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THE PEOPLE'S VACCINE: INTELLECTUAL PROPERTY, ACCESS TO ESSENTIAL MEDICINES, AND COVID-19

MATTHEW RIMMER

*

Abstract

This paper explores intellectual property and access to essential medicines in the context of the COVID-19 public health crisis. It considers policy solutions to counteract vaccine nationalism and profiteering by pharmaceutical companies and vaccine developers. It discusses the campaign for the development of a People's Vaccine led by the People's Vaccine Alliance, UNAIDS, Oxfam and Public Citizen. This paper charts the ACT Accelerator developed by the WHO in order to boost research, development, and deployment of COVID-19 technologies. It comments on the role of the Medicines Patent Pool in the coronavirus crisis, as well as Costa Rica's proposed for a COVID-19 Technology Access Pool. In the context of the coronavirus public health crisis, the article also discusses the use of compulsory licensing and Crown use to counteract profiteering and anti-competitive behaviour. The article takes note of the growing Open Science movement in response to the assertion of proprietary rights in respect of COVID-19 technologies. India and South Africa have put forward a waiver proposal in the TRIPS Council to enable countries to take action in respect of COVID-19 without fear of retribution under trade laws; however, this has been opposed by multiple countries. This paper makes the case that international intellectual property law should accommodate

a *People's* *Vaccine*

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INTRODUCTION

The current controversy over intellectual property and access to vaccines during the coronavirus crisis in 2020-2021 has its origins in a long history of international legal conflict over patent law and public health.

Legal systems have long had to deal with the emergency circumstances of public health epidemics.

¹ In the past, there has been concern about patent races in respect of medicines during public health epidemics.² In the 1980's, there was a debilitating patent race in respect of diagnostics for HIV/AIDS – which was eventually resolved through an agreement between the governments of France and the U.S..³ The Agreement on Trade-Related Aspects of Intellectual Property Rights [“TRIPS Agreement”] laid down a framework for the protection of intellectual property rights, with due recognition of public interest objectives, such as the protection of public health.⁴ In the 1990's, there were dramatic conflicts between South Africa and large pharmaceutical companies over access to medicines sourced from India.⁵ In the end, the resolution of this conflict led to the recognition of the Doha Declaration on the TRIPS Agreement and Public Health [“Doha Declaration”] in 2001 – which recognized that nation states could make use of flexibilities to address public health epidemics.⁶ There have nonetheless

¹ DAVID WALTNER-TOEWS, ON PANDEMICS: DEADLY DISEASES FROM BUBONIC PLAGUE TO CORONAVIRUS (2020); JONATHAN QUICK & BRONWYN FRYER, THE END OF EPIDEMICS: HOW TO STOP VIRUSES AND SAVE HUMANITY NOW (2020); PETER S. DOHERTY, PANDEMICS: WHAT EVERYONE NEEDS TO KNOW (2013); JOHN FABIAN WITT, AMERICAN CONTAGIONS: EPIDEMICS AND THE LAW FROM SMALLPOX TO COVID-19 (2020).

² GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS, AND DEVELOPMENT (Peter Drahos & Ruth Mayne eds., 2003); INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO MEDICINES (Thomas Pogge, Matthew Rimmer & Kim Rubenstein eds., 2010); CYNTHIA HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS (2011); BURCU KILIC, BOOSTING PHARMACEUTICAL INNOVATION IN THE POST-TRIPS ERA: REAL-LIFE LESSONS FOR THE DEVELOPING WORLD (2014); ELLEN ‘T HOEN, PRIVATE PATENTS AND PUBLIC HEALTH: CHANGING INTELLECTUAL PROPERTY RULES FOR ACCESS TO MEDICINES (2016); INTELLECTUAL PROPERTY LAW AND ACCESS TO MEDICINES: TRIPS AGREEMENT, HEALTH AND PHARMACEUTICALS (Srividhya Ragavan & Amaka Vanni eds., 2021); ACCESS TO MEDICINES AND VACCINES: IMPLEMENTING FLEXIBILITIES UNDER INTELLECTUAL PROPERTY LAW (Carlos Correa & Reto Hilty eds., 2021).

³ Michael Kirby, *Foreword*, in MATTHEW RIMMER, INTELLECTUAL PROPERTY AND BIOTECHNOLOGY: BIOLOGICAL INVENTIONS (2008).

⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

⁵ Mark Heywood, *South Africa's Treatment Action Campaign: Combining Law and Social Mobilization to Realize the Right to Health*, 1 J. HUM. RIGHTS PRACT. 14 (2009); Amy Kapczynski & Jonathan Michael Berger, *The Story of the TAC Case: the Potential and Limits of Socio-economic Rights Litigation, in South Africa*, in HUMAN RIGHTS ADVOCACY STORIES 43 (Deena Hurwitz & Margaret Satterthwaite eds., 2009); NATHAN GEFFEN, DEBUNKING DELUSIONS: THE INSIDE OF THE TREATMENT ACTION CAMPAIGN (2010); DYLAN MOHAN GRAY, FIRE IN THE BLOOD: MEDICINE MONOPOLY MALICE (2012).

⁶ World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration]. See generally, ELLEN ‘T HOEN, THE GLOBAL POLITICS OF PHARMACEUTICAL MONOPOLY POWER: DRUG PATENTS, ACCESS, INNOVATION AND THE

been controversies when developing nations have made use of domestic compulsory licensing provisions – with pharmaceutical companies making procedural and substantive complaints about such measures.⁷ The *WTO General Council Decision 2003* was intended to assist the export of pharmaceutical drugs to developing nations and least developed nations – and has been encoded into the *TRIPS Agreement* in Article 31bis. But in practice, this export mechanism has proven difficult to use – with generic pharmaceutical companies being reluctant to go through the convoluted, bureaucratic steps at a national level; to obtain a compulsory license for the export of medicines.⁸

There has been major litigation over patent law and access to medicines in India – particularly because it has been seen as a “*pharmacy of the developing world*”.⁹ There have been patent disputes about medicines related to infectious diseases – as well as drugs associated with non-communicable diseases, such as cancer. Patent opposition by government entities and civil society organisations has become particularly important in India.¹⁰ There has been much debate accordingly about the use of intellectual property flexibilities in India to address public health epidemics.¹¹ There has been complex politics in respect of disease outbreaks in the wider South- East Asia as well.¹²

There have also been public policy concerns about research and development in respect of neglected diseases – as well as emerging diseases. Especially given the global scale of the public health burden of malaria, there has been much worry about a lack of new treatments for malaria.¹³

APPLICATION OF THE WTO DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH (2009).

⁷ Decision of the General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 (Aug. 30, 2003). See generally, FREDERICK ABBOTT & RUDOLF VAN PUymbroeck, *COMPULSORY LICENSING FOR PUBLIC HEALTH A GUIDE AND MODEL DOCUMENTS FOR IMPLEMENTATION OF THE DOHA DECLARATION PARAGRAPH 6 DECISION* (2012).

⁸ Matthew Rimmer, *Race against Time: The Export of Essential Medicines to Rwanda*, 1 (2) PUBLIC HEALTH ETHICS, 89-103 (2008); James Love, *Open letter asking 37 WTO Members to Declare Themselves Eligible to Import Medicines Manufactured under Compulsory License in Another Country, under 31bis of TRIPS Agreement*, KNOWLEDGE ECOLOGY INTERNATIONAL (2020), <https://www.keionline.org/32707>; Weinian Hu, *Compulsory Licensing and Access to Future COVID Medicines*, CEPS RESEARCH REPORT (2020); Brook Baker, *The Impracticality of Relying on Compulsory Licenses to Expand Production Capacity for COVID-19 Vaccines*, HEALTH GAP (June 6, 2021), <https://healthgap.org/the-impracticality-of-relying-on-compulsory-licenses-to-expand-production-capacity-for-covid-19-vaccines/>; and Muhammad Zaher Abbas, *World Trade Organization's Export-oriented Compulsory Licensing Mechanism: Foreseen Policy Concern for Africa to Mitigate the COVID-19 Pandemic*, 17 (2) JOURNAL OF GENERIC MEDICINES 71-76 (2021).

⁹ *Novartis v. Union of India & Others*, (2014) 6 SCC 1; Hafiz Aziz Ur Rehman, *The Pharmacy of the Developing World: India, Patent Law and Access to Essential Medicines*, (open access PhD thesis, Australian National University), <https://openresearch-repository.anu.edu.au/handle/1885/110380>; Ravinder Gabbie & Jillian Clare Kohler, *To Patent or Not To Patent? The Case of Novartis' Cancer Drug Gleevec in India*, 10 GLOBALIZATION & HEALTH (2014).

¹⁰ Muhammad Zaheer Abbas, *Community-Based Patent Opposition in India: Access to Essential Medicines, Right to Health, and Sustainable Development*, QUT ePrints (2019), <https://eprints.qut.edu.au/205327/>.

¹¹ Janice Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491 (2007); HANS LOFGREN, *THE POLITICS OF THE PHARMACEUTICAL INDUSTRY AND ACCESS TO MEDICINES: WORLD PHARMACY AND INDIA* (2018); MURPHY HALLIBURTON, *INDIA AND THE PATENT WARS: PHARMACEUTICALS IN THE NEW INTELLECTUAL PROPERTY REGIME* (2017).

¹² Sara E. DAVIES, *CONTAINING CONTAGION: THE POLITICS OF DISEASE OUTBREAKS IN SOUTHEAST ASIA* (2019).

¹³ SONIA SHAH, *HOW MALARIA HAS RULED HUMANKIND FOR 500,000 YEARS* (2010); see also, *Malaria*,

There has been an under-investment by pharmaceutical drug companies in relation to tuberculosis.¹⁴ As the Médecins Sans Frontières [“MSF”] have noted, “*Obsolete treatments, the lack of an effective vaccine, and the lack of suitable diagnostic tools make it difficult to control the global TB epidemic.*”¹⁵ The emergence of new strains of influenza – such as avian influenza¹⁶ and porcine influenza¹⁷ – have also tested the intellectual property regime.¹⁸ There was a patent race in respect of genetic sequencing the severe acute respiratory syndrome [“SARS”] virus – and discussion as to whether a patent pool would be appropriate to share key technologies.¹⁹ There has also been controversy over patents being granted in respect of the Middle East respiratory syndrome [“MERS.”²⁰ Furthermore, complicated geopolitical factors were involved in terms of patent filings in respect of diagnostics and medicines developed in relation to the Ebola outbreak.²¹ There has also been intellectual property raised in relation to the Zika outbreak.²² The need is to learn from past history of unruly competition and rent-seeking in the field of medicine, and ensure a co-operative and collaborative approach to the development of COVID-19 technologies. Unfortunately, though, there has often been a historical amnesia – in which the lessons of past public health epidemics are forgotten by present day legislators and policy-makers. The Independent Panel for Pandemic Preparedness and Response has lamented: “*As soon as a health threat or deadly outbreak fades from memory, complacency takes over in what has been dubbed a cycle of panic and neglect.*”²³

MÉDECINS SANS FRONTIÈRES, <https://www.msf.org/malaria>.

¹⁴ Jisnu Das et al., *Use of Standardised Patients to Assess Quality of Tuberculosis Care: A Pilot, Cross-Sectional Study*, 15 (11) LANCET INFECT. DIS. 1305 (2015); Madhukar Pai et. al, *Tuberculosis*, in NATURE REVIEWS DISEASE PRIMERS 16076 (2016); Madhukar Pai et al., *Reducing Global Tuberculosis Deaths - Time for India to Step Up*, 389 (10075) THE LANCET 1174 (2017).

¹⁵ *Tuberculosis*, MÉDECINS SANS FRONTIÈRES, <https://www.msf.org/tuberculosis>.

¹⁶ Andrew Torrance, *Patents to the Rescue – Disasters and Patent Law*, 10 (3) DEPAUL J. HEALTH CARE L. 309 (2007); Dennis Crouch, *Nil: The Value of Patents in a Major Crisis Such as an Influenza Pandemic*, 39 SETON HALL L. REV. 1125 (2009); Eileen Kane, *Achieving Clinical Equality in an Influenza Pandemic: Patent Realities*, 39 SETON HALL L. REV. 1137 (2009); Samuel Oddi, *Plagues, Pandemics, and Patents: Legality and Morality*, 51 (1) IDEA (2011).

¹⁷ Dawn Dziuba, *TRIPS Article 31Bis and H1N1 Swine Flu: Any Emergency or Urgency Exception to Patent Protection*, 20 (2) IND. INT’L & COMP. L. REV. 195 (2010).

¹⁸ WORLD HEALTH ORGANIZATION, *PATENT LANDSCAPE FOR THE H5 VIRUS: INTERIM REPORT* (Nov. 17, 2007), https://www.who.int/influenza/resources/documents/avian_flu_landscape.pdf?ua=1; WORLD INTELLECTUAL PROPERTY ORGANIZATION, *WIPO PATENT SEARCH REPORT ON PANDEMIC INFLUENZA PREPAREDNESS (PIP)- RELATED PATENTS AND PATENT APPLICATIONS* (Apr. 1, 2011), https://www.who.int/influenza/resources/Influenza_FullReport_01Apr2011.pdf.

¹⁹ E. Richard Gold, *SARS Genome Patent: Symptom or Disease?*, 361 (9374) LANCET (2003); Matthew Rimmer, *The Race To Patent The SARS Virus: The TRIPS Agreement And Access To Essential Medicines*, 5 (2) MELB. J. INT’L L. MJIL 335 (2004); James Simon et al., *Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: the Possible Role of Patent Pooling*, 83 (9) BULL. WORLD HEALTH ORG. 707 (2005).

²⁰ Carsten Richter, *European Patent Office Grants Controversial Patent Protecting Virus: Lessons from the Middle East Respiratory Syndrome Coronavirus Outbreak*, 39 NATURE BIOTECHNOLOGY 287 (2021).

²¹ Amir Attaran & Jason Nickerson, *Is Canada Patent Deal obstructing Ebola Vaccine Development?*, 384 (9958) THE LANCET 61 (2014); Matthew Herder et al., *From Discovery to Delivery: Public Sector Development of the rVSV-ZEBOV Ebola Vaccine*, 7 (1) J. L. & BIOSCIENCES (2020), <https://academic.oup.com/ilb/article/7/1/lz019/5706941>; PAUL FARMER, *FEVERS, FEUDS, AND DIAMONDS: EBOLA AND THE RAVAGES OF HISTORY* (2020).

²² KNOWLEDGE ECOLOGY INTERNATIONAL, *An Exclusive License to Patents on a New Zika Vaccine to Sanofi is Contrary to the Provisions of 35 U.S.C. 209(a)(1)* (12 January 2017), <https://www.keionline.org/wp-content/uploads/Zika-12Jan2016-KEI-AFSCME-PFAM-UAEM-BAKER-35USC209a1.pdf>; Ana Santos Rutschman, *Vaccine Liensure in the Public Interest: Lessons from the Development of the U.S. Army Zika Vaccine*, 127 YALE L.J. 651 (2017).

²³ Main Report, *COVID-19: Make It The Last Pandemic*, THE INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE (2021), <https://theindependentpanel.org/wp->

The United Nations Secretary-General Ban Ki-Moon convened a special high-level committee to investigate ways and means of overcoming conflicts and deadlocks over intellectual property and access to medicines.²⁴ The report by former President of Switzerland, Ruth Dreifuss, and other eminent figures made a number of recommendations – such as suggesting that countries make use of intellectual property flexibilities to address public health epidemics.²⁵ Nonetheless, there was resistance to the implementation of the report from a number of developed nations – most notably the U.S. – as well as a range of pharmaceutical drug companies, biotechnology developers, and medical device manufacturers. If the recommendations of the high-level report had been implemented, the international legal system may well have been better prepared for the issues around intellectual property and access to medicines arising in the context of the covid-19 virus.

In the midst of the coronavirus crisis, there has been a growing concern about the problem of vaccine nationalism. Wealthy nations have especially showed a proclivity for buying up and hoarding the vast majority of vaccine supplies. Dr Tedros Adhanom Ghebreyesus, the Director-General of WHO, has said: “*Vaccine nationalism hurts us all and is self-defeating*”.²⁶ He also observed: “*But on the flipside, vaccinating equitably saves lives, stabilises health systems and would lead to a truly global economic recovery that stimulates job creation*.”²⁷ Jason Nickerson from the University of Ottawa and Matthew Herder from Dalhousie University contend: “*If nationalizing vaccine production is to help realize a globally accessible COVID-19 vaccine, then it cannot devolve into vaccine nationalism*”.²⁸ Colum Lynch warns: “*As the world races to develop a vaccine to end the still-raging coronavirus pandemic, ‘vaccine nationalism’ threatens both the near-term fight against COVID-19 and the longer-term prospects of multilateral cooperation*.”²⁹ Brook Baker cautions: “*This unbridled nationalism, interlinked with a broken, profit-driven pharmaceutical system risks obstructing access to life-saving medicines worldwide*.”³⁰ Richard Hass is fearful that the approach of vaccine nationalism will be disastrous, because “*only a handful of countries will be able to produce viable vaccines*.”³¹ Fatima

[content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf](https://www.un.org/content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf).

²⁴ Ban Establishes Eminent Panel to Help Broaden Access to Quality Medicines at Affordable Costs, UNITED NATIONS NEWS (Nov. 20, 2015), <https://news.un.org/en/story/2015/11/516102-ban-establishes-eminent-panel-help-broaden-access-quality-medicines-affordable>.

²⁵ Ruth Dreifuss et al., REPORT OF THE UNITED NATIONS SECRETARY-GENERAL'S HIGH LEVEL PANEL ON ACCESS TO MEDICINES: PROMOTING INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES (2016), <http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>.

²⁶ WHO Director-General, WHO Director-General's Opening Remarks at the Media Briefing on COVID-19, (Jan. 8, 2021), <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-8-january-2021>.

²⁷ *Id.*

²⁸ Jason Nickerson & Matthew Herder, COVID-19 Vaccines as Global Public Goods, in VULNERABLE: THE LAW, POLICY AND ETHICS OF COVID-19, 591 (Colleen Flood et al. eds., 2020).

²⁹ Colum Lynch, ‘America First’ vs. ‘The People’s Vaccine’, FORBES POLICY (July 6, 2020), <https://foreignpolicy.com/2020/07/06/coronavirus-vaccine-nationalism-america-first-covax/>.

³⁰ Brook Baker, US-, China- and EU-First Nationalism and COVID-19 Technology Hoarding Push the Rest of the World to the End of the Line, INFOJUSTICE (June 8, 2020), <http://infojustice.org/archives/42383>.

