

International Copyright Flexibilities for Prevention, Treatment and Containment of COVID-19

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TWN
Third World Network

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Containment of COVID-19**

Published in 2022 by

Third World Network Bhd (198701004592 (163262-P))

131 Jalan Macalister

10400 Penang, Malaysia

www.twn.my

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Acknowledgements

This was first published as an article in *The African Journal of Information and Communication (AJIC)* (2022, Issue 29, pp. 1-19, <https://doi.org/10.23962/ajic.i29.13985>) under a Creative Commons Attribution 4.0 International (CC BY 4.0) licence.

The article draws on the contents of the authors' 2021 PIJIP/TLS Research Paper (Flynn, Nkrumah, & Schirru, 2021). Research reported in the article was aided by members of civil society and academic networks of the Right to Research in International Copyright Law project of the Program on Information Justice and Intellectual Property at American University Washington College of Law (PIJIP). The authors thank Teresa Hackett of Electronic Information for Libraries (EIFL), who advised on the literature examined and reported on in the article, and Prof. Jorge Contreras and Prof. Jonas Anderson for their comments and assistance during the research. The researchers are grateful for the financial support provided by Arcadia, a charitable fund of Lisbet Rausing and Peter Baldwin, to PIJIP and PIJIP's Right to Research project.

1

Introduction

THERE is a growing understanding that COVID-19 vaccine patents – which cover inventions that were supported by substantial public funding – should be opened to competition in the public interest (see, for example, Buranyi, 2021; Tedros, 2021). This understanding is prominently expressed in the 2021 proposal by India and South Africa that the World Trade Organisation (WTO) implement a “Waiver from Certain Provisions of the TRIPS [Trade-Related Aspects of Intellectual Property Rights] Agreement for the Prevention, Containment, and Treatment of COVID-19” (hereafter “TRIPS waiver”) (WTO, 2021).¹ The final result was a June 2022 WTO Ministerial Decision (WTO, 2022) which waives a part of TRIPS rules on compulsory licences for patents so as to allow developing countries to more freely import and export generic vaccines.

The logic underlying calls for suspension of certain intellectual property rules in relation to COVID-19 vaccine inventions rests on a weighing of the costs and benefits of granting exclusive rights to information. Generally, the protection of exclusive rights to use information resources may benefit social welfare through incentives to create information goods, even where some access to those goods is curtailed. But enforcement of exclusive rights can also cut the other way. Enforcement of too many intellectual property rights can unduly raise the cost of innovation, “with strong IPR enforcement actually deterring innovative efforts” (Dosi & Stiglitz, 2013, p. 22). Especially when applied in countries with high income inequality, strong intellectual property rights can incentivise exclusionary pricing, causing undue economic and moral harm (Flynn et al., 2009; Pogge, 2005).

The economic and moral logic of opening intellectual property rights where necessary to promote the public interest is more broadly applicable. Copyright laws give authors of original expressive “works” an exclusive right to reproduce those works and make other uses of their expression. Copyright law, like patent law, contains numerous limitations and exceptions that allow certain uses of protected materials without permission of the right holder. All copyright laws permit quotation of works by others without licence, for example, because such use serves broader societal interests in free expression and information-sharing that outweigh the author’s interest in compensation and control. Most copyright laws also permit unlicensed uses for education, research and other uses. But as described more fully below, such exceptions are, around the world, much less uniform than the quotation right. The COVID pandemic provides a unique window into the problems that inadequate copyright exceptions can cause.

This paper surveys barriers to COVID responses that are posed by copyrights – barriers that would have been covered had the WTO adopted the broad TRIPS waiver proposal from South Africa and India. Chapter 2 explains copyright dimensions that can prevent equitable participation in scientific research. Chapter 3 discusses copyright dimensions that can block the creation, marketing, and repair of health technology. Chapter 4 surveys the copyright dimensions that can frustrate online learning and research in the context of mandatory social distancing that, over the past two years, closed down many schools and cultural heritage institutions. Chapter 5 concludes with reflections on international copyright law provisions that make clear that countries are free to implement exceptions to permit essential activities, including through emergency regulations. It is hoped that this brief review of copyright problems and solutions to them can help policymakers respond to the immediate crisis as well as to review their laws to ensure adequate flexibility for serving the general public interest.

