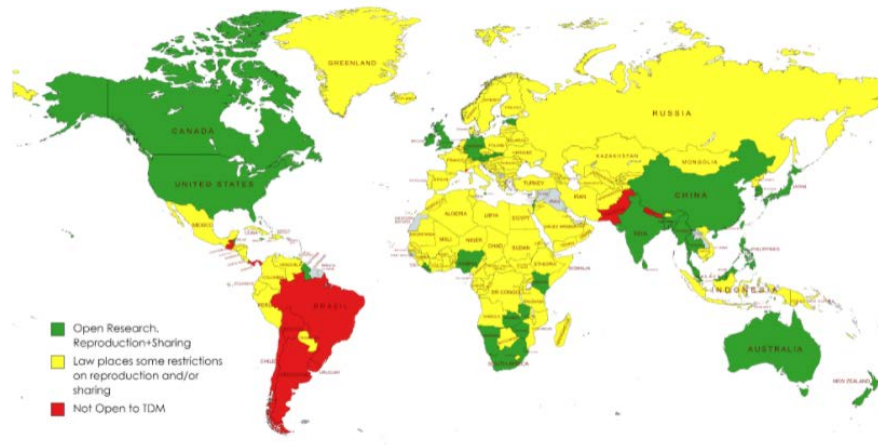
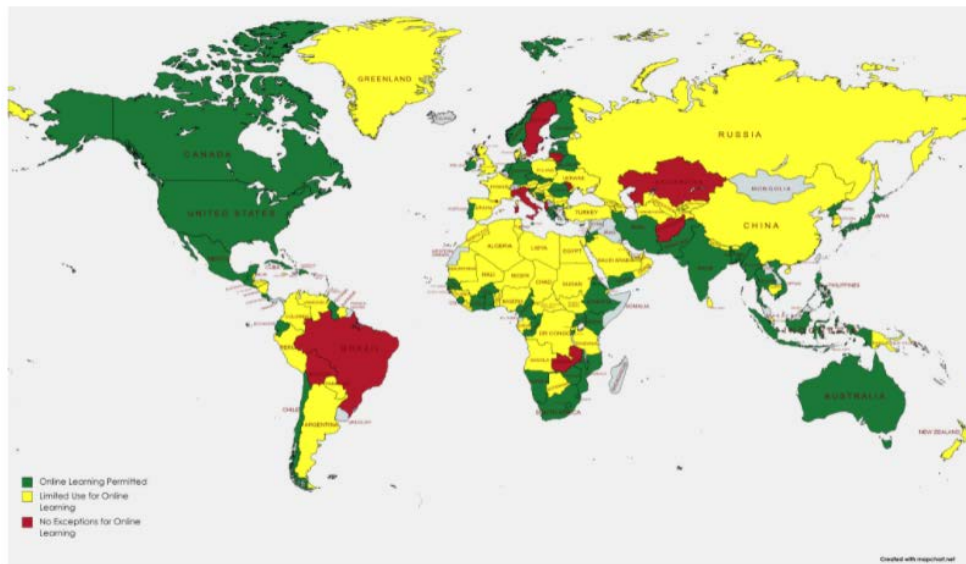
Research

Figure 2

Online Education

The lack of adequate exceptions in copyright legislation raises the question under international law whether countries can take non-legislative measures to permit uses of copyrighted works during an emergency. One possible source of such authorization can be found in Article 17 of the Berne Convention.

2. *Need for Clarification of the Emergency Use Authorization in Berne Article 17*

The Berne Convention and related copyright treaties make it clear that countries may *legislate* upon limitations and exceptions.⁵⁵ As shown in the figures above, a minority of countries have used that authority to permit uses of copyrighted works for research, online education, hardware repair, and for other essential uses to combat COVID-19. But for those that do not yet have such rights, legislative processes may not be sufficiently speedy to authorize uses needed immediately. Thus the question occurs whether the international treaty architecture permits more immediate *administrative* action to extend exceptions in an emergency.⁵⁶

Authorization for emergency administrative action to overcome copyright barriers in the case of a necessity is contained in Article 17 of the Berne Convention:

Article 17

The provisions of this Convention cannot in any way affect the right of the Government of each country of the Union to permit, to control, or to prohibit, by legislation or regulation, the circulation, presentation, or exhibition of any work or production in regard to which the competent authority may find it necessary to exercise that right.

It is common for commentators to point out that the main purpose of Article 17 was to allow countries to censor copyrighted articles, and that it does not generally authorize compulsory licenses for any purpose.⁵⁷ The full record of the Stockholm Revision Conference of 1967 makes it clear, however, that Article 17 was not thought to apply only to censorship, but also to other necessary powers such as to promote “public order” and control

⁵⁵ See Berne Convention for the Protection of Literary and Artistic Works art. 9 (2), Sep. 9, 1886, as revised at Paris on July 24, 1971 and amended in 1979, S. Treaty Doc. No. 99-27 (1986) (“It shall be *a matter for legislation* in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.”) (emphasis added).