³¹ Richard Hass, The Politics of a COVID-19 Vaccine, PROJECT SYNDICATE (July 14, 2020), <https://prosyn.org/WCaVyfd>.

Bhutto has questioned the morality of vaccine hoarding by wealthy nations.³² There have been concerns that vaccine nationalism will prolong the pandemic.³³ Equally, there has been a worry about entrusting the vaccine rollout to the capitalist marketplace – given the proclivities of intellectual property regimes to engage in price hiking and profiteering in the past.

This paper will explore how the COVID-19 pandemic has tested the strengths, limits, and flexibilities of patent law, policy, and practice. It will look at what patent flexibilities could be used to ensure the fair and equitable distribution of COVID-19 technologies. It will also examine long-term law reform in respect of intellectual property rights, which will better prepare us for global challenges like the COVID-19 public health pandemic. In terms of its methodology, this paper also builds upon the work of Duncan Matthews, which was focused upon the role of civil society organisations in pushing for access to essential medicines, human rights, and sustainable development.³⁴ Taking inspiration from such research, this paper focuses upon the People's Vaccine Campaign – which has merged into the broad-based People's Vaccine Alliance. This paper also considers the work of key non-government organisations and civil society groups – such as the MSF Access Campaign, Universities Allied for Essential Medicines, and Human Rights Watch. This paper is also informed by the economic scholarship of Mariana Mazzucato.³⁵ Her work is based upon the reform of health innovation – particularly of late in respect of the coronavirus crisis. This paper also draws upon innovation policy in its understanding of the responses of governments and corporations to the coronavirus crisis.³⁶

Drawing upon past research in the area of access to essential medicines, this paper considers a variety of options to address intellectual property and vaccines during the COVID-19 public health crisis. By design, this paper is intended to be an overview and a survey of various options which have been mooted in respect of intellectual property and access to essential medicines

Patricia B. Kirsch, *Rich Countries are Hoarding Vaccines. This is Morally Indefensible*, THE GUARDIAN (Mar. 17, 2021), https://theguardian.com/commentisfree/2021/mar/17/rich-countries-hoarding-vaccines-us-eu-africa?CMP=share_btn_tw.

³³ Elizabeth Melimopoulos, *Why Hoarding COVID Vaccines Could Prolong Pandemic*, AL JAZEERA (Feb. 19, 2021), <https://aje.io/c9ccv>.

³⁴ DUNCAN MATTHEWS, *INTELLECTUAL PROPERTY, HUMAN RIGHTS AND DEVELOPMENT: THE ROLE OF NGOS AND SOCIAL MOVEMENTS* (2011). See also Duncan Matthews, *Reappraising the Relationship between Intellectual Property Rights and Human Rights: A COVID-19 Pandemic Response*, Queen Mary Law Research Paper No. 366/2021, (September 9, 2021).

³⁵ KNOWLEDGE ACCUMULATION AND INDUSTRY EVOLUTION: THE CASE OF PHARMA-BIOTECH (Mariana Mazzucato & Giovanni Dosi eds., 2006); MARIANA MAZZUCATO, *THE ENTREPRENEURIAL STATE: DEBUNKING PUBLIC VS. PRIVATE SECTOR MYTHS* (2014); MARIANA MAZZUCATO, *THE VALUE OF EVERYTHING: MAKING AND TAKING IN THE GLOBAL ECONOMY* (2018); Joad Medeiros, *This Economist Has a Plan to Fix Capitalism. It's Time We All Listened*, WIRED (Oct. 8, 2019), <https://www.wired.co.uk/article/mariana-mazzucato>; Mariana Mazzucato, *How Does Innovation Really Happen?*, WIRED SMARTER (Feb. 21, 2020), <https://www.youtube.com/watch?v=uXWhwereXYo>; MARIANA MAZZUCATO, *MISSION ECONOMY: A MOONSHOT GUIDE TO CHANGING CAPITALISM* (2021).

³⁶ JOSHUA GANS, *THE PANDEMIC INFORMATION GAP AND THE BRUTAL ECONOMICS OF COVID-19: DESIGN THINKING, DESIGN THEORY* (2020).

(rather than just a concentrated focus on a single public policy proposal). Part II considers the call for a People's Vaccine by the People's Vaccine Alliance, Joint United Nations Programme on HIV and AIDS ["UNAIDS"], Oxfam, Public Citizen, and various other leaders. Part III provides an early evaluation of the Access to COVID-19 Tools Accelerator ["ACT Accelerator"] which is designed to accelerate the research, development, and deployment of COVID-19 vaccines, diagnostics, and treatments. Part IV considers the expansion of the role of patent pools considering the precedent of the Medicines Patent Pool, and the new proposal by Costa Rica for the WHO to establish a Coronavirus Technology Access Pool ["C-TAP"]. Part V looks at the threat of compulsory licensing to ensure access to COVID-19 technologies – both for domestic purposes and for export. It also examines the adoption of Crown Use and Government Use measures. Part VI examines the debate over public sector licensing in relation to technologies designed to combat the coronavirus. Part VII explores open models of innovation. After outlining the Open COVID Pledge, it considers various proposals for a model of Open Science. Finally, in Part VIII, there is a discussion of the proposal from India and South Africa to put in place a waiver of the TRIPS Agreement to enable countries to combat the coronavirus ["TRIPS Waiver"]. While the U.S. has been willing to support a TRIPS Waiver for vaccines, there remain a number of countries – such as members of the European Union, Switzerland, Norway, and the United Kingdom – which have opposed the adoption of a TRIPS Waiver. In the conclusion, this paper makes the case that the international intellectual property regime should accommodate a People's Vaccine.

I. THE PEOPLE'S VACCINE

A. The Origins of the People's Vaccine Alliance

In July 2020, UNAIDS and Oxfam called for the establishment of a People's Vaccine.³⁷ They have contended that, "*Governments and international partners must unite around a global guarantee which ensures that, when a safe and effective vaccine is developed, it is produced rapidly at scale and made available for all people, in all countries, free of charge.*"³⁸ They also called for a similar approach to other treatments, diagnostics, and technologies related to COVID-19.³⁹

The People's Vaccine Alliance ["PVA"] is an umbrella movement – "*a coalition of organisations and activists united under a common aim of campaigning for a 'people's vaccine' for COVID-19.*"⁴⁰ The group observes that in order to achieve a "People's Vaccine" it will be necessary to "*[b]reak the shackles of intellectual property on vaccines and*

³⁷ COVID-19 Vaccine Open Letter, UNAIDS (July 14, 2020), https://www.unaids.org/en/resources/presscentre/featurestories/2020/may/20200514_covid19-vaccine-open-letter.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *What is the People's Vaccine Alliance?*, THE PEOPLE'S VACCINE ALLIANCE, <https://peoplesvaccine.org/faq/>.

COVID-19 knowledge.”⁴¹ The PVA elaborates that every nation needs to be able to produce or buy vaccine doses at affordable rates: “All Government leaders must support the WTO proposal by India and South Africa to temporarily waive intellectual property on Covid-19 vaccines, treatments and related technologies.”⁴² The PVA has called on nation states to “force pharmaceutical companies to share their COVID-19-related technology and know-how through the World Health Organization’s COVID-19 Technology Access Pool.”⁴³ The members of the organization include Free the Vaccine, Global Justice Now, the Yunus Centre, Frontline AIDS, Amnesty International, Oxfam, SumOfUs and UNAIDS. The Washington DC based civil society organization Public Citizen have also supported this initiative for a People’s Vaccine.⁴⁴

Having witnessed the tragedy of the HIV/AIDS epidemic in Uganda, Winnie Byanyima has long been a steadfast advocate for access to essential medicines.⁴⁵ She was a panel member of the UN Secretary General’s High Level Panel on Access to Medicines in her capacity as the Executive Director of Oxfam International.⁴⁶ Recalling the tragedy of the HIV/AIDS epidemic, Byanyima has called for a fair and equitable approach to access to essential medicines during the coronavirus crisis.⁴⁷ She has emphasized the need for a human-rights based approach to the COVID-19 response, ensuring that there is health for all, and freedom from discrimination and stigma.⁴⁸ As the Executive Director of UNAIDS, Byanyima has been a champion of the People’s Vaccine: “The right to health is a human right—it should not depend on the money in your pocket or the colour of your skin to be vaccinated against this deadly virus.”⁴⁹ In her view, “A vaccine should be a global public good and free of charge for all.”⁵⁰ Byanyima has sought to frame the question of the People’s Vaccine in terms of human rights, the right to health, universal healthcare, sustainable development, equality, and justice. She observed: “UNAIDS and other members of the People’s Vaccine Alliance are calling for a new approach that puts public health first by sharing knowledge and maximizing supply to make sure that no one is left behind.”⁵¹ She feared that anything short of that would lead to more deaths and

⁴¹ *Id.*

⁴² *Our Demands*, THE PEOPLE’S VACCINE ALLIANCE, <https://peoplesvaccine.org/our-demands/>.

⁴³ *Id.*

⁴⁴ Zain Rizvi, *The People’s Vaccine*, PUBLIC CITIZEN (June 11, 2020), <https://www.citizen.org/article/the-peoples-vaccine/>.

⁴⁵ Jon Cohen, “I’m Known as An Activist.” *New UNAIDS Leader Takes Charge*, SCIENCE (27 November 2019), <https://www.sciencemag.org/news/2019/11/i-m-known-activist-new-unais-leader-takes-charge>.

⁴⁶ Dreifuss, *supra* note 25.

⁴⁷ Winnie Byanyima & Matthew Kavanaugh, *This World Aids Day: The Global Response to HIV Stands on a Precipice*, THE GUARDIAN (Dec. 1, 2020), https://www.theguardian.com/global-development/2020/dec/01/this-world-aids-day-the-global-response-to-hiv-stands-on-a-precipice?CMP=share_btn_tw.

⁴⁸ Winnie Byanyima, *Opening Remarks at the High-Level Meeting on AIDS*, UNAIDS (June 8, 2021), https://www.unaids.org/en/resources/presscentre/featurestories/2021/june/20210608_opening-remarks-unais-executive-director-hlm.

⁴⁹ Press Release, UNAIDS, As pandemic deaths pass 1 million, COVID survivors from 37 countries write to pharmaceutical bosses to demand a People’s Vaccine (Sept. 29, 2020), https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/september/20200929_covid-19-survivors-write-to-pharmaceutical-bosses-to-demand-a-peoples-vaccine.

⁵⁰ *Id.*

⁵¹ Press Release, UNAIDS, President of Nigeria Unites Behind the Call for a People’s Vaccine for COVID-19 (Oct. 16, 2020), https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/october/20201016_president-nigeria-unites-behind-call-for-peoples-vaccine-for-covid19.

economic chaos, forcing millions into destitution.⁵² She called upon the Big Pharma to share their intellectual property to achieve a People's Vaccine.⁵³

Helen Clark, the former Prime Minister of New Zealand, and Winnie Byanyima have expanded upon the case for a People's Vaccine.⁵⁴ The pair maintained: "*Granting one company exclusive rights to the science, know-how and intellectual property of a coronavirus vaccine will prevent us from getting the billions of doses that the world needs.*"⁵⁵ They argued: "*This extraordinary moment calls for a better approach than our current regime of monopoly rights.*"⁵⁶ They suggest: "*Aside from insisting on the sharing of knowledge and intellectual property, rich countries should be urgently financing the rapid expansion of safe manufacturing capacity in developing countries.*"⁵⁷ Clark has added that there is a need for legal guarantees for access to essential medicines: "*The COVID-19 vaccine must not belong to anyone and must be free for everyone.*"⁵⁸

Helen Clark expanded upon such concerns about access to medicines as part of her Independent Panel report on the impact of COVID-19.⁵⁹ For her part, Byanyima has been distressed by the lack of progress on vaccine equity in 2021.⁶⁰ She said that the current situation was inequitable and intolerable: "*Today we are witnessing vaccine apartheid that is only serving the interests of powerful and profitable pharmaceutical corporations while costing us the most harmful route out of this crisis.*"⁶¹ She has warned: "*Failure to change course will come at the cost of millions of lives and livelihoods; to our progress on tackling poverty; to businesses...; and to our collective public health and economic security.*"⁶² Byanyima observed that the costs of vaccine inequality would be global: "*The longer the virus spreads, the greater the risk of patchy immunity, the greater the chance of mutations that could render the vaccines we have and the medicines some people in the world have already received, less effective or ineffective.*"⁶³

Recommendations of the People's Vaccine Campaign

The Government of South Africa has endorsed the TRIPS Waiver – alongside India – in order to realise this ambition of a People's Vaccine.⁶⁴ Cyril Ramaphosa – the President of South Africa has

⁵² *Id.*

⁵³ Winnie Byanyima, *Letter: To Be a People's Vaccine, Big Pharma Must Share Intellectual Property*, FINANCIAL TIMES (Nov. 26, 2020), <https://www.ft.com/content/589c466b-81d1-5773ddf86449>.

Helen Clark and Winnie Byanyima, *World Needs A "People's Vaccine" for Coronavirus, Not a Big-Pharma Monopoly*, THE GUARDIAN (July 23, 2020), https://www.theguardian.com/commentisfree/2020/jul/23/world-needs-coronavirus-vaccine-big-pharma-monopoly-astrazeneca-patent-pandemic?CMP=share_btn_tw.

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ Press Release, OXFAM, *World Leaders Unite in Call for a People's Vaccine Against COVID-19* (May 14, 2020), <https://www.oxfam.org/en/press-releases/world-leaders-unite-call-peoples-vaccine-against-covid-19>.

⁵⁹ THE INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE, *supra* note 23.

⁶⁰ Winnie Byanyima, *We Are Seeing a Global Vaccine Apartheid. People's Lives Must Come Before Profit*, THE GUARDIAN (Jan. 29, 2021), <https://theguardian.com/global-development/2021/jan/29/a-global-vaccine-apartheid-is-unfolding-peoples-lives-must-come-before-profit>.

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ Communication from India and South Africa, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, IP/C/W/669 (Oct. 2, 2020),

supported the call for a People's Vaccine. He has stressed: "*Billions of people today await a vaccine that is our best hope of ending this pandemic*".⁶⁵ He observed: "*As the countries of Africa, we are resolute that the COVID-19 vaccine must be patent free, rapidly made and distributed, and free for all.*"⁶⁶ Ramaphosa observed: "*All the science must be shared between governments.*"⁶⁷ Muhammadu Buhari – the President of the Federal Republic of Nigeria – has endorsed the proposal: "*Only a People's Vaccine with equality and solidarity at its core can protect all of humanity and get our societies safely running again.*"⁶⁸ He noted that "*a bold international agreement cannot wait.*"⁶⁹ Former President of Liberia, Ellen Johnson Sirleaf said: "*Learning the lessons from the fight against Ebola, governments must remove all the barriers to the development and rapid roll out of vaccines and treatments.*"⁷⁰ Imran Khan, the Prime Minister of Pakistan commented: "*We must pool all the knowledge, experience and resources at our disposal for the good of all humanity.*"⁷¹

Nelson Barbosa, former Finance Minister of Brazil, noted: "*Market solutions are not optimal to fight a pandemic.*"⁷² He commented: "*A public health care system, including free vaccination and treatment when that becomes available, is essential to deal with the problem.*"⁷³ Traditionally, the Government of Brazil has been a supporter of the use of TRIPS flexibilities to support access to essential medicines – especially during the HIV/AIDS crisis. However, strangely, the Bolsonaro Government has been an opponent of the TRIPS Waiver.⁷⁴ The Brazilian Senate, though, has voted to suspend patent protection on COVID-19 vaccines.⁷⁵

The call for a People's Vaccine has also been supported by a range of eminent citizens, leaders, and elders. World leaders (past and present) join notable economists, health advocates and others, from the Chair of the Elders and the former President of Ireland, Mary Robinson, to the Nobel Laureate, Joseph Stiglitz, the Director of African Centres for Disease Control and Prevention, Dr John Nkengasong and Dainius Puras, the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

Survivors of COVID-19 from 37 countries have also lent their support to a letter, which advocates for the People's Vaccine.⁷⁶ The signatories to the letter include 242 COVID-19

<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>.

⁶⁵ Press Release, OXFAM, *supra* note 58.

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ UNAIDS, *supra* note 51.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ OXFAM, *supra* note 58.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Brazil: Support Wider Vaccine Production at WTO, HUMAN RIGHTS WATCH (Mar. 9, 2021), <https://www.hrw.org/news/2021/03/09/brazil-support-wider-vaccine-production-wto>.

⁷⁵ Ricardo Brito, Brazil Senate Votes to Suspend Patent Protection on COVID-19 Vaccines, REUTERS (Apr. 30, 2021), <https://www.reuters.com/business/healthcare-pharmaceuticals/brazil-senate-votes-suspend-patent-protection-covid-19-vaccines-2021-04-30/>.

⁷⁶ UNAIDS, *supra* note 49.

survivors from various countries, ranging from South Africa to Finland and New Zealand to Brazil. The signatories also included 190 people from 46 countries who have lost relatives to the virus, and 572 signatories with underlying health conditions, which made them vulnerable to COVID-19. The letter said: “We see no justification why your profit or monopolies should mean anyone else should go through this”.⁷⁷ The letter called on industry leaders to “ensure COVID-19 vaccines and treatments reach everyone who needs them by preventing monopolies, ramping up production and sharing knowledge.”⁷⁸ One of the signatories, Dilafruz Gafurova, 43, from Tajikistan, discussed the difficulties that her family faced during the coronavirus outbreak, and explained: “The reason I am signing this letter is to help others to get [a] vaccine.”⁷⁹ Heidi Chow from Global Justice Now, a member of the People’s Vaccine Alliance said: “Pharmaceutical companies need to pay attention to the demands of people from around the world who have experienced the fear and devastation of COVID-19.”⁸⁰

The economist Professor Mariana Mazzucato has also lent her support to the People’s Vaccine Campaign. She has written a piece with Els Torreele and Henry Lish on the challenges and proposals for delivering the People’s Vaccine.⁸¹ Torreele, Mazzucato and Lishi Li conclude: “Delivering a People’s Vaccine is only a first test: the public sector must finally rise to the challenge to reset its relationship with the private sector and prepare societies for even greater challenges.”⁸² She has also called for a mission-focused approach to biomedical innovation.⁸³ She observed: “The challenge was to develop and produce a COVID-19 vaccine that was affordable and globally accessible – and left no one behind.”⁸⁴ Sanjay Reddy and Arnab Acharya have articulated the economic case for a People’s Vaccine.⁸⁵ They comment: “the current challenge provides a stark demonstration of what is needed for research and development to serve the broader public good.”⁸⁶ Reddy and Acharya have warned: “Failing to do what both sound economics and morality require may keep a life-saving product out of the hands of many of the world’s people, unnecessarily prolonging a global calamity.”⁸⁷

In order to achieve this, the People’s Vaccine Alliance has supported a number of public policy initiatives – including patent pooling, compulsory licensing, government use or crown use, public sector licensing, and open innovation.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ Els Torreele et al., *Delivering a People’s Vaccine: Challenges and Proposals for the Biopharmaceutical Innovation System*, 12 UCL INST. FOR INNOVATION & PUB. PURPOSE POL’Y BRIEF, (2021), https://www.ucl.ac.uk/bartlett/public-purpose/sites/public-purpose/files/iipp-pb12_delivering-the-peoples-vaccine_final.pdf.