2

Copyright Barriers to COVID-19-Related Research

RESEARCH is essential to development of vaccines and treatments, and to contributions to scientific progress. Such research may require access to copyrighted works. For example, advanced research methodologies using text and data mining (TDM) can require the copying of thousands and millions of copyright-protected works. But in many countries, these critical uses of research materials can be prevented through a lack of copyright permissions.

Access to research material

Health professionals rely on researchers to track a virus, identify vaccine and treatment candidates, and search for other clues as to how society can best respond. Researchers, in turn, rely for their study on access to materials through libraries and other repositories. During COVID, many of those repositories of knowledge were physically closed, cutting researchers off from the sources they needed for their study. This constraining of access to materials during COVID may help to explain why about a fifth of researchers globally reported that COVID significantly altered, or halted, their work (Rijs & Fenter, 2020).

Researchers and governments have called for voluntary efforts by publishers to provide open access to research materials and data, so as to aid the global fight against the pandemic (European Commission, 2020b; White House Office of Science and Technology Policy, 2020).² Many publishers responded by making publications relevant to COVID-19 freely available (Wellcome, 2020). However, the number of articles being made available through open-licensed platforms is diminishing over time. Brainard (2021) reports, for example, that the number of free-to-read COVID-19 papers decreased from 85% in May 2020 to 77% in September 2021.

In the digital age, the closing of a physical library need not cut a researcher off from access to information. As described below, international copyright treaties include provisions permitting exceptions for public interest uses, including allowing for emergency access to copyrighted materials. Some repositories in countries with relatively open and flexible copyright exceptions adopted temporary digital access policies to aid researchers (HathiTrust, n.d.). But many copyright laws require libraries to restrict access to digital materials to “the premises” of the library.³ In such countries, researchers may face significant hurdles in continuing their work when physical premises close, as occurred frequently during COVID.

Text and data mining

Text and data mining – in which computational processes are used to derive data from or about a corpus of works – has been central to many research breakthroughs regarding COVID-19. The outbreak was discovered by BlueDot, a Canadian TDM company that tracks emerging health threats by analysing “a variety of information sources, including chomping through 100,000 news reports in 65 languages a day” (Stieg, 2020). TDM projects, including machine-learning systems and computational analyses, have also “played an important role in the vaccine quest” (Waltz, 2020), including “helping researchers understand the virus and its structure, and predict which of its components will provoke an immune response” (Arnold, 2020).

Many of the materials used for COVID-related data mining projects are covered by copyright. These include the news articles mined by BlueDot and the scientific articles mined by vaccine researchers. Nearly every copyright law in the world has an exception allowing research uses of copyrighted works. But few of those research exceptions are broad enough to fully permit even non-commercial TDM research (see Carroll, 2019, describing the flexibility in US law as providing a “comparative advantage” for US researchers and firms). The lack of copyright exceptions for text and data mining may be one reason that research on COVID has been primarily located in the US and EU, where research exceptions are common. In July 2021, for example, a group of researchers in India was forced to retract a paper on vaccine hesitancy and COVID-19 because the group lacked a licence to mine a database of news articles used in the study (Retraction Watch, 2021).

3

Copyright Barriers to COVID-19 Vaccines and Treatment

USES of vaccines, treatments and devices are essential to save lives threatened by COVID-19. Patents are not the only form of intellectual property that can prevent such uses. Copyright protections can also be a hindrance.

Algorithms for mRNA vaccines

Vaccine developers use computational algorithms in the creation of mRNA vaccines. Such algorithms aid in the identification of microRNAs (miRNAs) that “target gene expression at post-transcriptional level” (Ray & Pandey, 2017). Critical to this process is the use of computational algorithms and other research tools that have been identified as essential to understanding the virus and its structure (Waltz, 2020). Algorithms are subject to copyright protection in many countries, raising the possibility that even without patent barriers mRNA production can be blocked by a refusal to share essential intellectual property (see Asay, 2020; Michaels, 2018; Noto La Diega, 2018).

Product labels and package inserts

Labels and package inserts may be considered protected by copyright in some countries. A recent report by the WTO, the World Health Organisation (WHO), and the World Intellectual Property Organisation (WIPO) (2020) provides examples of litigation in South Africa and Australia that used such copyright claims to block generic entry into medicine markets. A South African court, for example, precluded a generic manufacturer from reproducing copies of package inserts for its generic antibacterial medicine – due to the existence of copyright coverage. Package inserts are often required by regulations to

be included with marketed products, and thus a refusal to license reproduction of such inserts may block generic entry into the market.