⁵⁶ Whether constitutional systems permit administrative action to expand or interpret copyright limitations and exceptions is beyond the scope of this article.

⁵⁷ See 1 SAM RICKETSON & JANE C. GINSBURG, INTERNATIONAL COPYRIGHT AND NEIGHBORING RIGHTS: THE BERNE CONVENTION AND BEYOND 841 (2nd ed. 2006) (arguing that “[t]he words to permit give rise to two differing interpretations” and rejecting an interpretation that the provision permits uses outside the limited context of censorship of works); SILKE VON LEWINSKI, INTERNATIONAL COPYRIGHT LAW AND POLICY 171 (2008) (“The governmental right to permit, to control, or to prohibit certain acts reflects the ordinary activity of censorship authorities, which is to decide whether the relevant public order reasons require the prohibition or other control of the work’s circulation.”); PAUL GOLDSTEIN & BERN HUGENHOLTZ, INTERNATIONAL COPYRIGHT: PRINCIPLES, LAW, AND PRACTICE 37 (4th ed., 2019) (“it seems clear that Article 17 does not constitute authority for the governmental imposition of compulsory licenses”).

abuses of monopoly.⁵⁸ At least three countries have implemented Article 17 in their legislation, permitting the executive to order the sharing of copyrighted works to promote critical public interests.⁵⁹

Whether through the TRIPS waiver or an interpretation by WIPO or other bodies, it would be useful to clarify the application of Article 17 as a means for authorizing uses of works needed during COVID-19. A government might be able to use the authority to declare that a copyright exception for

⁵⁸ Together with the proposal for deleting “to permit” from Berne Convention Art. 17, the United Kingdom also proposed “(document S/171)...(ii) the insertion of a new paragraph leaving countries free to enact such legislation as is necessary ‘to prevent or deal with any abuse, by persons or organizations exercising one or more of the rights in a substantial number of different copyright works, of the monopoly position they enjoy’”. Report on the Work of Main Committee I (Substantive Provisions of the Berne Convention: Articles 1 to 20), Svante Bergström (Rapporteur) in 2 WIPO, Records of the Intellectual Property Conference of Stockholm, 1967, at 1174 (1971) (supporting the claim that Article 17 should not be interpreted as limited to censorship). On this matter, “The Committee accepted, without opposition, the proposal of its Chairman that mention should be made in this Report of the fact that questions of public policy should always be a matter for domestic legislation and that the countries of the Union would therefore be able to take all necessary measures to restrict possible abuse of monopolies. Whereupon, the proposals of Australia and the United Kingdom relating to abuse of monopoly were withdrawn.” *Id.* at 1175

⁵⁹ See Law No. 65-00 on Aug. 21, 2000, art. 48 [Copyright Act] (Dom. Rep.) (“Prior to the expiry of the term of protection of a work, the State may order the use, for reasons of public necessity, of the economic rights in a work that is considered to be of high cultural, scientific or educational value for the country, or of social or public interest, subject to payment of fair compensation to the holder of said rights.”); Ley n. 14 de 28 de diciembre de 1977 de Derecho de Autor, art. 37 [Copyright Act] (Cuba) (“For reasons of social interest, the competent authority may grant a license to reproduce and publish in printed or other analogous a work published in the same way, or to translate and edit it, or to broadcast it on radio, television or other sound or visual media, in its original language or in translation, or to reproduce in audiovisual form any fixation of the same nature, without the authorization and remuneration provided in subsections c), ch) and d) of Article 4 of this Law, and provided that the following conditions are met: a) that the work is necessary for the development of science, technology, education or professional improvement; b) that its distribution or dissemination is free of charge or, in the case of sale of printed materials, it is carried out non-profit; c) that its distribution or diffusion takes place exclusively in the territory of the Cuban State.”); Ley Federal del Derecho de Autor, publicada en el Diario Oficial de la Federación el 24 de diciembre de 1996, art. 147 [Copyright law] (Mex.) (“The publication or translation of literary or artistic works necessary for the advancement of national science, culture and education is considered of public utility. When it is not possible to obtain the consent of the owner of the corresponding economic rights, and through the payment of compensatory remuneration, the Federal Executive, through the Ministry of Culture, ex officio or at the request of a party, may authorize the mentioned publication or translation. The foregoing shall be without prejudice to the international treaties on copyright and related rights signed and approved by Mexico.”).