⁸² *Id.*

⁸³ MAZZUCATO, MISSION ECONOMY, *supra* note 35.

⁸⁴ *Id.* at 83.

⁸⁵ Sanjay Reddy & Arnab Acharya, *The Economic Case for a People’s Vaccine*, BOSTON REVIEW (Sept. 15, 2020), <http://bostonreview.net/science-nature/sanjay-g-reddy-arnab-acharya-economic-case-peoples-vaccine#.X492ccXLblc.twitter>.

⁸⁶ *Id.*

⁸⁷ *Id.*

C. Opposition to the People's Vaccine Campaign

Ellen 't Hoen laments that there has been little support for the rhetoric about the People's Vaccine amongst wealthy nations.⁸⁸ She noted: *"Unfortunately, despite the lofty promises of the vaccine as a global public good, wealthy nations are not making such demands."*⁸⁹ Achal Prabhala, Benny Kuruvilla, Burcu Kilic and Dana Brown have been concerned that the WTO may seek to stymie the proposal for a "People's Vaccine".⁹⁰ They have advocated: *"As the COVID-19 pandemic aggressively advances, the WTO has the opportunity to sway the planet away from monopoly medicine, and towards a new planetary health system."*⁹¹ They presented the debate as a choice between *"People or profit; a people's vaccine or a debilitating vaccine apartheid."*⁹²

II.

THE ACT ACCELERATOR

In April 2020, the World Health Organization ["WHO"] and its partners launched the Access to COVID-19 Tools ["ACT Accelerator"].⁹³ This initiative was designed to promote research, development, and deployment of vaccines, treatments, diagnostics, and other health equipment designed to address the COVID-19 crisis.

A. The Establishment of the ACT Accelerator

For its part, the WHO has set up the ACT Accelerator – a global collaboration to accelerate the development, production and equitable access to new COVID-19 diagnostics, therapeutics and vaccines.⁹⁴ This new institution was launched at the end of April 2020. According to the WHO, *"The goal of the ACT-A is to end the COVID-19 pandemic as quickly as possible by reducing COVID-19 mortality and severe disease through the accelerated development, equitable allocation, and scaled-up delivery of vaccines, therapeutics and diagnostics to reduce mortality and severe disease, restoring full societal and economic activity globally in the near term, and facilitating high-level control of COVID-19 disease in the medium term."*⁹⁵ WHO emphasized that a key principle underpinning the ACT-Accelerator was the need for equitable distribution of COVID-19 tools to those most in need.⁹⁶

⁸⁸ Ellen 't Hoen, *COVID-19 Crisis and WTO: Why India and South Africa's Proposal on Intellectual Property is Important*, THE WIRE (Oct. 12, 2020), <https://thewire.in/law/covid-19-crisis-wto-intellectual-property-vaccine-public-health>.

⁸⁹ *Id.*

⁹⁰ Achal Prabhala et al., *We can't let the WTO get in the way of a "People's Vaccine"*, THE GUARDIAN (Oct. 15, 2020), http://www.theguardian.com/commentisfree/2020/oct/15/peoples-vaccine-coronavirus-covid-wto?CMP=share_btn_tw. See also Achal Prabhala, *On the Margins of Creative Commons and Open*, CREATIVECOMMONS, YOUTUBE, (October 14, 2021), <https://youtu.be/HIM29oZ6KGE>.

⁹¹ *Id.*

⁹² *Id.*

⁹³ The Access to COVID-19 Tools (ACT) Accelerator, WORLD HEALTH ORGANIZATION, <https://www.who.int/initiatives/act-accelerator>.

⁹⁴ Access to COVID-19 Tools (ACT) Accelerator, WORLD HEALTH ORGANIZATION (Apr. 24, 2020), [https://www.who.int/publications/m/item/access-to-covid-19-tools-\(act\)-accelerator](https://www.who.int/publications/m/item/access-to-covid-19-tools-(act)-accelerator).

⁹⁵ ACT-Accelerator – Frequently Asked Questions, WORLD HEALTH ORGANIZATION, <https://www.who.int/initiatives/act-accelerator/faq>.

⁹⁶ *Id.*

A number of nation states, philanthropists, and civil society organisations have endorsed this initiative. The governments of Austria, Belgium, Canada, France, Germany, Italy, Mexico, Morocco, New Zealand, Norway, Saudi Arabia, South Africa, Spain, and the United Kingdom, as well as the European Commission have supported the ACT-Accelerator. The participating global health organizations include: the Bill and Melinda Gates Foundation, Coalition for Epidemic Preparedness Innovations [“CEPI”], the Global Alliance for Vaccines and Immunizations [“GAVI”], Global Fund to fight AIDS Tuberculosis and Malaria [“GFATM”], UNITAID, the Foundation for Innovative New Diagnostics [“FIND”], the Wellcome Trust, the World Bank Group and the WHO.

The ACT-Accelerator comprises four pillars - diagnostics, therapeutics, vaccines, and the strengthening of the health system. CEPI and GAVI would manage the vaccines program – which is known as COVAX. UNITAID and the Wellcome Trust would look after therapeutics. FIND and the Global Fund will be in charge of diagnostics. There have been costed plans for the work of the ACT-Accelerator. Overall, \$US 31.3 billion has been sought for the ACT-Accelerator.⁹⁷

Germany’s Chancellor Angela Merkel said in 2020 that the global response to the pandemic would be a *“test of our generation’s human kindness”*: *“We will only be able to overcome the pandemic if we achieve a truly global solution to the COVID-19 crisis.”*⁹⁸ However, Merkel shifted her position in 2021 somewhat regarding the sharing of scientific knowledge and innovation in respect of COVID-19, becoming an opponent of the TRIPS Waiver.

Australia’s Prime Minister Scott Morrison has called for the development of *“a safe vaccine, available to all, affordable to all.”*⁹⁹ Likewise New Zealand’s Prime Minister Jacinda Ardern has said: *“We will advocate for universal access for any treatments and vaccines.”*¹⁰⁰ Australia and New Zealand have been playing a productive diplomatic role in encouraging co-operative efforts in respect of research upon the coronavirus COVID-19. However, both nations only belatedly supported a TRIPS Waiver – after the Biden administration declared that it would support a TRIPS Waiver.

Canada’s Prime Minister Justin Trudeau and a number of other world leaders wrote a letter to the

⁹⁷ ACT-Accelerator Investment Case, UNITAID (June 26, 2020), <https://unitaid.org/assets/act-consolidated-investment-case-at-26-june-2020-vf.pdf>.

⁹⁸ European Commission Press Release IP/20/952, Coronavirus Global Response: Kick Off Of New Campaign with Support of Global Citizen (May 28, 2020), https://ec.europa.eu/commission/presscorner/detail/en/ip_20_952.

⁹⁹ Prime Minister of Australia, Transcript of Video Message - Coronavirus Global Response International Pledging Event (May 5, 2020), <https://www.pm.gov.au/media/coronavirus-global-response-international-pledging-event>.

¹⁰⁰ Press Release, Global Citizen, Statements of Support for the ‘Global Goal: Unite For Our Future’ Campaign (June 22, 2020), <https://www.globalcitizen.org/en/enquiries/press/global-citizen-and-european-commission-announce-global-goal-unite/statements-of-support/>.

Washington Post, emphasizing that “where you live should not determine whether you live.”¹⁰¹ The letter emphasized that “we must urgently ensure that vaccines will be distributed according to a set of transparent, equitable and scientifically sound principles.”¹⁰² In spite of such sentiments, the Canadian Government has been uncommitted as to whether it will support a TRIPS waiver.

B. The Operation of the ACT Accelerator

There has been a range of academic work, which has considered and evaluated the operation of the ACT-Accelerator generally, and the COVAX scheme in particular.

Mark Eccleston-Turner and Harry Upton commented that “the prevalence of vaccine nationalism threatens to limit the ability of the facility to meet both its funding targets and its ambitious goals for vaccine procurement.”¹⁰³ They observed that “a failure to adequately address the underlying lack of infrastructure in developing countries threatens to further limit the success of the COVAX Facility.”¹⁰⁴ Lisa Herzog and her colleagues maintain that COVAX must go beyond a proportional allocation of COVID vaccines to ensure fair and equitable access.¹⁰⁵ *The Lancet* editorialized that there was a need to go beyond the institution of COVAX: “An authoritative voice with moral credentials is needed to support global access to vaccines, to intervene when that goal is under threat, and to call out unfair practices.”¹⁰⁶

In practice, though, there have been difficulties with the COVAX scheme struggling to obtain sufficient supplies in the face of vaccine nationalism and shortages.¹⁰⁷ In April 2021, the WHO published its priorities, strategies, and budget for the ACT-Accelerator for 2021.¹⁰⁸ In its report, the WHO highlighted the multitude of challenges posed by the COVID-19 crisis: “We are facing an economic, humanitarian, security, and human rights crisis.”¹⁰⁹ The document highlighted the key achievements of the institution and discussed the ways and means that the ACT-Accelerator could maximise its impact. The document also emphasized its priorities for 2021. The ACT-Accelerator has four key priorities-

1. Rapidly scale up the delivery of at least 2 billion doses of vaccines;

¹⁰¹ Justin Trudeau et al., *The International Community Must Guarantee Equal Global Access to a COVID-19 Vaccine*, THE WASHINGTON POST (July 16, 2020), <https://www.washingtonpost.com/opinions/2020/07/15/international-community-must-guarantee-equal-global-access-covid-19-vaccine/>.

¹⁰² *Id.*

¹⁰³ Mark Eccleston-Turner & Harry Upton, *International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility*, 99 (2) THE MILBANK Q. 426 (2021).

¹⁰⁴ *Id.*

¹⁰⁵ Lisa Herzog et al., *COVAX must go beyond Proportional Allocation of Covid Vaccines to ensure Fair and Equitable Access*, 372 BRITISH MED. J. (2021).

¹⁰⁶ Editorial, *Access to COVID-19 Vaccines: Looking Beyond COVAX*, 397 (10278) THE LANCET (2021).

¹⁰⁷ Donato Paolo Mancini & Michael Peel, “Vaccine Nationalism” delays WHO’s Struggling COVAX Scheme, FINANCIAL TIMES (Sept. 2, 2020), <https://www.ft.com/content/502df709-25ac-48f6-aec1-aec7ac03c759>.

¹⁰⁸ Meeting Report, *ACT-A Prioritized Strategy and Budget for 2021*, WORLD HEALTH ORGANIZATION (12 April 2021), <https://www.who.int/publications/m/item/act-a-prioritized-strategy-and-budget-for-2021>.

¹⁰⁹ *Id.* at 4.

2. Bolster R&D, evaluations & regulatory pathways to optimize products and address variants;
3. Stimulate rapid and effective uptake and use of COVID-19 tests, treatments and PPE;
4. Ensure a robust pipeline of essential tests, treatments and PPE.¹¹⁰

The April 2021 document also highlights a significant funding gap. Delivering on the ACT-Accelerator's promises requires an additional \$US22.1 billion in 2021. The document discusses the issues around financing COVAX. It also makes an economic case for investing in the ACT-Accelerator, noting that: *"In January 2021, a study commissioned by the ICC demonstrated that even with strong COVID-19 vaccine coverage in high-income countries, inequitable access to COVID-19 tools elsewhere would cost high income economies an additional US\$ 2.4 trillion in 2021 alone."*¹¹¹ The report observed: *"Investing in ACT-Accelerator dwarfs the potential multiplier benefits of domestic fiscal support investments"*.¹¹²

In a resolution, the European Parliament pointed out that *"11 billion doses are needed to vaccinate 70 % of the world's population and that only a fraction of that amount has been produced"*.¹¹³ It was observed that an approach based on pledges of excess doses was insufficient.¹¹⁴ The European Parliament noted that *"COVAX is facing a shortfall of 190 million doses due to the current COVID-19 situation in India and will not meet its supply objectives for the foreseeable future."*¹¹⁵ In its resolution, the European Parliament underlined the need to prioritise supplying COVAX and regretted moves by the UK and the US in developing a secondary re-sale market to sell surplus vaccines to other industrialised countries.¹¹⁶

The Independent Panel for Pandemic Preparedness and Response – co-chaired by Helen Clark and Ellen Sirleaf – considered the operation of COVAX as part of its inquiry.¹¹⁷ In its summary, the Panel acknowledged: *"The uneven access to vaccination is one of today's pre-eminent global challenges."*¹¹⁸ The Panel expressed its concern about the international inequities in the distribution of vaccines and how any progress with regard to the COVAX goals of delivering vaccine doses to low- and middle-income countries was hampered by a lack of sufficient funds, vaccine nationalism, and vaccine diplomacy. The Panel recommended: *"High income countries with a vaccine pipeline for adequate coverage should, alongside their scale up, commit to provide to the 92 low and middle income countries of the Gavi COVAX Advance Market Commitment, at least one billion vaccine doses no later than 1 September 2021 and more than two billion doses by mid-2022, to be made available through COVAX and other*

¹¹⁰ *Id.* at 12.

¹¹¹ *Id.* at 3.

¹¹² *Id.*

¹¹³ *Meeting the Global COVID-19 Challenge: Effects of Waiver of the WTO TRIPS Agreement on Covid-19 Vaccines, Treatment, Equipment and Increasing Production and Manufacturing capacity in Developing Countries*, EUR. PARL. DOC. P9_TA (2021) 0283.

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ THE INDEPENDENT PANEL ON PANDEMIC PREPAREDNESS AND RESPONSE, *supra* note 23.

¹¹⁸ *Id.* at 12.

coordinated mechanisms.”¹¹⁹

Investigative journalism by STAT and the Bureau of Investigative Journalism has suggested that COVAX has been “*naively ambitious*” in its plans to vaccinate the world.¹²⁰ The study noted: “*Some said COVAX failed to push for the IP sharing that will be needed to produce sufficient vaccines.*”¹²¹ One informant told the journalists: “Of course they understood this [intellectual property sharing] was necessary, but the focus was on developing the vaccines and getting them approved.”¹²²

There has been further controversy that developed nations, such as Canada and Australia, have purchased medicines and vaccines from COVAX.¹²³ On June 6, 2021, the Health Minister Greg Hunt announced that Australia paid \$123 million to buy the option to purchase 24 million doses from COVAX.¹²⁴ The chief executive of the Australian Council for International Development, Marc Purcell, said that the Australian Government had shown “*desperation to get the preferable vaccine, Pfizer, from any sources into Australia*”.¹²⁵ He emphasized: “*But we can’t forget that our fortunes are tied up with reducing and eradicating Covid in the developing countries that surround Australia.*”¹²⁶ Purcell noted: “*The COVAX facility is open to countries in genuine need, but clearly countries like Indonesia, Philippines and Malaysia should be a priority for donors like Australia.*”¹²⁷ The Shadow Foreign Affairs Minister Penny Wong commented: “*If Mr Morrison has had to resort to accessing vaccines intended for developing countries, he should be upfront about that.*”¹²⁸

Nick Dearden of Global Justice Now observed that key vaccine developers had ignored the COVAX mechanism: “*Just 1% of Pfizer’s supplies have been sold to the international distribution mechanism COVAX, as the company has put sales of third and fourth doses in wealthy markets ahead of selling doses to where they’re most needed.*”¹²⁹ He feared

¹¹⁹ *Id.* at 14 and 63.

¹²⁰ Olivia Goldhill, Rosa Furneaux, and Madlen Davies, “*Naively Ambitious*”: How COVAX Failed On Its Promise to Vaccinate the World, STAT, (October 8, 2021), <https://www.statnews.com/2021/10/08/how-covax-failed-on-its-promise-to-vaccinate-the-world/>.

¹²¹ *Id.*

¹²² *Id.*

¹²³ Anthony Galloway, *Australia Dipped into COVAX Pfizer Stockpile Intended for Poor Nations*, THE SYDNEY MORNING HERALD (Aug. 17, 2021), <https://www.smh.com.au/politics/federal/australia-dipped-into-covax-pfizer-stockpile-intended-for-poor-nations-20210816-p58j2j.html>; Paul Karp, *Australia’s Pfizer Purchase from Vaccine-Sharing COVAX Stockpile Under Fire*, THE GUARDIAN (Aug. 17, 2021), <https://www.theguardian.com/australia-news/2021/aug/17/australia-pfizer-purchase-from-vaccine-sharing-covax-stockpile-under-fire>; Chris Barrett & Karuni Rompies, *Australia Should Return COVAX Vaccines, Says Ex-Indonesian Minister*, THE SYDNEY MORNING HERALD (Aug. 18, 2021), <https://www.smh.com.au/world/asia/australia-should-return-covax-vaccines-says-ex-indonesian-minister-20210817-p58jkm.html>.

¹²⁴ The Hon. Greg Hunt, Transcript – COVID-19 Vaccine Rollout, Minister for Health and Aged Care, AUSTRALIA PARLIAMENT (June 6, 2021), https://parlinfo.aph.gov.au/parlInfo/download/media/pressrel/8000210/upload_binary/8000210.pdf;fileType=application%2Fpdf#search=%22hunt%20covax%20%20minister%20for%20health%20and%20aged%20care%22.

¹²⁵ Galloway, *supra* note 123.

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ Karp, *supra* note 123.