A similar decision was reached by an Australian court in 2011, prior to the amendment of the country's copyright legislation to permit the use of already existing product information. There is a similar history in the United States of pharmaceutical companies making (ultimately ineffective) copyright-protection claims on labels and inserts to block generic market entry (Rosen, 2017; Termini & Miele, 2013).⁴

Right to repair

COVID-19 has created a significant increase in the need for health professionals to repair ventilators and other devices. But copyright can stand in the way. Repair professionals often need access to manuals that are protected by copyright. Koebler (2020) describes how manufacturers have established 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”. In a recent example reported by the Electronic Frontier Foundation (EFF), a maker of sterilisation-related devices used during COVID treatment demanded that its products' documentation be taken down from an open-access repository (Walsh, 2020; Wheatley, 2020).

Ventilators and other medical devices may also have copyrighted software integrated into their operation (see Medtronic, n.d.). Accordingly, to repair such equipment, copyright permission to access the software and bypass technological protection measures may be required (see Grinvald & Tur-Sinai, 2019). The small number of instances of voluntary licensing of COVID-related software (see Baharundin, 2020; Bluetrace Protocol, n.d.) do not include the most-needed copyrighted software for COVID-related medical devices. A complaint to the US Congress by over 300 hospital repair experts (Proctor, 2020) led to the introduction of a bill to eliminate “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” (Wyden, 2020). Right-to-repair laws and regulations have

been proposed in numerous other countries as well (see Moore, 2019; Montello, 2020).

3D-printing files and 3D-printed objects

3D-printing technology can produce replacement parts for ventilators and other devices. Copyright can cover the 3D digital file needed to print such objects, and copyright or design rights may cover the form and shape of the printed object (Malaty & Rostama, 2017). In one recent example in Italy, access to copyrighted files and manuals needed to print ventilator valves was reportedly denied to researchers attempting to use 3D printing to fill critical parts shortages during the COVID-19 outbreak (see Brown, 2020; Urian B, 2020a, 2020b).

Equipment standards

The production of personal protective equipment (PPE) can be subject to copyright-protected standards that need to be licensed from standard-setting organisations. To address shortages of PPE, the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation granted open access to their copyrighted standards for PPE production (European Commission, 2020a). 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” (European Commission, 2020a).

4

Copyright Barriers to COVID-19 Containment Through Social Distancing

TO promote social distancing during COVID, as encouraged by WHO (2019), essential public institutions – including schools, universities, libraries, archives, and museums – were closed for extended periods. According to the UN (2020), COVID-19 “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”.

To enable essential activities like education and research to continue when physical institutions are closed, it is essential that copyright laws permit digital access for public interest uses such as education and research. The WIPO Copyright Treaty (1996) requires that its members’ national laws provide copyright holders with a right of “communication” or of “making available” of works through digital platforms. In the absence of an operative exception to this right, materials from a library or school cannot be shared online.

In response to COVID, some publishers have adopted voluntary efforts to make some works available for digital uses by libraries and schools, such as to conduct children’s storytime readings online (see Access Copyright, n.d.1). But these efforts have been largely insufficient. In reviewing publishers’ voluntary pledges to allow copyright-free educational uses of their materials, Craig and Tarantino (2020) find 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” (2020, p. 20). In the South African context, Nicholson (2020) reports that university professors faced problems obtaining permission for sharing of learning materials on password-protected e-learning platforms when physical reserves for course materials in the library were closed because of COVID.

5

Copyright Flexibilities for COVID-19

COPYRIGHT law need not stand in the way of critical activities that are necessary to respond to COVID or to serve other public interests. Copyright laws, like laws on patents, are governed by international treaties that create certain minimum standards of protection that most countries have agreed to follow. The Berne Convention for the Protection of Literary and Artistic Works (1886) requires that all countries protect a right of authors to exclude others from reproducing their works.⁵ The 1996 WIPO Copyright Treaty (WCT) requires its members to protect a right to exclude others from “communicating” a work, such as on the internet.⁶ All of the activities described above in Chapters 2 to 4 require either a reproduction or communication of protected works that could implicate the copyright protections that are internationally required in terms of the Berne Convention and the WCT. But these protections are not absolute. The international copyright architecture contains ample flexibility for countries to adopt exceptions to these rights to serve the public interest, including the particular public interest needs present in an emergency.