uses in the classroom⁶⁰ or “on the premises”⁶¹ of a library apply during COVID to digital extensions of the institution. Or a government might declare that, during COVID, exceptions for “reproductions” for “research” should be interpreted to permit text and data mining as well as the reverse engineering of software needed to repair critical devices. And all countries should be advised to integrate the Article 17 authority into their laws, as have Cuba, the Dominican Republic and Mexico.⁶²

B. Trade Secret Compulsory Licensing

International guidance is also needed to clarify the rights of countries to compulsory license or otherwise permit the use of trade secrets and know how. In Brazil, for example, the legislature is considering a draft law on compulsory licensing that compels patent holders to divulge all “necessary technical information, including biological materials, to enable the reproduction of the technology by third parties.”⁶³ TRIPS does not, however, provide governments the explicit authority to compel disclosure of trade secrets.⁶⁴ The TRIPS Waiver applied to trade secrets may be the best short term option for clarifying that international law permits emergency orders to disclose trade secrets for COVID-19 related treatments and devices.⁶⁵

⁶⁰ See, e.g., Law of Ukraine No. 3792-XII of Dec. 23, 1993, on Copyright and Related Rights (as amended up to April 26, 2017) art.23 (Ukr.) (“It is allowed without the consent of the author or another person who has copyright: ... 2) *reprographic reproduction by educational institutions for classrooms* of published articles and other small-volume works, as well as excerpts from written works with or without illustrations, provided that: a) the volume of such reproduction meets the specified purpose; b) the reproduction of the work is an isolated case and is not systematic;”) (emphasis added)

⁶¹ See, e.g., Copyright Act 2018, art. 20 (4) (Act n. 8/2018) (Kiribati) (“A cultural institution does not infringe copyright in a work in its collection by copying the work for the purpose of allowing access to that copy by users of the institution whether for personal use or study *on the institution's premises* (with or without technical equipment) or by way of a loan”) (emphasis added).

⁶² See note 59 above.

⁶³ Medecins Sans Frontieres Access Campaign, *Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies* (MSF Briefing Document, 2021) https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf. India ordered the release of trade secrets and know how from companies in the past. See Kasturi Rangan, *India Demands ‘Know-How’ and 60% Share of Coca-Cola Operation*, THE NEW YORK TIMES (Aug. 9, 1977), <https://www.nytimes.com/1977/08/09/archives/india-demands-knowhow-and-60-share-of-cocacola-operation-company.html> (describing Coca-Cola’s cessation of operations in India in 1977 due to the government’s demand for compulsory transfer of know-how).

⁶⁴ TRIPS obliges countries to protect trade secrets, Art. 39(2), subject to a right to order the disclosure of undisclosed data or other information required “as a condition of approving the marketing of pharmaceutical or of agricultural chemical products” if such disclosure is “necessary to protect the public.” Art. 39(3). Not all of the needed know how discussed above may have been submitted to regulatory authorities and therefore may not fall within the exception in 39(3).

⁶⁵ Promoting the disclosure of trade secrets could require programs to incentivize

CONCLUSION

The WTO TRIPS waiver proposal is one example of international action that can be taken to clarify the flexibilities in international intellectual property law to address COVID-19. Extending the waiver to the uses of all intellectual property law needed for vaccines, treatments and containment measures would clarify that no country could be challenged under the WTO's dispute settlement mechanism for actions to permit uses of intellectual property for the purposes discussed in this Article. Given that the Berne Convention is incorporated into the TRIPS Agreement, the waiver could provide a supplementary means of interpreting Berne Article 17. Alternatively, an agreement or recommendation could be adopted by WIPO to similar effect. Technical assistance and other projects are also needed to help countries implement the flexibilities they have, including through legislative change and emergency regulations authorized by Berne Article 17.

voluntary action as well, for example through buy outs. See James Love, *Buying Know-How to Scale Vaccine Manufacturing*, MEDIUM (March 20, 2021) (describing US government purchase of manufacturing know-how from BioNtech and AstraZeneca's purchase of know-how from Oxford University) <https://jamie-love.medium.com/buying-know-how-to-scale-vaccine-manufacturing-586bdb304a36>; Siva Thambisetty et al., *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic*, 6 (LSE Legal Studies Working Paper No. 06-2021) (opining that "incentives ('carrots') for voluntary disclosures" "may be more palatable, politically"), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737. Commitments to share know how and trade secrets can be included in government funding contracts, for example. Garrison, *supra* note 40; Pascale Boulet et al., *Advanced Purchase Agreements for COVID-19 Vaccines: Analysis and Comments*, MEDICINES LAW & POLICY (Juj. 2021) (criticizing lack of disclosure requirements in funding contracts from western governments), <https://left.eu/content/uploads/2021/07/Advanced-purchase-agreements-1.pdf>.