¹²⁹ Julia Kollewe, *Pfizer raises Covid-19 vaccine sales forecast to \$36bn for 2021*, THE GUARDIAN, (November 2, 2021), <https://www.theguardian.com/business/2021/nov/02/pfizer-covid-19-vaccine-sales-2021-biontech>.

that this situation would “*undoubtedly prolong the pandemic.*”¹³⁰

C. Reform of COVAX

Stakeholders have commissioned a strategic review of the ACT Accelerator to inform decision-making on enhancing its current functioning and its potential role beyond the 1st quarter of 2022.¹³¹ The strategic review considered the ACT Accelerator’s achievements, best practices, challenges, and gaps as a basis for recommendations to enhance its future work. The report emphasized the need to “*close the equity gap in COVID-19 tools*” and “*support all communities around the world to access and use the life-saving tools they need to end the acute phase of the COVID-19 pandemic.*”¹³² The review also emphasized that recipient countries and their representatives must play a central role in shaping the work of the ACT Accelerator. The review also called for strengthened visibility and accountability – so that stakeholders could follow and evaluate the collective work of the ACT Accelerator. The review also discussed sequencing and prioritization; the mandate; health systems and country support; participation and engagement; communication and information-sharing; and external collaboration and co-ordination.

The PVA has been critical of COVAX as a knowledge-sharing initiative, noting that “*rich countries continue to cut bilateral supply deals with pharmaceutical companies which undermine this global effort and limit supply to poorer nations.*”¹³³ The Alliance has been disappointed by the opaque nature of the organization: “*So far COVAX has not been transparent about the deals it is making with pharmaceutical companies and remains silent on how it will tackle monopolies.*”¹³⁴ The Alliance also laments the lack of democratic input into the decision-making process of the organization from civil society and developing countries. The Alliance has also been critical that “*COVAX does not use its purchasing power to push corporations to share the science, knowledge and technology behind their vaccines, which could lead to scaled up production.*”¹³⁵ The Alliance was also deeply concerned at the prospect that COVAX would adopt a tiered pricing model. Accordingly, the Alliance has called for a reformation of COVAX.¹³⁶

III. PATENT POOLS

Patent pools can be “defined as an agreement between two or more patent owners to license one or

¹³⁰ *Id.*

¹³¹ Dalberg, ACT ACCELERATOR STRATEGIC REVIEW: AN INDEPENDENT REVIEW, (October 8, 2021) <https://www.who.int/publications/m/item/act-accelerator-strategic-review>.

¹³² *Id.*, 66.

¹³³ FAQ, THE PEOPLE’S VACCINE ALLIANCE, <https://peoplesvaccine.org/faq/>.

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.*

more of their patents to one another or to third parties”.¹³⁷ Patent pools have been used to address access issues - particularly where there are patent thickets, which are impeding access to essential technologies.¹³⁸ Michael Heller has discussed the role of patent pools as a means of addressing the “*gridlock economy*”.¹³⁹ Increasingly, patent pools have been deployed in the context of medicine, biotechnology, and healthcare.¹⁴⁰ Joseph Stiglitz and his collaborators comment that “*patent pools... are part of a broader agenda to reform how life-saving drugs are developed and made available.*”¹⁴¹ The People’s Vaccine Alliance has also been a supporter of patent pools during the coronavirus crisis.¹⁴²

A. The Medicines Patent Pool

In 2006, the MSF Access Campaign and Knowledge Ecology International mooted the establishment of a patent pool to help provide access to HIV medicines.¹⁴³ The Medicines Patent Pool [“MPP”] was established as an independent public health entity in 2010 - with the support of UNITAID. According to the MPP, “[o]ur mission is to increase access to, and facilitate the development of, life-saving medicines for low- and middle income countries [“LMIC”].”¹⁴⁴ The MPP discusses its strategies: “*We do this through an innovative approach to voluntary licensing and patent pooling.*”¹⁴⁵ It emphasized that it takes a collaborative approach to patent licensing: “*We work with a range of partners — civil society, international organisations, industry, patient groups and governments — to prioritise and license novel and existing medicines and health technologies for people in these countries.*”¹⁴⁶

The mandate of the MPP is to “*accelerate access to affordable quality treatments for people living with HIV, hepatitis C and tuberculosis, as well as HIV-associated co-morbidities.*”¹⁴⁷ Its role has evolved over the years: “*Since 2018, MPP has expanded its mandate to other patented essential medicines on the World Health Organization (WHO)’s Model List of Essential*

¹³⁷ World Intellectual Property Organization, PATENT POOLS AND ANTITRUST: A COMPARATIVE ANALYSIS, March 2014. https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf.

¹³⁸ Anne Layne-Farrar and Josh Lerner, *To Join or Not to Join: Examining Patent Pool Participation and Rent Sharing Rules*, 29 (2) INTERNATIONAL JOURNAL OF INDUSTRIAL ORGANIZATION 294-303 (2011).

¹³⁹ MICHAEL HELLER, THE GRIDLOCK ECONOMY: HOW TOO MUCH OWNERSHIP WRECKS MARKETS, STOPS INNOVATION, AND COSTS LIVES (2009).

¹⁴⁰ David Resnik, *A Biotechnology Patent Pool: An Idea Whose Time Has Come*, 3 (1) THE JOURNAL OF PHILOSOPHY, SCIENCE & LAW 1-22 (2003); GEERTRUI VAN OVERWALLE, GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES (2009); DEVDATTAMALSHE, PATENT POOLS, COMPETITION AND BIOTECHNOLOGY (2020).

¹⁴¹ Joseph Stiglitz et al., *Patents vs. the Pandemic*, PROJECT SYNDICATE (Apr. 23, 2020), <https://www8.gsb.columbia.edu/articles/chazen-global-insights/patents-vs-pandemic>.

¹⁴² THE PEOPLE’S VACCINE ALLIANCE, *supra* note 133.

¹⁴³ Michelle Childs, *Towards a Patent Pool for HIV Medicines: The Background*, 4 THE OPEN AIDS J. 33 (2010); and Krista Cox, *The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses* 4 HASTINGS SCIENCE & TECHNOLOGY LAW JOURNAL 291-324 (2012); Alberto Galasso and Mark Schankerman, *Licensing Life-Saving Drugs for Developing Countries: Evidence from the Medicines Patent Pool*, NATIONAL BUREAU OF ECONOMIC RESEARCH (2021) <https://www.nber.org/papers/w28545>.

¹⁴⁴ Who We Are, MEDICINES PATENT POOL, <https://medicinespatentpool.org/who-we-are/about-us/>.

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

*Medicines (EML) as well as medicines with strong potential for future inclusion on the EML.”*¹⁴⁸

In 2020, the MPP temporarily expanded its mandate to include COVID-19 related technologies.¹⁴⁹ Marie-Paule Kieny and Charles Gore from the MPP argued that there needs to be a master plan to address the licensing of COVID-19 patents.¹⁵⁰ They offered to share their institutional expertise in terms of patent information and databases: “*This repository of patent intelligence was established to allow countries and procurement agencies to identify patents that could hinder access to new medical innovations.*”¹⁵¹ Kieny and Gore observed that the MPP was in discussions with the WHO about how MPP could support the intellectual property pool and tap into their relationships with governments, industry, and key public health organizations to seek licensing agreements that could speed access to COVID-19 drugs, diagnostics, and vaccines.¹⁵²

The chair of the Unitaid Executive Board, Marisol Touraine, has also offered her support for the initiative: “*Unitaid is fully engaged in the global response to COVID-19 and supports the call by the President of Costa Rica for voluntary pooling of intellectual property rights for medicines and diagnostics to promote the global fight against COVID-19.*”¹⁵³ She added: “*The Medicines Patent Pool, set up and funded by Unitaid a decade ago, has a proven track record and is immediately available to the WHO to begin this urgent work.*”¹⁵⁴

Charles Gore of the MPP has discussed the difficulties of engaging with intellectual property holders: “*Unfortunately what we’ve seen is too little of, ‘Let’s do this all together as a world’, and a little too much of me-first.*”¹⁵⁵ He noted that vaccine nationalism was also distorting the operation of the marketplace: “*If countries are saying the most important thing is, ‘I want you to do a deal now with me’, the companies can’t say, ‘We’ll come back to you later, we’re trying to do a deal for global access.’*”¹⁵⁶

In July 2021, the MPP announced that it was joining a new consortium to boost vaccine capacity in South Africa and Sub-Saharan Africa.¹⁵⁷ Dr. Soumya Swaminathan, Chief Scientist of WHO, noted:

¹⁴⁸ *Id.*

¹⁴⁹ Disease Areas COVID-19, MEDICINES PATENT POOL, <https://medicinespatentpool.org/what-we-do/disease-areas/#pills-COVID-19>.

¹⁵⁰ Marie-Paule Kieny & Charles Gore, *The World Needs a Master Plan for COVID-19 Patents. We’re Creating One*, BARRONS (Apr. 10, 2020), <https://barrons.com/articles/the-world-needs-a-master-plan-for-covid-19-patents-were-building-one-51586524940>.

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ Press Release, Medicines Patent Pool, The Medicines Patent Pool and Unitaid Respond to Access Efforts for COVID-19 Treatments and Technologies (Mar. 31, 2020), <https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-and-unitaid-respond-to-access-efforts-for-covid-19-treatments-and-technologies/>.

¹⁵⁴ *Id.*

¹⁵⁵ Michael Safi, *WHO Platform for Pharmaceutical Firms Unused Since Pandemic Began*, THE GUARDIAN (Jan. 22, 2021), <https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firms-unused-since-pandemic-began>.

¹⁵⁶ *Id.*

¹⁵⁷ Press Release, Medicines Patent Pool, New Consortium Working to Boost Vaccine Production in South Africa (July 30, 2021), <https://medicinespatentpool.org/news-publications-post/south-africa-tech-transfer-hub-loi-press-release/>.

*“Inequitable manufacturing and distribution of vaccines is behind the wave of death, which is now sweeping across many low- and middle-income countries that have been starved of vaccine supply.”*¹⁵⁸ She stressed: *“Building vaccine manufacturing capacity in South Africa is the first step in a broader effort to boost local production to address health emergencies and strengthen regional health security.”*¹⁵⁹ Charles Gore commented: *“Within the consortium, MPP will provide appropriate intellectual property analysis, define and negotiate terms and conditions of the agreements, provide alliance management and make use of our established robust selection process to allow further technology recipients to benefit.”*¹⁶⁰ Other partners of the consortium include the biotechnology company Afrigen Biologics Vaccines; vaccine company Biovac; the South African Medical Research Council; and the Africa Centres for Disease Control and Prevention [“Africa CDC”]. This initiative is designed to improve regional biomanufacturing capacity – which has been a significant shortfall during the coronavirus public health crisis.

In October 2021, the MPP and MSD (the tradename of Merck & Co) entered into a license agreement for molnupiravir, an investigational oral antiviral COVID-19 medicine.¹⁶¹ This agreement will help create broad access for molnupiravir use in 105 low- and middle-income countries, subject to appropriate regulatory approvals. The MPP emphasized that this was its first agreement to provide access for a COVID-19 medical technology. Bangladesh’s Beximco has announced in November 2021 that it would sell a generic version of the Merck COVID-19 pill.¹⁶²

In a background paper for the Independent Panel, Ellen ‘t Hoen and her colleagues supported the involvement of the Medicines Patent Pool in licensing COVID-19 technologies: *“The Medicine Patent Pool’s expertise in licensing IP to maximise access together with a COVID-19 vaccine technology transfer hub engaging manufacturers and potential manufacturers should be an integral part of this initiative”*.¹⁶³

The Independent Panel made recommendations for the World Trade Organization and WHO to convene major vaccine-producing countries and manufacturers to get agreement on voluntary licensing and technology transfer arrangements for COVID-19 vaccines (including through the MPP).¹⁶⁴ It was suggested: *“If actions do not occur within three months, a waiver of intellectual property rights under the [TRIPS*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ Press Release, Medicines Patent Pool, *The Medicines Patent Pool (MPP) and MSD enter into Licence Agreement for Molnupiravir, an Investigational Oral Antiviral COVID-19 Medicine, to Increase Broad Access in Low- and Middle- income Countries*, (October 27, 2021), <https://medicinespatentpool.org/news-publications-post/mpp-msd-new-licence-announcement-molnupiravir/>.

¹⁶² Sachin Ravikumar, *Bangladesh’s Beximco to sell First Generic Version of Merck COVID-19 Pill*, REUTERS, (November 9, 2021), <https://www.reuters.com/business/healthcare-pharmaceuticals/asian-firm-beximco-sell-generic-version-merck-covid-19-pill-2021-11-09/>.

¹⁶³ Ellen ‘t Hoen et al., *Scaling-Up Vaccine Production Capacity: Legal Challenges and Recommendations*, INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE (May 2021), <https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-6-Scaling-up-vaccination-legal-aspects.pdf>.

¹⁶⁴ THE INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE, *supra* note 23.

*Agreement] should come into force immediately.”*¹⁶⁵

B. C-TAP

The Government of Costa Rica has been a policy entrepreneur during the global public health crisis, and has put forward the diplomatic proposal of establishing a COVID-19 Technology Access Pool [“C-TAP”].¹⁶⁶

Taking up the proposal, the WHO issued a Solidarity Call to Action in May 2020.¹⁶⁷ The WHO emphasized: “*The COVID-19 pandemic has revealed the fallibility of traditional ways of working when it comes to equitable access to essential health technologies.*”¹⁶⁸ WHO stressed: “*This initiative sets out an alternative, in line with WHO’s efforts to promote global public health goods, based on equity, strong science, open collaboration and global solidarity.*”¹⁶⁹ WHO called on all stakeholders to “*place, in the WHO COVID-19 Technology Access Pool or its implementing partner platforms, references to shared information and/or commitments to all relevant technologies, knowledge, intellectual property, and data on terms that facilitate their use in research, development and innovation and manufacturing and that would permit effective technology transfer and early access to key technologies for the detection, prevention, treatment and response of COVID-19.*”¹⁷⁰

President of Costa Rica, Carlos Alvarado Quesada and the Director-General of WHO, Tedros Adhanom Ghebreyesus contended: “*When a COVID-19 vaccine does become available, it should be treated as a global public good*”.¹⁷¹ The pair called on all governments to ensure that the outcomes of publicly funded COVID-19 research are affordable, available, and accessible to everyone around the world.¹⁷² Costa Rica and the WHO have established a plan for the C-TAP: “*The COVID-19 Technology Access Pool which will compile, in one place, pledges of commitment made under the Solidarity Call to Action to voluntarily share COVID-19 health technology related knowledge, intellectual property and data.*”¹⁷³ The new institution is designed to complement existing mechanisms:

¹⁶⁵ *Id.* at 14, 63.

¹⁶⁶ Knowledge Ecology International, *President Carlos Alvarado Quesada of Costa Rica at the C-TAP Solidarity Call to Action Launch*, YOUTUBE (May 29, 2020), <https://www.youtube.com/watch?v=GQLjsDx1I5s>; Press Release, *Medicines Patent Pool, Launch of the COVID-19 Technology Access Pool (C-TAP)*, (May 29, 2020), <https://medicinespatentpool.org/news-publications-post/launch-of-the-covid-19-technology-access-pool-c-tap/>.

¹⁶⁷ Solidarity Call to Action, WORLD HEALTH ORGANIZATION (May 29, 2020), <https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action>.

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ Carlos Alvarado Quesada & Tedros Adhanom Ghebreyesus, *Globalizing the Fight against the Pandemic*, PROJECT SYNDICATE (May 29, 2020), <https://www.project-syndicate.org/commentary/covid19-access-pool-vaccine-data-ip-sharing-by-carlos-alvarado-quesada-and-tedros-adhanom-ghebreyesus-2020-05>.

¹⁷² *Id.*

¹⁷³ COVID-19 Technology Access Pool, WORLD HEALTH ORGANIZATION, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019->

“The Pool will draw on relevant data from existing mechanisms, such as the Medicines Patent Pool and the UN Technology Bank-hosted Technology Access Partnership.”¹⁷⁴ The People’s Vaccine Alliance emphasized that there was a need to ensure maximum production of vaccine doses by pushing pharmaceutical companies and research institutions to share the science, technology and know-how behind their vaccines with the C-TAP.¹⁷⁵

However, some pharmaceutical companies and biotechnology developers have been unwilling to join this voluntary initiative thus far.¹⁷⁶ Ellen ‘t Hoen reflected that “the success of C-TAP will depend on the political support it will receive.”¹⁷⁷ She noted that 40 countries had endorsed the initiative.¹⁷⁸ Ellen ‘t Hoen commented that “persuasion will need to come from governments and institutions that spend public resources on the development of new drugs and vaccines by demanding from their recipients that they share the IP and know-how they create with the funds with the WHO C-TAP.”¹⁷⁹

Access to medicines scholar and civil society activist Brook Baker has maintained that there is a strong rationale for Costa Rica’s proposal for an emergency COVID-19 technology intellectual property pool.¹⁸⁰ Dr Muhammad Zaheer Abbas has argued that Costa Rica’s proposal for the creation of a global pooling mechanism deserved serious consideration.¹⁸¹ He contended: “The COVID-19 pooling mechanism has the potential to accelerate scientific discovery by acting as a clearinghouse for fast-track and equitable licensing of rights for collaborative follow-on innovation of priority health technologies.”¹⁸²

In January 2021, a coalition of public-health and humanitarian groups including the People’s Vaccine Alliance sent a letter to the WHO raising their concerns about the management of C-TAP and calling for public clarification of the programme.¹⁸³ The civil society organizations Knowledge Ecology Action and Health Action International [“HAI”] expressed concerns about the WHO’s leadership of C-TAP. Knowledge Ecological International exhorted the WHO to “to exert greater leadership in measures to scale production, increase competition, and speed the delivery of vaccines, therapeutics and other technologies and other technologies in the COVID-19 response.”¹⁸⁴ HAI said that the Director-General’s report on the COVID-

ncov/covid-19-technology-access-pool.

¹⁷⁴ *Id.*

¹⁷⁵ THE PEOPLE’S VACCINE ALLIANCE, *supra* note 133.

¹⁷⁶ World Health Organization, Summary Report: Special press conference to mark the first anniversary of the COVID-19 Technology Access Pool, (May 28, 2021), <https://www.who.int/publications/m/item/summary-report-special-press-conference-to-mark-the-first-anniversary-of-the-covid-19-technology-access-pool>.

¹⁷⁷ ‘t Hoen, *supra* note 88.

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ Brook Baker, *Rationale for Supporting Costa Rica’s Proposal for Emergency COVID-19 Technology IP Pool for All Countries*, INFOJUSTICE (Mar. 27, 2020), <http://infojustice.org/archives/42137>.