Reproductions

The Berne Convention was originally drafted in 1886 and has been subject to numerous amendments since then. The original Convention focused on ensuring that all countries treated foreign and local authors similarly through a so-called “national treatment” requirement. That version did not require countries to protect a right of reproduction, even though such a right was the core of most copyright laws at the time. It nevertheless included a specific exception, then in Article 8, safeguarding the ability of each country to

recognise “the liberty of extracting portions from literary or artistic works for use in publications destined for educational or scientific purposes”.

The 1967 Stockholm revision of the Berne Convention added the right of reproduction in Article 9(1).⁷ The Stockholm revision’s Article 9(2) grants countries the general authority “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”. Furthermore, the Stockholm revision’s Article 10(2) added a permissive exception for educational uses – allowing countries to authorise utilisation “by way of illustration in publications, broadcasts or sound or visual recordings for teaching”.

Articles 9(2) and 10(2) are open to a variety of public interest exceptions. Article 9(2) allows countries to permit reproductions of any work, by any user, for any purpose – as long as the other steps of the test protecting the author’s rights are adhered to. Article 10(2) is restricted to educational uses, but similarly applies to a use of any work by any user. The terms are drafted in such a way that they are flexible enough to be applicable in the digital environment and to permit uses needed in a pandemic.

Communication to the public

The 1996 WIPO Copyright Treaty was the first to require copyright laws to protect an exclusive right of “communication to the public”. The WCT was specifically crafted to apply on the internet – applying to acts of sharing “by wire or wireless means, including the making available to the public of their works in such a way that members of the public may access these works from a place and at a time individually chosen by them” (WCT, Art. 8). Thus, depending on how it is implemented in national law, the WCT’s copyright protection of communication may restrict libraries, schools, and other institutions from sharing access to their collections digitally, including during COVID. This protection is not, however, absolute.

Like the Berne Convention, the WCT authorises limitations and exceptions to the communication right through an open exception:

Contracting Parties may, in their national legislation, provide for limitations of or exceptions to the rights granted to authors of literary and artistic works under this Treaty in certain special cases that do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the author. (WCT, Art. 10(1))

Moreover, an agreed statement makes clear that WCT Contracting Parties may “carry forward and appropriately extend into the digital environment limitations and exceptions in their national laws which have been considered acceptable under the Berne Convention”.⁸ It is thus clear that countries may extend traditional exceptions, such as for educational and research uses, to digital uses. A country could, for example, permit course materials to be used online to the same extent as in a classroom, or permit libraries to share research materials digitally with their patrons.

Emergency uses

Despite the flexibility provided for in international copyright legal instruments, many national copyright laws fail to provide adequate exceptions for modern digital uses. This is in part because many laws are highly specific as to the uses, works and users that may benefit from exceptions, thus not anticipating present needs (see Flynn et al., 2022, describing measurements of the “openness” of limitations and exceptions). A study by Flynn, Schirru, Palmedo, and Izquierdo (2022) reviews research exceptions around the world and finds that while nearly every national copyright law has at least one exception that promotes uses for research purposes, very few (those in green in Figure 1) fully authorise the full range of research uses of all works by all users that are needed to engage in TDM and many of the other activities, as described above, necessary to respond to COVID.

The lack of adequate limitations and exceptions for addressing COVID in many national copyright laws raises the question, under international law, of whether countries can take non-legislative measures to permit uses of copyrighted works during an emergency. One possible source of such authorisation can be found in Article 17 of the Berne Convention.

The WTO's June 2022 Ministerial Decision on the TRIPS Agreement (WTO, 2022) includes international recognition of an ability to administratively override patent rights:

2. For greater clarity, an eligible Member may authorize the use of the subject matter of a patent under Article 31 without the right holder's consent through any instrument available in the law of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place. For the purpose of this Decision, the "law of a Member" referred to in Article 31 is not limited to legislative acts such as those laying down rules on compulsory licensing, but it also includes other acts, such as executive orders, emergency decrees, and judicial or administrative orders.

Although the WTO Ministerial Decision does not extend to copyright, a similar authorisation has long existed in Article 17 of the Berne Convention, which states:

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.

Article 17's authorisation of "necessary" measures to permit uses of copyrighted works by "regulation" and "legislation" parallels paragraph 2 of the 2022 WTO Ministerial Decision. Article 17 permits a country to use general emergency authorities to interpret or declare copyright protections to not apply to certain necessary uses of materials.