¹⁸¹ Muhammad Zaheer Abbas, *Treatment of the novel COVID19: Why Costa Rica’s Proposal for the Creation of a Global Pooling Mechanism deserves Serious Consideration?*, 7 J. L. BIOSCI 1 (2020)

¹⁸² *Id.*

¹⁸³ Safi, *supra* note 155.

¹⁸⁴ Thiru Balasubramaniam, *EB 148 – WHO’s COVID-19 Technology Access Pool (C-TAP) Comes Under Scrutiny*, KNOWLEDGE ECOLOGY INTERNATIONAL (Jan. 20, 2021), <https://www.keionline.org/35064>.

19 response should “*acknowledge the C-TAP, a platform which, by gathering and channelling IP, know-how and other relevant data could play a critical role in transferring technology and scaling up production of vaccines, diagnostics and other health goods necessary to vanquish this pandemic.*”¹⁸⁵ The People’s Vaccine Campaign added: “*We have been advocating that governments, manufacturers and research institutions support the pool and will continue to do that, but the WHO needs to be more transparent about its activities and proactive as regards its leadership of and advocacy for C-TAP if it is to succeed.*”¹⁸⁶

In February 2021, the Director-General of the WHO called on vaccine developers to do more to share their data and technology, seemingly making a renewed effort to get intellectual property holders to re-engage with C-TAP.

In correspondence with *Nature* in March 2021, the researchers, Etienne Billette de Villemeur, Vianney Dequiedt and Bruno Versaevael despaired: “*The WHO’s C-TAP has so far received no contributions from industry.*”¹⁸⁷ They observed: “*The practice of pooling patented technologies for the production of medicines already occurs for HIV, hepatitis C and tuberculosis treatments.*”¹⁸⁸ They also emphasized that “*fees are typically lower when licences are negotiated as a bundle with generics producers, implying increased volume.*”¹⁸⁹ They observed: “*Yet firms can anticipate extra revenue from participation in a voluntary pool, and thus be more willing to maintain innovation and share know-how than with compulsory licensing.*”¹⁹⁰

In May 2021, Spain formally joined the C-TAP initiative. The President of the Government of Spain, Pedro Sanchez said: “*We invite governments and especially the pharmaceutical industry to join us so that the initiative can achieve tangible results.*”¹⁹¹ Spain is collaborating with the C-TAP initiative to openly licence a serological test for COVID-19 developed by CSIC researchers.¹⁹² Sanchez stressed that “*only by leading by example will we be effective in preaching solidarity*” and “*only through solidarity can this crisis be overcome and the wounds of our societies healed*”.¹⁹³ There has also been interest expressed in the initiative by the governments of Indonesia and Belgium.¹⁹⁴

¹⁸⁵ *Id.*

¹⁸⁶ Gabriela Bucher, *Letter to the Director-General of the World Health Organization from Oxfam on Behalf of the People’s Vaccine Alliance, and Health Action International, KNOWLEDGE ECOLOGY INTERNATIONAL* (Jan. 21, 2021), <https://www.keionline.org/wp-content/uploads/HE-Dr-Tedros-Letter-from-Peoples-Vaccine-Alliance-and-Health-Action-International.pdf>.

¹⁸⁷ Etienne Billette de Villemeur et al., *Pool Patents to get COVID Vaccines and Drugs to All*, *NATURE* (Mar. 19, 2021), <https://www.nature.com/articles/d41586-021-00759-9>.

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ World Health Organization, *Spain Has Formally Joined The C-TAP Initiative*, *TWITTER* (May 25, 2021), <https://twitter.com/who/status/1397138437120090114?lang=en>.

¹⁹² Sánchez announces that Spain will donate an additional 15 million vaccines to fight COVID-19, *GOVERNMENT OF SPAIN* (June 2, 2021), <https://www.lamoncloa.gob.es/lang/en/presidente/news/Paginas/2021/20210602gavcovax-summit.aspx>.

¹⁹³ *Id.*

¹⁹⁴ World Health Organization, *Summary Report: Special press conference to mark the first anniversary of the COVID-19 Technology Access Pool*, (May 28, 2021), <https://www.who.int/publications/m/item/summary-report-special-press-conference-to-mark-the-first-anniversary-of-the-covid-19-technology-access-pool>.

In the United Kingdom Parliament, Liberal Democrat Layla Moran has chided the United Kingdom Government for its lack of co-operation with C-TAP.¹⁹⁵ She posed the question: “*Why did we not endorse the WHO COVID technology access protocol?*”¹⁹⁶ She noted: “*That global initiative is meant to prevent monopolies from blocking global access to coronavirus vaccines, and I do not understand how we in this House can say that we believe in global access to these vaccines, yet not back that protocol.*”¹⁹⁷ Dr Philippa Whitford MP of the Scottish National Party has also asked the Prime Minister Boris Johnson to “*make a public statement in support of the proposal from the President and Minister of Health of Costa Rica for the WHO to create a global pooling mechanism for rights in COVID19 related technologies for the detection, prevention, control and treatment of the COVID-19 pandemic.*”¹⁹⁸

Likewise, in Ireland, there has been a debate about the role of C-TAP. Dr Aisling McMahon told legislators: “*The C-TAP model is needed because production capacity for vaccines, medicines and diagnostics for COVID can be increased globally but, in order to do this, more companies must license and share intellectual property rights, know-how and technologies to enable others to produce them.*”¹⁹⁹ In response, a number of legislators have called for the Government of Ireland to support C-TAP.²⁰⁰ The Joint Committee on Foreign Affairs and Defence recommended formal endorsement of C-TAP by the government; Government advocacy for C-TAP and other mechanisms at an international level, particularly at the EU and at the UN Security Council; government assistance to encourage more pharmaceutical companies to join C-TAP; and an increase of financial support for the WHO’s ACT Accelerator.²⁰¹ The President of Ireland Michael Higgins has provided vocal support for C-TAP.²⁰² He has called for co-operation in respect of the sharing of COVID-19 technologies: “*The possibility of safe, effective and affordable diagnostics, therapeutics and vaccines provides vital hope of overcoming COVID-19, but unless such medical tools are fully accessible to all on an equitable basis the world remains at risk.*”²⁰³

¹⁹⁵ 683 PARL DEB HC (Nov. 5, 2020) (UK) (Remarks of Layla Moran), <https://hansard.parliament.uk/Commons/2020-11-05/debates/78F58139-2878-4CC8-A220-1980A0025D6A/InternationalCovid-19ResponseInnovationAndAccessToTreatment#contribution-CD682B35-CCC2-4A90-8677-81A6DF6DA6DB>.

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ The Hon. Philippa Whitford MP, *Equitable Access to COVID-19 Diagnostics, Vaccines and Treatments*, STOPAIDS UK (Apr. 2020), <https://stopaids.org.uk/wp-content/uploads/2020/04/Equitable-access-to-COVID-19-diagnostics-vaccines-and-treatments-1-1.pdf>.

¹⁹⁹ JOINT COMMITTEE ON FOREIGN AFFAIRS AND DEFENCE DEBATE, DISTRIBUTION OF COVID-19 VACCINES TO DEVELOPING COUNTRIES, (Feb. 9, 2021) (Ir.), https://www.oireachtas.ie/en/debates/debate/joint_committee_on_foreign_affairs_and_defence/2021-02-09/2/.

²⁰⁰ Press Release, Foreign Affairs Committee, Report on the Distribution of COVID-19 Vaccines to Developing Countries, (Mar. 11 2021), <http://www.oireachtas.ie/en/press-centre/press-releases/20210311-foreign-affairs-committee-launches-report-on-the-distribution-of-covid-19-vaccines-to-developing-countries/>; JOINT COMMITTEE ON FOREIGN AFFAIRS AND DEFENCE, REPORT ON THE DISTRIBUTION OF COVID-19 VACCINES TO DEVELOPING COUNTRIES (Mar. 2021), https://data.oireachtas.ie/ie/oireachtas/committee/dail/33/joint_committee_on_foreign_affairs_and_defence/reports/2021/2021-03-05_report-on-the-distribution-of-covid-19-vaccines-to-developing-countries_en.pdf.

²⁰¹ JOINT COMMITTEE ON FOREIGN AFFAIRS AND DEFENCE, *supra* note 200, at 12.

²⁰² Costa Rica, UNAIDS and World Health Organization, *High Level Event – The Challenge of a Lifetime: Ensuring Universal Access to COVID-19 Health Technologies – with the President of Costa Rica Carlos Alvarado Quesada, the President of Ireland Michael Higgins, the Executive Director of UNAIDS Winnie Byanyima, and the Director-General of the World Health Organization, Tedros Adhanom Ghebreyesus*, FACEBOOK (Sep. 25, 2020), https://www.facebook.com/watch/live/?v=3321649844589012&ref=watch_permalink.

²⁰³ President Michael Higgins, Address at the UN Meeting on Universal Access to Covid-19 Health Technologies (Sept. 25,

The President of Ireland underlined that access to essential medicines raised fundamental questions about global social justice: “*Solidarity among nations is key if we are to optimise the world’s management and eventual exit from this pandemic.*”²⁰⁴

The European Parliament has lent its support for the WHO effort to create C-TAP.²⁰⁵ In a resolution, the European Parliament “*reaffirms its support for the WHO COVID-19 C-TAP initiative and the mRNA vaccine technology transfer hub; regrets that so far pharmaceutical companies have decided not to engage in the C-TAP initiative; urges the Commission to incentivise pharmaceutical companies to share their technologies and know-how through C-TAP and include commitments on technology transfer partnerships with third parties, particularly developing countries, in the EU’s future advance purchase agreements.*”²⁰⁶ However, the European Commission has shown less enthusiasm for sharing intellectual property as part of a pool.

In a background paper for the Independent Panel, Ellen ‘t Hoen and her colleagues conclude C-TAP could be an effective policy solution: “*A more effective solution will therefore be the implementation of an initiative such as C-TAP that, in a predictable manner, assures access to all relevant Intellectual Property: patents, know-how, data, technology and materials.*”²⁰⁷ As of August 2021, C-TAP has assembled a number of implementing partners- including the MPP, the Open COVID Pledge, and the Tech Access Partnership.²⁰⁸ The role of these collaborators will be further discussed in some of the subsequent parts of the paper.

C. Opposition to Patent Pools

There remains concern that wealthy nations – who are donors to the WHO – have been trying to sideline and marginalise C-TAP.²⁰⁹ Moreover, leaders of pharmaceutical drug companies and vaccine developers have been uncooperative with sharing their data and technology with C-TAP.²¹⁰ Notably, the chief executive of Pfizer, Albert Bourla, has maintained that companies are “*investing billions to find a solution and, keep in mind if you have a discovery, we are going to take your (intellectual property), I think, is dangerous.*”²¹¹ Similarly, AstraZeneca chief executive, Pascal Soriot, argued that, “*if you don’t protect intellectual*

2020), <https://president.ie/en/diary/details/president-addresses-un-meeting-on-universal-access-to-covid-19-health-technologies/speeches>.

²⁰⁴ *Id.*

²⁰⁵ Ed Silverman, *European Parliament Backs WHO Effort to Create A COVID-19 Technology Access Pool*, STAT (July 13, 2020), <https://www.statnews.com/pharmalot/2020/07/13/europe-who-covid19-patents-vaccine-pandemic/>.

²⁰⁶ EUR. PARL. DOC., *supra* note 113.

²⁰⁷ T HOEN, *supra* note 163.

²⁰⁸ *How WHO C-TAP Works?*, WORLD HEALTH ORGANISATION (Aug. 2021), <https://www.who.int/initiatives/covid-19-technology-access-pool/what-is-c-tap>.

²⁰⁹ Priti Patnaik, *WHO Donors seek a New Tech Transfer Hub under ACT-A, C-TAP Sidelined*, GENEVA HEALTH FILES (Mar. 19, 2021), <https://genevahealthfiles.substack.com/p/who-donors-seek-a-new-tech-transfer>.

²¹⁰ Ed Silverman, *Pharma Leaders Shoot Down WHO Voluntary Pool for Patent Rights on COVID-19 Products*, STAT (May 28, 2020), <https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/>.

²¹¹ *Id.*

property, then essentially, there is no incentive for anybody to innovate”.²¹² Thomas Cuni, the director of the International Federation of Pharmaceutical Manufacturers and Associations, a lobby group for the industry, maintained: “Circumventing IP rights will not solve perceived access challenges.”²¹³ The statement by the Pfizer and AstraZeneca leaders seems to suggest that private companies are wholly responsible for developing vaccines, treatments, and diagnostics for COVID-19 – when, of course, there has been massive public investment in such technologies.

As the economist Mariana Mazzucato has noted, innovation has long been underpinned by public investment.²¹⁴ Mazzucato is the chair of a new WHO Council on the Economics of Health for All – which seeks to incorporate lessons learned during the COVID-19 pandemic.²¹⁵ The Council has suggested that there is a need to rethink health innovation in light of the COVID-19 crisis.²¹⁶ The Council has highlighted problems in the pharmaceutical innovation ecosystem – including misaligned directionality and priority-setting; knowledge and access barriers; excessive financialization and de-industrialization; lack of resilience and limited spread of manufacturing infrastructure; and lack of public stewardship for access. The Council has called for purpose-driven innovation and reshaping knowledge governance for the common good. The Council has also highlighted the need for corporate governance – particularly ensuring that the principle of Health for All governs public-private partnerships, and for the building of resilient and diverse manufacturing capacity and infrastructure.

C-TAP will still be extended if it is unable to play a role in the facilitation of the transfer of knowledge and technology to low-income countries. The Director-General of the WHO, Dr Tedros Adhanom Ghebreyesus, said: “Without substantial public funding, we encourage all manufacturers to share their data and technology to ensure equitable access to vaccines.”²¹⁷ He was disappointed by the response of intellectual property holders to C-TAP. Dr Tedros reflected:

²¹² *Id.*

²¹³ Safi, *supra* note 155.

²¹⁴ KNOWLEDGE AND INNOVATION IN THE PHARMACEUTICAL INDUSTRY EVOLUTION: THE CASE OF PHARMA-BIOTECH (Mariana Mazzucato, *The Entrepreneurial State*, 2018); MAZZUCATO, THE ENTREPRENEURIAL STATE, *supra* note 35; MAZZUCATO, THE VALUE OF INNOVATION, *supra* note 35; MEDEIROS, *supra* note 35; MAZZUCATO, HOW DOES INNOVATION REALLY WORK?, *supra* note 35; MAZZUCATO, MISSION ECONOMY, *supra* note 35.

²¹⁵ *Global Health: The New WHO Council on the Economics of Health for All Announced*, WORLD HEALTH ORGANISATION (May 6, 2021), <https://www.who.int/news-room/feature-stories/2021-05-2021-global-health-the-new-who-council-on-the-economics-of-health-for-all-announced>.

²¹⁶ The WHO Council on the Economics of Health for All, *Governing Health Innovation for the Common Good*, WORLD HEALTH ORGANISATION (June 2021), https://www.who.int/media/docs/default-source/council-on-the-economics-of-health-for-all/council-briefing-note-2021-06-2021-who-council-on-the-economics-of-health-for-all.pdf?sfvrsn=2_6.

²¹⁷ WHO Director-General Opening Remarks at the Media Briefing on COVID-19, WORLD HEALTH ORGANISATION (February 2021), <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-2019-ncov-23-february-2021>.

Kerry Cunniff, *Indonesia and Bangladesh Reveal Massive Untapped Vaccine Production Capacity at C-TAP Anniversary*, HEALTH POLICY WATCH (May 28, 2021), <https://healthpolicy-watch.news/indonesia-and-bangladesh-reveal-massive-untapped-vaccine-production-capacity-at-c-tap-anniversary/>.

*“We’re holding the door open for pharmaceutical companies that have become household names, although too few households have benefited from the lifesaving tools they have developed. They control the [intellectual property] that can save lives today, end this pandemic soon, and prevent future epidemics from spiralling out of control and undermining health economies and national security.”*²¹⁹

The recalcitrance of technology developers to participate in such cooperative intellectual property sharing schemes may come back to haunt them. The refusal to license technology may lead to more dramatic options such as compulsory licensing and Crown use being deployed to deal with the competition issue.

IV. COMPULSORY LICENSING AND CROWN USE/ GOVERNMENT USE

Under the *TRIPS Agreement* and the *Doha Declaration*, nation states are entitled to use patent flexibilities such as compulsory licensing and crown use to address public health epidemics. The United Nations Secretary-General’s High-Level Panel on Access to Medicines expressed concern that nation states had not made the most of the patent flexibilities.²²⁰

In a briefing note, the World Trade Organization observes that “*the TRIPS Agreement allows compulsory licensing and government use of a patent without the authorization of its owner under a number of conditions aimed at protecting the legitimate interests of the patent holder.*”²²¹ The Secretariat comments: “*All WTO members may grant such licences and government-use orders for health technologies, such as medicines, vaccines and diagnostics, as well as any other product or technology needed to address COVID-19.*”²²²

The People’s Vaccine Alliance has also supported the use of intellectual property flexibilities to provide access to essential medicines: “*We are saying that in these unprecedented times, companies should share their knowledge and not enforce intellectual property rights in the interests of public health.*”²²³

A. Compulsory Licensing for Domestic Purposes

Compulsory licensing is a mechanism which provides for access to patented inventions in return for compensation to the patent holders.²²⁴ Compulsory licensing has been used as a flexible policy

²¹⁹ *Id.*

²²⁰ Dreifuss, *supra* note 25.

²²¹ *The TRIPS Agreement and COVID-19: Information Note*, WORLD TRADE ORGANIZATION (Oct. 15, 2020), https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf.

²²² *Id.*

²²³ THE PEOPLE’S VACCINE ALLIANCE, *supra* note 133.

²²⁴ FREDERICK ABBOTT AND RUDOLF VAN PUymbROECK, COMPULSORY LICENSING FOR PUBLIC HEALTH: A GUIDE AND MODEL DOCUMENTS FOR IMPLEMENTATION OF THE DOHA DECLARATION PARAGRAPH 6 DECISION, (2005); Charles Lawson, *Accessing and Affording Drugs despite the Patent Barrier: Compulsory Licensing and Like Arrangements*, 24 (2) AUSTRALIAN INTELLECTUAL PROPERTY JOURNAL 94-108 (2013); COMPULSORY LICENSING: PRACTICAL EXPERIENCES AND WAYS FORWARD (Reto Hilty & Kung-

doctrine in patent law to address unfair competition, public health concerns, as well as technology transfer.

A number of countries passed specific measures, indicating that they are willing to use compulsory licensing during the COVID-19 pandemic if need be. Bill C-13 amended Canada's Patent Act to empower the Commissioner of Patents, on the application of the Minister of Health, to authorize the Government of Canada or another specified person to supply a patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern.²²⁵ Germany has passed amendments to an Act on the Prevention and Control of Infectious Diseases in Humans.²²⁶ The legislation authorizes the Ministry of Health to issue use orders in the context of an epidemic situation of national importance with respect to patented inventions related to medical products. Hungary's 2020 Government Decree 212/2020 (16 May) allowed for public health compulsory licensing for exploitation within Hungary based on Article 31 of the TRIPS Agreement.²²⁷ In March 2020, Israel's Minister of Health issued a permit allowing the government to import generic versions of lopinavir/ritonavir from India for the purpose of exploring the possibility of treating COVID-19 patients.²²⁸ The Parliament of Chile also supported compulsory licensing for coronavirus medicines and vaccines.²²⁹ The Legislative Committee in Ecuador has approved a resolution on compulsory licensing of patents relating to the coronavirus.²³⁰ A number of Latin American countries may well contemplate the use of compulsory licensing – given the aggressive, overbearing negotiating tactics of vaccine developers.²³¹

Chung Liu eds., 2014); VAN ANH LE, COMPULSORY PATENT LICENSING AND ACCESS TO MEDICINES: A SILVER BULLET APPROACH TO PUBLIC HEALTH? (2021).

²²⁵ An Act respecting certain measures in response to COVID-19, S.C. 2020, C-13 (Can.); Ed Silverman, *A Canadian Bill would make it easier to issue Compulsory Licenses for Covid-19 Products*, STAT (Mar. 25, 2020), <https://www.statnews.com/pharmalot/2020/03/25/canada-compulsory-license-coronavirus-covid19/>.

²²⁶ Sebastian Fuchs, *COVID-19: New German Legislation to Fight Pandemic May Affect Granted German Patents*, BIRD & BIRD (May 2020), <https://www.twobirds.com/en/news/articles/2020/germany/covid-19-new-german-legislation-to-fight-pandemic-may-affect-granted-patents>; Liat Sanz Martínez, *Compulsory Licensing Germany*, KLUWER PATENT BLOG (May 10, 2021), <http://patentblog.kluweriplaw.com/2021/05/10/compulsory-licensing-germany/>.

²²⁷ WORLD TRADE ORGANIZATION, *supra* note 221.

²²⁸ Steven Scheer & Julie Steenhuisen, *Israel Approves Generic HIV Drug to Treat COVID-19 Despite Doubts*, REUTERS (Mar. 19, 2020), <https://www.reuters.com/article/us-health-coronavirus-israel-drug-idUSKBN216237>; Ed Silverman, *AbbVie Will allow Generic Copies of its HIV pill in Israel after the Government Approved a License*, STAT (Mar. 20, 2020), <https://www.statnews.com/pharmalot/2020/03/20/abbvie-israel-hiv-kaletra-coronavirus-covid19/>; Thiru Balasubramaniam, *Israel Issues Compulsory License to Allow the Government to Import Generic Versions of Kaletra*, KNOWLEDGE ECOLOGY INTERNATIONAL (Mar. 23, 2020), <https://www.keionline.org/32503>.

²²⁹ Ed Silverman, *Chilean Lawmakers Support Compulsory Licensing for Coronavirus Medicines and Vaccines*, STAT (Mar. 18, 2020), <https://www.statnews.com/pharmalot/2020/03/18/chile-compulsory-licensing-coronavirus-covid19-vaccines/>.

²³⁰ Luis Gil Abinader, *Legislative Committee in Ecuador Approves Resolution on Compulsory Licensing of Patents Relating to the Coronavirus*, KNOWLEDGE ECOLOGY INTERNATIONAL (Mar. 20, 2020), <https://www.keionline.org/32429>; Ed Silverman, *Ecuador Becomes The Latest Country to Eye Compulsory Licensing for COVID-19 Products*, STAT (Mar. 23, 2020), <https://www.statnews.com/pharmalot/2020/03/23/ecuador-compulsory-licensing-covid19-coronavirus/>.

²³¹ Madlen Davies et al., *"Held to Ransom": Pfizer Demands Governments Gamble with State Assets to Secure Vaccine Deal*, THE BUREAU OF INVESTIGATIVE JOURNALISM (Feb. 23, 2021), <https://www.thebureauinvestigates.com/stories/2021-02-23/held-to-ransom-pfizer-demands-governments-gamble-with-state-assets-to-secure-vaccine-deal>; Investigation: Drugmaker "Bullied" Latin American Nations, AL JAZEERA (Mar. 11, 2021), <https://www.aljazeera.com/news/2021/3/11/investigation-pfizer-bullied-latin-american-nations>.

In 2021, the Supreme Court of India considered the unprecedented humanitarian crisis in India, following the outbreak of the COVID-19 pandemic.²³² It investigated the supply of essential drugs; the method and manner of vaccination; the supply of oxygen; and the declaration of lockdown. The Supreme Court of India said that it sought to facilitate a dialogue between the stakeholders: *“This bounded-deliberative approach is exercised so that the UOI and States can justify the rationale behind their policy approach which must be bound by the human rights framework which presently implicates the right to life under Article 21 and right to equality under Article 14 of the Constitution.”*²³³ The Supreme Court of India highlighted the importance of human rights – the right to life (including the right to health), and the right to equality – to questions of access to essential medicines and oxygen during the pandemic.

The Supreme Court of India discussed the potential for compulsory licensing in respect of vaccines and essential drugs covered by patents during the coronavirus crisis.²³⁴ The Supreme Court of India noted: *“Several drugs that are at the core of the COVID treatment protocol are under patents in India including Remdesivir, Tocilizumab and Favipiravir.”*²³⁵ The Supreme Court of India made reference to intellectual property flexibilities available under the TRIPS Agreement, the Doha Declaration, the WTO General Council Decision 2003, and the TRIPS Waiver (co-sponsored by India). The Supreme Court of India discussed the compulsory licensing powers available under the Patents Act, 1970 (India). The Supreme Court of India noted: *“In the context of the COVID-19 pandemic, we note that several countries such as Canada and Germany have relaxed the legal regimes governing the grant of compulsory licenses.”*²³⁶ The Supreme Court of India also observed that there were patent provisions regarding government use; government acquisition; and patent revocation.

The Supreme Court of India urged the Indian government to consider making use of intellectual property flexibilities to address the public health epidemic: *“We have only outlined the legal framework within which the Central Government can possibly consider compulsory licensing and government acquisition of patents.”*²³⁷ The Supreme Court of India noted: *“The Central Government is free to choose any other course of action that it deems fit to tackle the issue of vaccine requirements in an equitable and expedient manner, which may involve negotiations with domestic and foreign producers of vaccines.”*²³⁸ The Supreme Court of India encouraged the Government to take decisive action: *“We clarify that it is up to the Central Government to choose the best possible measures it can undertake during the current crisis keeping in mind that public interests of paramount importance.”*²³⁹ The Supreme Court of India concluded that the Central Government could

²³² In Re: Distribution of Essential Supplies and Services During Pandemic, (2021) LL 2021 SC 2036 (India).

²³³ *Id.*

²³⁴ *Id.*

²³⁵ *Id.*

²³⁶ *Id.*

²³⁷ *Id.*

²³⁸ *Id.*

²³⁹ *Id.*

also consider using its powers under Sections 92, 100 or 102 of the Patents Act to increase production of essential drugs to ensure that it is commensurate to the demand.²⁴⁰

There has been some disquiet that, while internationally the Government of India has been promoting the TRIPS Waiver in diplomatic negotiations, the Government of India has not fully utilized domestic patent flexibilities and exceptions during the coronavirus crisis.²⁴¹

The African Group has discussed the need to make use of flexibilities – such as compulsory licensing.²⁴² Canadian scholar Chidi Oguamanam has argued that “*Africa needs to strengthen its own regional health bodies as important pathways to scaling and dispersal of R&D efforts.*”²⁴³ He suggested: “*A harmonization of regional and national institutional health capacities is necessary to prepare the continent to participate in the local production of a COVID19 vaccine under a global public good model.*”²⁴⁴

The South Centre, a policy research organization, has provided guidance as to the use of compulsory licenses during the COVID-19 crisis.²⁴⁵

Australian lawyers have contemplated the operation of compulsory licensing in the context of the COVID-19 crisis.²⁴⁶

Hilary Wong of the University of California, Berkeley, has argued that there is a strong case for the use of compulsory licensing during the public health pandemic.²⁴⁷ She observes: “*Compulsory licensing is a powerful public health tool – it can be instrumental for alleviating insufficient supplies of necessary pharmaceuticals as well as mitigating prohibitively expensive drug prices.*”²⁴⁸ Wong noted that, while the rewards of patent protection are necessary to support continual innovation, the compulsory licensing exception exists for public health

²⁴⁰ *Id.*

²⁴¹ Priti Patnaik, *Where does India truly stand on the TRIPS Waiver: Q&A with Murali Neelakantan*, GENEVA HEALTH FILES (Aug. 6, 2021), <https://genevahealthfiles.substack.com/p/where-does-india-truly-stand-on-the-trips-waiver-just-published=true>.

²⁴² Ed Silverman, *Africa Union urges Member Countries to remove Intellectual Property Barriers to Covid-19 vaccines*, STAT (July 1, 2020), <https://www.statnews.com/pharmalot/2020/07/01/africa-covid19-coronavirus-vaccines-patents-intellectual-property/>; Yusuf Vawda, *The TRIPS COVID-19 Waiver, Challenges for Africa and Decolonizing Intellectual Property*, SOUTH CENTRE (2021), <https://www.southcentre.int/wp-content/uploads/2021/08/PB-99.pdf>.

²⁴³ Chidi Oguamanam, *COVID-19 and Africa: Does “One Size Fit All”*, in *Public Health Intervention*, in VULNERABLE: THE LAW, POLICY AND ETHICS OF COVID-19, 591 (Colleen Flood et al. eds., 2020) at 553.

²⁴⁴ *Id.*

²⁴⁵ *Scope of Compulsory License and Government Use of Patented Medicines in the Context of the COVID-19 Pandemic*, SOUTH CENTRE (Mar. 2021), <https://www.southcentre.int/covid-19-compulsory-licenses-table-march-2021/>; Carlos Correa, *Expanding the Production of COVID-19 Vaccines to Reach Developing Countries: Lift the Barriers to Fight the Pandemic in the Global South*, SOUTH CENTRE (Apr. 2021), <https://www.southcentre.int/policy-brief-92-april-2021/>.

²⁴⁶ Sarah Matheson and Artemis Kirkinis, *Compulsory Licence and Crown Use Provisions in the Covid-19 Pandemic—The Australian Perspective*, 16 (6) JOURNAL OF INTELLECTUAL PROPERTY LAW & PRACTICE 484–497 (2021).

²⁴⁷ Hilary Wong, *The Case for Compulsory Licensing During COVID-19*, 10 J. GLOB. HEALTH 1 (2020), <http://www.jogh.org/documents/issue202001/jogh-10-010358.pdf>.

²⁴⁸ *Id.*

emergencies such as the current COVID-19 crisis.²⁴⁹

She emphasized that governments must do what is necessary to fight the present pandemic.²⁵⁰ She also suggested that international organizations can play a key role by providing the legal know-how as well as setting a supportive tone for using compulsory licensing.²⁵¹ Wong warned intellectual property owners against retaliation: “*In the process, pharmaceutical companies and G20 countries should not deter or retaliate against developing countries pursuing such public health measures in the time of a pandemic.*”²⁵²

Ellen ‘t Hoen and her collaborators have noted the limitations of compulsory licensing, observing that compulsory patent licences are granted product-by-product and country-by-country, and are time-limited.²⁵³ Moreover, the compulsory licensing decision is subject to judicial review which may suspend the execution of the compulsory license.²⁵⁴ ‘t Hoen and her team comment: “*It is not possible to grant blanket Compulsory Licenses for an entire field of technology or for an overarching purpose such as ‘combating a pandemic.’*”²⁵⁵

B. Compulsory Licensing for the Export of Essential Medicines

There have been issues with the implementation of the *WTO General Council Decision* 2003, now codified as Article 31bis of the *TRIPS Agreement*, dealing with the export of pharmaceutical drugs.²⁵⁶ Nobel Laureate Professor Joseph Stiglitz has expressed his concern about the operation of the export mechanism under Article 31bis. He commented: “*Life should always be put before profits, and never more so than in the midst of a pandemic.*”²⁵⁷ In his view, “*The WTO should not have rules that deliberately create barriers to importing needed drugs, whether it’s rich countries or poor; and especially so because those rules limit the ability of firms to achieve efficient economies of scale.*”²⁵⁸ Stiglitz maintained: “*The opt-out provision in Article 31bis is protectionism at its worst – where it is lives that may be lost as a result – and something clearly not in the interests of any country, large or small, importer or exporter, during the COVID-19 crisis.*”²⁵⁹

Given the nature of the coronavirus public health epidemic, the limited framework for

²⁴⁹ *Id.*

²⁵⁰ *Id.*

²⁵¹ *Id.*

²⁵² *Id.*

²⁵³ ‘T HOEN, *supra* note 158.

²⁵⁴ *Id.*

²⁵⁵ *Id.*

²⁵⁶ DECISION OF THE GENERAL COUNCIL, *supra* note 7.

²⁵⁷ James Love, *Open Letter Asking 37 WTO Members to Declare Themselves Eligible to Import Medicines Manufactured Under Compulsory License in Another Country under 31bis of TRIPS Agreement*, KNOWLEDGE ECOLOGY INTERNATIONAL (Apr. 7, 2020), <https://www.keionline.org/32707>.

²⁵⁸ *Id.*

²⁵⁹ *Id.*

compulsory licensing for the purposes of export must be reconsidered. Stiglitz has called for substantive action for reform of the export system in the face of the coronavirus crisis.²⁶⁰

In the past, India has acted as a “Pharmacy of the Developing World”, and has provided generic medicines to other countries during public health epidemics.²⁶¹ As India needed to become TRIPS-compliant, there has been debate as to whether the compulsory export licence system is effective in India.²⁶² However, during the coronavirus crisis, the Serum Institute of India has struggled with the demands of domestic supply – let alone the global demand for COVID-19 vaccines.²⁶³

There has been an effort to use the compulsory licensing scheme for the export of pharmaceutical drugs in Canada. As the author has written about previously, the export scheme has proven to be awkward and cumbersome in its operation.²⁶⁴ In Canada, St. Catharines pharmaceutical company Biolyse Pharma has wanted to help with the global COVID-19 vaccine rollout.²⁶⁵ The company has expressed an interest in obtaining generic vaccines from Biolyse Pharma. Biolyse Pharma has made a license request to Johnson & Johnson, but that was denied.²⁶⁶ In 2021,²⁶⁷ Biolyse has been critical of the obstacles that it has faced in obtaining a license. John Fulton of Biolyse observed: “*If we can’t get a compulsory licensing agreement to work right now, what’s the use?*”²⁶⁹ Knowledge Ecology International, a Canadian advocacy group, has refused to tell KEI and Biolyse whether COVID-19 vaccines will be added to the list of essential medicines for that amendment to take place.”²⁷⁰ Knowledge Ecology International has also recommended that the Canadian government consider law reform in Canada to promote access to essential

260 Amy Joseph Stiglitz: The Economic Plans Are Not Enough to Meet Coronavirus Challenge, DEMOCRACY NOW (Mar. 1, 2020), https://www.democracynow.org/2020/3/19/us_economy_coronavirus_stimulus_joseph_stiglitz.

261 REF *para note 8*

²⁶² Hafiz, *supra* note 261, at 10; see also *Indian Patent Law*, NORD. J. COMMER. LAW 1 (2011).

263 Lau, "The Book of David: The Indian Firm Making More Covid Jabs Than Anyone," THE GUARDIAN (Feb. 14, 2021), <https://www.theguardian.com/development/2021/feb/14/we-took-a-huge-risk-the-indian-firm-making-more-covid-jabs-than-anyone>.

264 STI AND HIV IN THE CARIBBEAN AGAINST RESEARCHING FOR HOPE IN AIDS-RAVAGED AFRICA
(2006); *Journal of Intellectual Property Law*, 15 (7) EXPERT OPINION ON
THERAPY PATENT LAW AND HUMANITARIAN AID, 15 (7)
PUBLISHED BY RACE AGAINST TIME: THE EXPORT OF ESSENTIAL MEDICINES TO RWANDA, 1 (2)

Shenoy, [REDACTED] *Help with Global COVID-19 Vaccine Rollout*, IHEARTRADIO (Mar. 11, 2021), [https://www.iheartradio.com/indian-pharmaceutical-company-wants-to-help-with-global-covid-19-vaccine-rollout/](#).

For more information on the above, please visit the Knowledge Centre for Vaccines from Biohyse, if Canada Grants them a Compulsory License, KNOWLEDGE CENTRE FOR VACCINES FROM BIOHYSE, www.keionline.org/36119.

Kerry Cumman, *Company Pushes to Grant Compulsory License for Johnson & Johnson COVID-19 Vaccine*, HEALTH POLICY WATCH (May 11, 2021), <https://healthpolicy-watch.news/company-pushes-canada-to-grant-compulsory-license-for-johnson-johnson-covid-19-vaccine/>.

²⁶⁸ Francesca Bruce, *Canadian Firm Scathing on Obstacles to Compulsory Licensing: Biolyse is Determined to Manufacture J&J's COVID-19 Vaccine*, PINK SHEET: INFORMA PHARMA INTELLIGENCE (May 27, 2021), <https://pink.pharmaintelligence.informa.com/PS144384/Canadian-Firm-Scathing-On-Obstacles-To-Compulsory-Licensing>.

269 *Id.*

²⁷⁰ CULLINAN, *supra* note 264.

medicines.

The government of Bolivia has been disappointed by the uncooperative approach to compulsory licensing for the purposes of export.²⁷¹ Benjamin Blanco, Minister of Foreign Trade and Integration, Ministry of Foreign Relations for Bolivia, commented: “*It is time to make decisions in the name of humanity.*”²⁷²

In addition to Bolivia, Antigua and Barbuda have notified the WTO of their intent to import products using compulsory licences.²⁷³ The Caribbean country has previously articulated its support for the TRIPS Waiver during the coronavirus crisis.

The Biolyse case highlights how the compulsory licensing system established by the *WTO General Council Decision 2003* – and embedded in Article 31bis of the *TRIPS Agreement* – is broken. There is a need for fundamental overhaul of the regime to facilitate the distribution and dissemination of essential medicines during pandemics – like in respect of the coronavirus.