At least three countries (the Dominican Republic, Cuba and Mexico) have implemented the Berne Convention's Article 17 in their national copyright legislation, permitting the executive to order the sharing of copyrighted works to promote critical public interests.⁹

One possible government response to COVID, in terms of Article 17, “to permit [...] by [...] 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”, could be a declaration that a copyright exception for uses “in the classroom” or “on the premises” of a library will be administratively interpreted as applying to digital access to the same extent as to person use. Alternatively, a government might declare that, during COVID, exceptions for “reproductions” for “research” should be interpreted as permitting TDM, and/or permitting the reverse engineering of software needed to repair critical devices.

6

Conclusion

COPYRIGHTED works are critical non-patent forms of intellectual property that can be used to monopolise health markets and impede equitable responses to COVID. Copyrighted materials, including software, are essential for COVID-19-related research, for manufacture and repair of medical devices and equipment, for manufacture of mRNA vaccines, and for social distancing in education and other spheres required to contain outbreaks. Copyright issues were left out of the 2022 WTO Ministerial Decision implementing a limited waiver of TRIPS rules on the compulsory licensing of patents. However, that omission need not dissuade governments from acting. International copyright treaties contain flexibilities that permit exceptions to copyright protections for reproductions and digital communications, including through emergency decrees and executive action.

Endnotes

1. The 2021 proposal was a revised version of the original proposal made by the same two countries in 2020.
2. A letter from the national science and technology advisors of 12 countries to the members of the scholarly publishing community (13 March 2020), <https://wellcome.org/sites/default/files/covid19-open-access-letter.pdf>, called for action to open access to research materials to help scientists “to 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”.
3. See, e.g., Australian Copyright Act, 1968 (Act No. 63, 1968, consolidated as of 1 January 2019), Art. 9(1)(v) (limiting the ability of libraries to communicate works in their collections “for the purpose of research or private study, to individual members of the public by dedicated terminals on the premises of establishments”); Law of Ukraine No. 3792-XII of 23 December 1993, on Copyright and Related Rights (as amended up to 26 April 2017), Art. 23 (limiting digital uses to “on the premises” of a library); and Kiribati Copyright Act 2018 (Act No. 8/2018), Art. 20(4) (limiting educational uses to a “classroom”).
4. See, for example, *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm, Inc.*, 211 F.3d 21 (2d Cir. 2000), cert. denied, 531 US 872 (2000), rejecting copyright claims to label information as grounds for restricting marketing of a generic drug.
5. Berne Convention for the Protection of Literary and Artistic Works (1886), <https://wipolex.wipo.int/en/treaties/textdetails/12214>
6. WIPO Copyright Treaty, 20 December 1996. S. Treaty Doc. No. 105-17 (1997); 2186 U.N.T.S. 121; 36 I.L.M. 65 (1997), <https://wipolex.wipo.int/en/treaties/textdetails/12740>
7. Berne Convention for the Protection of Literary and Artistic Works (1886), as revised at Stockholm on 14 July 1967, <https://wipolex.wipo.int/en/text/278720>
8. See agreed statement on Article 10, in Agreed Statements Concerning the WIPO Copyright Treaty (adopted by the Diplomatic Conference on 20 December 1996), <https://wipolex.wipo.int/en/text/381455>
9. See the Dominican Republic’s Law No. 65-00 on 21 August 2000, Art. 48; Cuba’s Ley n. 14 de 28 de diciembre de 1977 de Derecho de Autor, Art. 37; and Mexico’s Ley Federal del Derecho de Autor, publicada en el Diario Oficial de la Federación el 24 de diciembre de 1996, Art. 147.

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INTERNATIONAL COPYRIGHT FLEXIBILITIES FOR PREVENTION, TREATMENT AND CONTAINMENT OF COVID-19

Most policymaking attention with respect to intellectual property barriers to COVID-19 prevention, treatment and containment has been focused on patents. This focus is reflected in the World Trade Organisation (WTO) Ministerial Decision on the TRIPS Agreement, adopted on 17 June 2022, which provides a limited waiver of TRIPS rules on compulsory licences for production of COVID-19 vaccines. The original WTO proposal for a TRIPS waiver, however, explicitly applied to all forms of intellectual property, including copyright. This paper outlines the numerous ways in which copyright can create barriers to addressing COVID-19. It also provides a description of international copyright treaty provisions that permit uses of copyright materials in response to the barriers identified, despite the exclusion of copyright from the final TRIPS waiver.

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