The European Union has opposed a proposal for a TRIPS Waiver. Instead, the EU has proposed a ‘third way’ of simplifying and streamlining the use of compulsory licensing under the *TRIPS Agreement*, the *Doha Declaration*, and the *WTO General Council Decision 2003*.²⁷⁴ The EU noted: “*The discussions in the Council for TRIPS since the start of the COVID-19 pandemic have identified aspects related to the use of compulsory licensing that, in the view of a number of WTO Members, limit the use of this tool.*”²⁷⁵ The EU suggested that WTO Members should agree to a number of propositions – including that “*(a) The pandemic is a circumstance of national emergency and therefore the requirement to negotiate with the right holder may be waived; (b) To support manufacturers ready to produce vaccines or therapeutics at affordable prices, especially for low- and middle-income countries, on the basis of a compulsory licence, the remuneration for patent holders should reflect such affordable prices; and (c) The compulsory licence could cover any exports destined to countries that lack manufacturing capacity, including via the COVAX facility.*”²⁷⁶ The EU emphasized that it was “*ready to engage on other points regarding the facilitation of the use of compulsory licensing as provided for in the TRIPS Agreement.*”²⁷⁷ Leaked documents have shown that the EU Council of Ministers defined its position on the TRIPS Waiver for

²⁷¹ Ahmar Khan, *Canada lacks ‘political will’ to waive COVID-19 vaccine patents, Bolivian minister says*, GLOBAL NEWS, (October 6 2021) <https://globalnews.ca/news/8243635/bolivian-minister-canada-covid-vaccine-waiver/>.

²⁷² *Id.*

²⁷³ Luis Gil Abinader, *Antigua and Barbuda Notified the WTO Of Their Intent to Import Products Using Compulsory Licences*, KNOWLEDGE ECOLOGY INTERNATIONAL (June 7, 2021), <https://www.keionline.org/36241>.

²⁷⁴ Communication from the European Union to the Council for TRIPS, *Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property* (Jun. 4, 2021), https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159606.pdf; See generally, Ed Silverman, *EU Pushes Rival Plan to COVID-19 IP Waiver, But Some Deride It As “Meaningless”*, STAT (Jun. 4, 2021), <https://www.statnews.com/pharmalot/2021/06/04/covid19-vaccine-patents-europe-waiver/>.

²⁷⁵ *Id.*

²⁷⁶ *Id.*

²⁷⁷ *Id.*

vaccines in secret.²⁷⁸ There has been concern that the Big Pharma have had an undue influence on the formation of the EU position.

Human Rights Watch have questioned the justifications of the EU for opposing the TRIPS Waiver.²⁷⁹ It also observed that “there are significant barriers to making compulsory licenses a practical solution to the severe supply shortages the world is facing now.”²⁸⁰ A collection of scholars have suggested that “existing TRIPS flexibilities around compulsory licensing are incapable of addressing the present pandemic context adequately, both in terms of procedure and legal substance.”²⁸¹ Jorge Contreras has considered the use of compulsory licensing, government use, and march-in rights during the coronavirus pandemic.²⁸²

C. Crown Use, Government Use, and Government Acquisition

In addition to compulsory licensing, there is also the option of Crown use or government use of patented inventions. In the United Kingdom, the Hon. Philippa Whitford has called on the United Kingdom to utilize its crown use powers under patent law.²⁸³ She commented: “Where patents, monopolies or exclusivities already exist on medical products that are potentially useful for tackling COVID-19, the UK government should issue crown use licenses where necessary to ensure scale up of production and ensure affordable access to these products.”²⁸⁴ Whitford stressed: “COVID-19 is unprecedented as a public health emergency, and access to these medical products cannot be restricted by intellectual property rights.”²⁸⁵

There has been a parliamentary debate about this topic of patent law and crown use in Australia. In 2013, the Productivity Commission discussed the merits of compulsory licensing and crown use in a law reform review.²⁸⁶ The Productivity Commission suggested that crown use was a “less costly and time-consuming alternative to compulsory licensing”.²⁸⁷ The Productivity Commission made some recommendations as to how to improve the clarity, transparency and accountability of the crown use provisions. The *Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2019* (Cth) sought to modernise the Crown use provisions. Senator Duniam, the Assistant Minister,

²⁷⁸ *Leaked Documents show EU Council of Ministers defined its position on TRIPS Waiver for Vaccines in Secret*, CORPORATE EUROPE OBSERVATORY (Jul. 4, 2021), <https://corporateeurope.org/en/2021/06/leaked-documents-show-eu-council-ministers-defined-its-position-trips-waiver-vaccines>.

²⁷⁹ *Seven Reasons the EU is Wrong to Oppose the TRIPS Waiver*, HUMAN RIGHTS WATCH (Jun. 3, 2021), <https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver>.

²⁸⁰ *Id.*

²⁸¹ 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*, SSRN (May 24, 2021), <https://ssrn.com/abstract=3851737>.

²⁸² Jorge Contreras, *Patents and Coronavirus— Compulsory Licensing, Government Use and March-In Rights*, INFOJUSTICE (Mar. 28, 2020), <http://infojustice.org/archives/42184>.

²⁸³ WHITFORD, *supra* note 197.

²⁸⁴ *Id.*

²⁸⁵ *Id.*

²⁸⁶ Productivity Commission, *COMPULSORY LICENSING OF PATENTS*, Report No. 61, (March 28, 2013) <https://www.pc.gov.au/inquiries/completed/patents/report>

²⁸⁷ *Id.*, 2.

noted: “*There is some uncertainty about when Crown use can be invoked at the present, and this Bill makes it clear that while it is rarely used, it can be invoked when any Australian Federal, State or Territory government has the primary responsibility for providing or funding a service.*”²⁸⁸ The Assistant Minister observed that the bill “*ensures that Crown use can cover the full range of services that the public expects our Government to provide.*”²⁸⁹

During the coronavirus public health crisis, a Shadow Minister, the Hon. Brendan O’Connor suggested that the Australian Government should make use of the Crown Use provisions: “*I also think the government will need to detail how Crown use of patents may be invoked, particularly for use for repurposed manufacturing businesses, to address shortages of essential goods impacted by disrupted supply chains.*”²⁹⁰ He commented that the Minister should explore the use of this provision, “*particularly for urgent manufacturing of suppliers, such as facial masks or goods in short supply due to disrupted supply chains.*”²⁹¹ The Australian Government has warned that it will use its Crown Use powers if patent inventors engage in profiteering in respect of essential inventions. Australian lawyers have considered the dynamics of Crown use in the context of the COVID-19 crisis.²⁹²

As the United Nations Secretary General’s High-Level Panel on Access to Medicines made clear, there is a need for nation states to make better use of intellectual property flexibilities – such as compulsory licensing, Crown use, and government acquisition.²⁹³

V. PUBLIC SECTOR LICENSING

Universities and public research organisations are playing a key role in the development of vaccines, diagnostics, and treatments for the coronavirus COVID-19.

There has been a growing corpus of literature on intellectual property, education, and technology transfer. Corynne McSherry, the Legal Director of the Electronic Frontier Foundation, wrote a classic book about the battle for the control of intellectual property in academia.²⁹⁴ In a series of works, Professor Jacob Rooksby, the Dean of Gonzaga Law School, has written about the growing pressures of commercialization of intellectual property generated by higher education institutions.²⁹⁵ Hans Radder has explored how the higher education system has been affected by

²⁸⁸ Commonwealth, *Parliamentary Debates*, Senate, 25 July 2019, 844 (Jonathon Duniam, Senator).

²⁸⁹ *Id.*

²⁹⁰ Commonwealth, *Parliamentary Debates*, House of Representatives, 23 March 2020, 2801 (Brendan O’Connor, Member of Parliament (Austl.)).

²⁹¹ *Id.*

²⁹² Sarah Matheson and Artemis Kirkinis, *Compulsory Licence and Crown Use Provisions in the Covid-19 Pandemic—The Australian Perspective*, 16 (6) JOURNAL OF INTELLECTUAL PROPERTY LAW & PRACTICE 484–497 (2021).

²⁹³ U.N. Secretary-General, *Access to Medicines: Promoting Innovation and Access to Health Technologies* (Sept. 14, 2016).

²⁹⁴ CORYNNE MCSHERRY, WHO OWNS ACADEMIC WORK? BATTLING FOR CONTROL OF INTELLECTUAL PROPERTY (2001).

²⁹⁵ Jacob Rooksby, *Universities that Litigate Patents*, (May. 1, 2012)(unpublished thesis, University of Virginia)(on file with

commodification.²⁹⁶ Professor Joseph Stiglitz, the Nobel Laureate in Economics, has considered the relationship between intellectual property and learning, and has called for an expansion of the knowledge commons.²⁹⁷

There has been an array of legal conflicts over essential inventions developed by educational organisations and public research institutions in relation to biomedicine. There were conflicts between the University of California and Genentech in respect of patents and biotechnology, relating to human growth hormone and insulin.²⁹⁸ Public researchers were involved in patent races with private biotechnology firms like Myriad Genetics, in respect of genetic testing.²⁹⁹ There have also been controversies over access to essential medicines in respect of HIV/AIDS, malaria, and tuberculosis, which had been developed by public institutions.³⁰⁰ Amy Kapczynski and her colleagues called for an open licensing approach to university innovations in order to address global health inequities.³⁰¹ There have been significant clashes in respect of patent rights and stem cell research.³⁰² More recently, there have been patent races between rival universities in respect of CRISPR, gene-editing technologies.³⁰³ There has also been emerging disputes over 3D printing and bioprinting developed by public research institutions.³⁰⁴ The USPTO has sought to encourage humanitarian innovation with its 'Patents for Humanity' programme – although that scheme has

Online Archive of University of Virginia Scholarship).); JACOB ROOKSBY, *BRANDING OF THE AMERICAN MIND: HOW UNIVERSITIES, CAPTURE, MANAGE, AND MONETIZE INTELLECTUAL PROPERTY AND WHY IT MATTERS* (2016); *RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER* (Jacob Rooksby ed., 2020); WILLIAM KAPLIN, BARBARA LEE, NEAL HUTCHENS AND JACOB ROOKSBY, *THE LAW OF HIGHER EDUCATION* (Jossey-Bass 6th ed. 2020).

²⁹⁶ HANS RADDER, *FROM COMMODIFICATION TO THE COMMON GOOD: RECONSTRUCTING SCIENCE, TECHNOLOGY, AND SOCIETY* (2019).

²⁹⁷ JOSEPH STIGLITZ AND BRUCE GREENWALD, *CREATING A LEARNING SOCIETY: A NEW APPROACH TO GROWTH, DEVELOPMENT, AND SOCIAL PROGRESS* (2014); DEAN BAKER, ARJUN JAYADEV, AND JOSEPH STIGLITZ, *INNOVATION, INTELLECTUAL PROPERTY, AND DEVELOPMENT: A BETTER SET OF APPROACHES FOR THE 21ST CENTURY* (2017), <http://ip-unit.org/wp-content/uploads/2017/07/IP-for-21st-Century-EN.pdf>.

²⁹⁸ Matthew Rimmer, *Genentech and The Stolen Gene: Patent Law and Pioneer Inventions*, 5 *BIOSCI. L. REV.* 198, 198 (2004); and SALLY SMITH HUGHES, *GENENTECH: THE BEGINNINGS OF BIOTECH* (2011).

²⁹⁹ Jessica Lai, *Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision*, 5 *IRVINE L. REV.* 1041, 1041-1076 (2015); Matthew Rimmer, *An Exorbitant Monopoly: The High Court of Australia, Myriad Genetics, and Gene Patents*, in *RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND THE LIFE SCIENCES* 56 (Duncan Matthews and Herbert Zech eds., 2017); Shubha Ghosh, *Myriad Post-Myriad*, 47 *SCIENCE AND PUBLIC POLICY* 638 (2020); and JORGE CONTRERAS, *THE GENOME DEFENSE: INSIDE THE EPIC LEGAL BATTLE TO DETERMINE WHO OWNS YOUR DNA* (2021).

³⁰⁰ Pogge, *supra* note 2.

³⁰¹ Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 *BERKELEY TECHNOL. LAW J.* 1031 (2005).

³⁰² Matthew Rimmer, *The Attack of The Clones: Patent Law and Stem Cell Research*, 10 *J. LAW MED.* 488 (2003); and Matthew Rimmer, *The Last Taboo: Patenting Human Beings*, 14 *EXPERT OPIN. THER PAT* 1061 (2004).

³⁰³ Jacob Sherkow, *The CRISPR Patent Landscape: Past, Present, and Future*, 1 *THE CRISPR J.*, (2018), JENNIFER DOUDNA AND SAMUEL STERNBERG, *A CRACK IN CREATION: GENE EDITING AND THE UNTHINKABLE POWER TO CONTROL EVOLUTION* (2018); HENRY GREELY, *CRISPR PEOPLE: THE SCIENCE AND ETHICS OF EDITING HUMANS* (2021); WALTER ISAACSON, *THE CODE BREAKER: JENNIFER DOUDNA, GENE EDITING, AND THE FUTURE OF THE HUMAN RACE* (2021).

³⁰⁴ Matthew Rimmer, *Make and Share: Intellectual Property, Higher Education, Technology Transfer, and 3D Printing in a Global Context*, in *RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER* 447 (Jacob Rooksby ed., 2020).

been marginal in dealing with access to medicines.³⁰⁵

Economist Mariana Mazucatto has highlighted that the pharmaceutical and biotechnology industries have benefitted enormously from publicly-funded blue sky research and state policies designed to facilitate commercialization.³⁰⁶ The People's Vaccine Alliance have expressed concern that publicly-funded inventions are being exploited for private profit during the coronavirus crisis.³⁰⁷ Anna Marriott, Oxfam's Health Policy Manager, commented: "*These vaccines were funded by public money and should be first and foremost a global public good, not a private profit opportunity.*"³⁰⁸ She emphasized: "*We need to urgently end these monopolies so that we can scale up vaccine production, drive down prices and vaccinate the world.*"³⁰⁹

A. U.S.

The student-based group Universities Allied for Essential Medicines ["UAEM"] was established in 2001 in order to advocate flexible licensing in respect of publicly-funded humanitarian research. It helped convince Yale University and Bristol-Myers Squibb to permit generic production of a HIV-AIDS drug. Since this early victory, UAEM has grown into a worldwide student organization, which asks universities to promote global access to their inventions.

Given the public investment in respect of COVID-19 technologies, there has been much debate as to whether such research should be made publicly accessible and available. UAEM have been mapping public investment in COVID-19 technologies.³¹⁰ The organization has called upon public research institutions to 'free the vaccine.'³¹¹

Klara Lou, a member of UAEM from Vanderbilt University, wrote a stirring op-ed about the need for universities to commit to free the vaccine.³¹² She stressed: "*As a student, I believe that our universities have the opportunity and great responsibility to increase universal access to crucial medicines such as the COVID-19 vaccine, especially since the research is done in our own labs.*"³¹³ Lou argued: "*To do this, universities have the power to influence pricing with their research choices,*

³⁰⁵ *Patent for Humanity COVID-19*, U.S. PATENT AND TRADEMARK OFFICE, <https://www.uspto.gov/ip-policy/patent-policy/patents-humanity-covid-19>; For a critique, see: Matthew Rimmer, *Patents for Humanity*, 3 W.I.P.O. J. 198 (2012).

³⁰⁶ MAZZUCATO, KNOWLEDGE ACCUMULATION AND INDUSTRY EVOLUTION, *supra* note 37; MAZZUCATO, THE ENTREPRENEURIAL STATE, *supra* note 37.

³⁰⁷ Press Release, OXFAM International, COVID Vaccines Create 9 New Billionaires with Combined Wealth Greater than Cost of Vaccinating World's Poorest Countries (May 20, 2021), <https://www.oxfam.org/en/press-releases/covid-vaccines-create-9-new-billionaires-combined-wealth-greater-cost-vaccinating>.

³⁰⁸ *Id.*

³⁰⁹ *Id.*

³¹⁰ UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES, Tracking COVID-19 Investment, (2021) <https://www.publicmeds4covid.org/>.

³¹¹ *Id.*

³¹² Klara Lou, *Dear Vanderbilt, Commit to A Free Vaccine*, VANDERBILT HUSTLER (Jul. 15, 2020), <https://vanderbilthustler.com/33236/featured/guest-editorial-dear-vanderbilt-commit-to-a-free-vaccine/>.

³¹³ *Id.*

*and we can reform the American research and development (R&D) pipeline from within our institutions.”*³¹⁴ She stressed: “*We, the students, must speak up through our actions for the #FreeTheVaccine movement.*”³¹⁵

Navya Dasari, a student at the New York University School of Law and UAEM member, explained about the campaign: “*We’re serious about the cause, we demand a seat at the table, and we have the knowledge and research to back our ideas up*”.³¹⁶ She said: “*The lives of my loved ones abroad matter as much as the life of any American.*”³¹⁷ Dasari commented: “*Although rich countries are getting vaccinated more quickly, the message of this pandemic remains true: None of us are safe until all of us are safe.*”³¹⁸

UAEM have campaigned vigorously for universities and research institutions to better transfer their technologies to combat global public health challenges – like the coronavirus.³¹⁹

The University of California developed university licensing guidelines to support humanitarian efforts in respect of sustainable development goals in respect of public health, clean water, food security, and renewable energy.³²⁰

Stanford University and a number of other universities have engaged in public sector licensing of intellectual property for the purpose of making products to prevent, diagnose, and treat COVID-19 during the pandemic.³²¹ The COVID-19 Technology Access Framework declares its commitment to implement the COVID-19 patenting and licensing strategies to enable global access,³²² noting that this usually involves use of “*rapidly executable non-exclusive royalty-free licenses to intellectual property rights*” which they have the right to license during the pandemic.³²³ The Framework further elaborates: “*In return for these royalty-free licenses, we are asking the licensees for a commitment to distribute the resulting products as widely as possible and at a low cost that allows broad accessibility during the term of the license.*”³²⁴ The initial signatories included Stanford University, Harvard University, and the Massachusetts Institute of Technology. Additional signatories included the Broad Institute, Cornell University, Dartmouth University,

³¹⁴ *Id.*

³¹⁵ *Id.*

³¹⁶ Jacqui Germain, *Vaccine Nationalism: What Is It and How Is It Playing Out During COVID-19*, TEEN VOGUE (May 6, 2021), <https://www.teenvogue.com/story/vaccine-nationalism-what-is>.

³¹⁷ *Id.*

³¹⁸ *Id.*

³¹⁹ Ed Silverman, *Most U.S. Universities Get an “F” on Ensuring Access to Drugs They Discover*, STAT (Mar. 30, 2021), <https://www.statnews.com/pharmalot/2021/03/30/universities-covid19-patents-drug-prices-clinical-trials/>.

³²⁰ Goldie Blumenstyk, *Graduate Students Press for “Humanitarian Licensing” Vow in U. of California Patent Policy*, THE CHRONICLE OF HIGHER EDUCATION (Dec. 14, 2011), <https://www.chronicle.com/article/graduate-students-press-for-humanitarian-licensing-vow-in-u-of-california-patent-policy/>; and *University Licensing Guidelines*, UNIVERSITY OF CALIFORNIA (2012), https://www.ucop.edu/research-policy-analysis-coordination/files/licensing_guidelines_2012.pdf.

³²¹ Stanford Office of Technology Licensing, *COVID-19 Technology Access Framework*, STANFORD UNIVERSITY, <https://otl.stanford.edu/covid-19-technology-access-framework>.

³²² *Id.*

³²³ *Id.*

³²⁴ *Id.*

and a range of other universities.

In a letter to the U.S. Government, Knowledge Ecology International has argued that the U.S. Government should make use of its powers under the Bayh-Dole Act to ensure access to patents on coronavirus relevant inventions.³²⁵ The Civil Society Organization have highlighted powers in respect march-in-rights on federally funded inventions; a global royalty free right in patents; the ability to retain title to contractor patents; and the capacity to assign rights in patents to the World Health Organization and other entities. The National Institutes of Health has responded to Knowledge Ecology International's letter, observing: "*The NIH will consider the use of all its authorities, including the ones you identified, to hasten the goal of identifying safe and effective technologies to treat and prevent COVID-19 infections.*"³²⁶

Professor Jorge Contreras has observed that the U.S. Government has been reluctant to invoke its march-in-rights under the Bayh-Dole Act, and the provisions are limited in their scope: "Notwithstanding these drawbacks, march-in rights under the Bayh-Dole Act could be valuable tools to lift patent barriers that may currently impede the supply of goods and services needed to fight coronavirus."³²⁷ The economist Mariana Mazucatto has lamented: "*And even though there are march-in rights under the Bayh-Dole Act, which allowed publicly financed research to be patented, unfortunately, the NIH seems not to be interested in using them effectively.*"³²⁸

Public Citizen have been concerned about the investment of the Trump administration into vaccines – without conditions ensuring public access:

"The public is paying for research, development, and manufacturing—with no strings attached. More funding is imminent. Yet the government requires that vaccines be patented. To make these vaccines essentially public goods, a proven vaccine may not reach the person who needs it."³²⁹

Public Citizen has conducted a number of case studies of companies which have received U.S. Government public funding for COVID-19 vaccines, treatments, and diagnostics.

Some companies such as Moderna have given no guarantees that they will not seek to profit from vaccines.³³⁰ In particular, Public Citizen has highlighted that the Moderna vaccine was the

³²⁵ James Love, *Three Areas in Section 202 of the Bayh-Dole Act that Require Action to Ensure Sufficient Rights in Patents on Coronavirus Relevant Inventions*, KNOWLEDGE ECOLOGY INTERNATIONAL (Mar. 14, 2020), <https://www.keionline.org/32364>.

³²⁶ Mark Lemley, *Letter Concerning Section 202 of the Bayh-Dole Act and the Novel Coronavirus Pandemic*, KNOWLEDGE ECOLOGY INTERNATIONAL (Apr. 6, 2020), <https://www.keionline.org/wp-content/uploads/2020/04/NIH-Response-to-Knowledge-Ecology-International-Bayh-Dole-Coronavirus-Letter-6April2020.pdf>.

³²⁷ CONTRERAS, *supra* note 280.

³²⁸ M. Mazucatto, *supra* note 87.

³²⁹ RICHARD L. STOLAR, *Moderna Say They Plan to Profit From Coronavirus Vaccine*, THE NEW YORK TIMES (Jul. 21, 2020),

result of public investment in the research of the National Institutes of Health [“NIH”].³³¹ Peter Maybarduk, director of Public Citizen’s Access to Medicines program, observed:

*“This is the people’s vaccine. The NIH’s vaccine. It is not merely Moderna’s vaccine. Federal scientists helped invent it and taxpayers are funding its development. We all have played a role. It should belong to humanity.”*³³²

He argued that the U.S. Government should *“make this vaccine a public good that is free and available to all and help scale up global manufacturing, in order to prevent medical rationing that could become a form of global vaccine apartheid.”*³³³

Dr Barney Graham, one of the US NIH scientists who invented a key piece of technology used in the Moderna and BioNTech/Pfizer vaccines, said that the government’s patent gave the Biden administration leverage over manufacturers.³³⁴ He observed: *“Virtually everything that comes out of the government’s research labs is a non-exclusive licensing agreement so that it doesn’t get blocked by any particular company.”*³³⁵ Graham noted: *“That’s one of the reasons [I joined the NIH]: it’s to be able to use the leverage of the public funding to solve public health issues.”*³³⁶ It remains to be seen whether the Biden Administration will use this patent power to secure better production and distribution of these key vaccines.

There is an emerging dispute between Moderna and the U.S. Government over patent rights in respect of named inventors.³³⁷ Moderna has filed a patent application – naming several of its employees as the only inventors of a crucial component of its coronavirus vaccine.³³⁸ The NIH says that three scientists at its Vaccine Research Center – Dr. John Mascola, the center’s director; Dr. Barney Graham; and Dr. Kizzmekia Corbett – should be named as inventors on the principal patent application. Kathy Stover, a spokeswoman for the National Institute for Allergy and Infectious Diseases, commented: *“Omitting N.I.H. inventors from the principal patent application deprives N.I.H. of a co-ownership interest in that application and the patent that will eventually issue from it.”*³³⁹

B. United Kingdom

In the United Kingdom, Oxford University played a key role in the development of what has

<https://www.nytimes.com/2020/07/21/health/covid-19-vaccine-coronavirus-moderna-pfizer.html>.

³³¹ *Moderna Vaccine Belongs to the People*, PUBLIC CITIZEN (Nov. 16, 2020), <https://citizen.org/news/statement-moderna-vaccine-belongs-to-the-people/>.

³³² *Id.*

³³³ *Id.*

³³⁴ Donato Paolo Mancini and Kiran Stacey, *Vaccine Patent Gives US “Leverage” Over Manufacturers*, FINANCIAL TIMES (Apr. 21, 2001), <https://www.ft.com/content/d0c70cc2-0ffa-42dd-b0d0-0f76ceb273f0>.

³³⁵ *Id.*

³³⁶ *Id.*

³³⁷ Sheryl Gay Stolberg and Rebecca Robbins, *Moderna and U.S. at Odds Over Vaccine Patent Rights*, *The New York Times*, (November 9, 2021), <https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html>.

³³⁸ *Id.*

³³⁹ *Id.*

become known as the Oxford AstraZeneca vaccine.³⁴⁰ Oxford University vowed that “*the default approach of the University and [Oxford University Innovation] ... will be to offer non-exclusive, royalty-free licences to support free of charge, at-cost or cost + limited margin supply as appropriate, and only for the duration of the pandemic, as defined by the WHO.*”³⁴¹ Nonetheless, urged by the Bill & Gates Foundation, Oxford University entered into an exclusive vaccine deal with Astra Zeneca.³⁴²

There has been an anguished debate over the decision of Oxford University to develop its vaccine with AstraZeneca – given the implications that choice has had for the production and distribution of the COVID-19 vaccine. Christopher Garrison has provided a briefing note on the transformation of the Oxford COVID-19 vaccine into the AstraZeneca COVID-19 Vaccine.³⁴³ He reflects: “*Rather than being a simple story of a non-profit academic research institute handing over its vaccine candidate to a ‘Big Pharma’ firm, ... there are a number of other non- and for-profit parties involved, including Vaccitech and OSI.*”³⁴⁴ Garrison suggests that “*the operation of Consortium B during the pandemic may perhaps be a forerunner pointing to the development of new R&D coalitions and funding models that could serve humanity long beyond the Covid-19 pandemic.*”³⁴⁵

However, others have been critical of Oxford’s COVID-19 vaccine deal with AstraZeneca.³⁴⁶ Ameet Sarpatwari, an epidemiologist and lawyer at Harvard Medical School, regretted that “*it is business as usual, where the manufacturers are getting exclusive rights and we are hoping on the basis of public sentiment that they will price their products responsibly.*”³⁴⁷ Professor Duncan Matthews also lamented the secrecy surrounding such public-private partnerships: “*The biopharma industry is applying old rules of commercial confidentiality in a situation that is unprecedented.*”³⁴⁸

In the United Kingdom, a number of legislators have questioned why publicly funded vaccines have not been publicly licensed. On behalf of a bevy of politicians, Dr Philippa Whitford MP wrote to the Prime Minister Boris Johnson and relevant ministers, emphasizing: “*The government needs to impose public interest conditions on all UK funding committed to develop COVID-19 vaccines and treatments to ensure widespread access and transparency.*”³⁴⁹ She also commented that “*conditions should include full transparency in all stages of R&D, including registration*

³⁴⁰ SARAH GILBERT AND CATHERINE GREEN, VAXXERS: THE INSIDE STORY OF THE OXFORD ASTRAZENECA VACCINE AND THE RACE AGAINST THE VIRUS (2021).

³⁴¹ *Expedited Access for COVID-19 Related IP*, OXFORD UNIVERSITY INNOVATION, <https://innovation.ox.ac.uk/technologies-available/technology-licensing/expedited-access-covid-19-related-ip/>.

³⁴² Jay Hancock, *Oxford’s COVID vaccine deal with AstraZeneca raises concerns about access and pricing*, FORTUNE (Aug. 2020), <https://fortune.com/2020/08/24/oxford-astrazeneca-covid-vaccine-deal-pricing-profit-concerns/>.

³⁴³ Christopher Garrison, *How the “Oxford” COVID-19 Vaccine Became the “AstraZeneca” COVID-19 Vaccine*, MEDICINES LAW & POLICY (Oct. 2020), <https://medicineslawandpolicy.org/wp-content/uploads/2020/10/How-the-Oxford-Covid-19-Vaccine-became-the-AstraZeneca-Covid-19-Vaccine-Final.pdf>.

³⁴⁴ *Id.*, at 12.

³⁴⁵ *Id.*, at 16.

³⁴⁶ Jay Hancock, *Oxford’s COVID Vaccine Deal with AstraZeneca raises Concerns about Access and Pricing*, FORTUNE (Aug. 23, 2020), <https://fortune.com/2020/08/24/oxford-astrazeneca-covid-vaccine-deal-pricing-profit-concerns/>.

³⁴⁷ *Id.*

³⁴⁸ *Id.*

³⁴⁹ WHITFORD, *supra* note 197.

and public reporting of clinical trial data, R&D costs, manufacturing costs and product prices.”³⁵⁰ Whitford also called for transparency in respect of public funding agreements: “Any contracts agreed with companies and partners using public funds should also be made publicly available.”³⁵¹ She stressed: “We need to use global governance mechanisms to ensure equitable distribution and supply of health technologies according to public health need.”³⁵²

C. The European Union

The EU has made extensive investments in vaccine development for COVID-19.³⁵³ The European Parliament has observed that “vaccines are a textbook case where huge positive externalities require them to be treated as global public goods and to be provided for free; whereas in developed countries, all citizens are getting free vaccines.”³⁵⁴ The European Parliament noted that “huge amounts of private and public funds and resources have been invested in research and development, clinical trials and procurement in order to develop vaccines and COVID-19 treatments in an open and accessible way.”³⁵⁵ It also observed that “private and public sector research, health institutions, frontline workers, scientists, researchers and patients have all gathered information on the virus, which pharmaceutical companies have utilized.”³⁵⁶ Samira Rafaela – a Dutch member of the European Parliament – has been an eloquent advocate for the need for access to essential medicines and the adoption of the TRIPS Waiver.³⁵⁷

D. Australia

There was also discussion about the terms of the partnership for an Australian vaccine effort led by the University of Queensland, which was ultimately unsuccessful.³⁵⁸ In the end, this vaccine project did not proceed further.³⁵⁹

During the coronavirus crisis, there has been regret about the past privatization of the Commonwealth Serum Laboratories [“CSL”] – as that has meant that Australia has lacked a key public facility for local vaccine production and dissemination.

³⁵⁰ *Id.*

³⁵¹ *Id.*

³⁵² *Id.*

³⁵³ EU Research and Innovation Supporting Vaccine Development for COVID-19, EUROPEAN COMMISSION (Feb 11, 2021), https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/documents/ec_rtd_cc-vaccine-development_factsheet.pdf.

³⁵⁴ EUR. PARL. DOC., *supra* note 113.

³⁵⁵ *Id.*

³⁵⁶ *Id.*

³⁵⁷ Samira Rafaela, *Plenary Speech on COVID-19 Challenge*, YOUTUBE (May 19, 2021), <https://www.youtube.com/watch?v=DDbIUssHF44>.

³⁵⁸ Press Release, THE UNIVERSITY OF QUEENSLAND, COVID-19 Vaccine Agreement: UQ and CEPI partner with CSL to Advance COVID-19 Vaccine (June 5, 2020), <https://stories.uq.edu.au/news/2020/covid-19-vaccine-agreement/index.html>.

³⁵⁹ Jess Rendall & Lily Nothling, *Cancellation of University of Queensland's COVID-19 vaccine trial 'reassuring'*, ABC NEWS, (Dec. 12, 2020), <https://www.abc.net.au/news/2020-12-12/coronavirus-queensland-vaccine-uq-trial-cancellation-setback/12973724>.

The Australian Greens have called for the establishment of a public pharmaceutical company to develop life-saving vaccines.³⁶⁰ In Queensland, the Australian Greens would establish a Queensland Public Pharmaceutical Company that would: “(1) *Focus on crucial research and production of vaccines, antibiotics, drugs and other supplies that private pharmaceutical corporations deem unprofitable, including potential future coronavirus vaccines;* (2) *Work with universities and public medical research teams to produce new drugs, keeping the benefits, revenue and jobs in Queensland;* and (3) *Produce cheap generic drugs as an alternative supply for Queensland Health, reducing the amount of public money that goes into the pockets of private pharmaceutical corporations.*”³⁶¹ The Australian Greens contend that such a public pharmaceutical company “*would reduce drug costs for Queensland Health, produce life-saving vaccines and antibiotics, and develop the state’s capacity to rapidly produce crucial vaccines in the future.*”³⁶² This is an interesting model to realise a People’s Vaccine in Australia.

VI. PATENT PLEDGES, OPEN LICENSING, AND OPEN INNOVATION

A. Patent Pledges

A group of researchers, scientists, and lawyers developed the Open COVID Pledge to help companies make their “*intellectual property available free of charge for use in ending the COVID-19 pandemic and minimizing the impact of the disease.*”³⁶³ Such patent pledges enable scientists and researchers to have the freedom to work on their research, without fear of patent infringement actions.

Professor Jorge Contreras has been a key researcher in respect of patent pledges.³⁶⁴ He has been one of the architects of the Open COVID Pledge. He has also highlighted the importance of identifying intellectual property available under the Open COVID Pledge.³⁶⁵ Contreras and his collaborators have made a case for the adoption of voluntary pledges made by patent holders in respect of COVID-19 technologies.³⁶⁶ They contend: “*Such pledges — temporary in duration and narrow in scope — can enable critical public health research and manufacturing of crisis-critical products, while preserving for their owners the prospect of financial rewards and influence over markets after the pandemic ends.*”³⁶⁷ Contreras and his collective of collaborators claim that patent pledges will be an efficient mechanism: “*By the same token, such pledges are lightweight and efficient, avoiding the administrative, legal and political delays that have hindered previous pooling proposals in response to public health emergencies.*”³⁶⁸

Professor Mark Lemley of Stanford Law School observed: “*Companies might be reluctant to do this if they thought*

³⁶⁰ Public Pharmaceutical Company, QUEENSLAND GREENS, <https://greens.org.au/qld/publicpharma>.

³⁶¹ *Id.*

³⁶² *Id.*

³⁶³ OPEN COVID PLEDGE, <https://opencovidpledge.org/>.

³⁶⁴ PATENT PLEDGES: GLOBAL PERSPECTIVES ON PATENT LAW’S PRIVATE ORDERING FRONTIER (Jorge L. Contreras & Meredith Jacob eds., 2017).

³⁶⁵ Jorge Contreras, *Putting Pledged IP to work - Identifying IP available under the Open COVID Pledge*, INFOJUSTICE (June 12, 2020), <http://infojustice.org/archives/42399>.

³⁶⁶ Jorge Contreras et al., *Pledging Intellectual Property for COVID-19*, 38 NATURE BIOTECHNOLOGY 1146 (2020).

³⁶⁷ *Id.*

³⁶⁸ *Id.*

they were the only ones, so the commitment provides a way for universities and companies to feel comfortable that they are not alone.”³⁶⁹ He was hopeful that the scheme would boost co-operation and collaboration to end the coronavirus pandemic: “Companies, institutions, and universities would give freelicense to their patents, copyrights and certain other property rights to anyone developing technologies for the diagnosis, prevention, or treatment of COVID-19, the disease caused by the new coronavirus.”³⁷⁰ Lemley noted that such licenses were time-bound, and would last until a year after WHO declared the end of the coronavirus pandemic. He also stressed: “This is not a permanent grant of rights, but a temporary measure to make sure that we aren’t restricting research, testing, or treatment during the pandemic.”³⁷¹ Lemley noted: “The pledge prevents them from being sued for things they do during the pandemic.”³⁷² He commented: “Once things return to normal, we hope companies will work together to come up with commercially reasonable license terms, but they can go back to owning and asserting their Intellectual Property.”³⁷³ Stanford Postdoctoral student Ariel Ganz also played a part in the development of the Open COVID Pledge.³⁷⁴

A range of information technology companies – including HP Enterprise, Intel, IBM, Amazon, Facebook, Uber, AT&T, Fujitsu, Seagate Technology, and SAP – have taken up the pledge thus far.³⁷⁵ Public research organisations such as NASA’s Jet Propulsion Laboratory, Sandia National Laboratories and the New Jersey Institute Technology have joined the Open COVID Pledge. There has been a concern that pharmaceutical drug companies, biotechnology developers, and medical device companies have not participated in the Open COVID Pledge.

Diane Peters of the Creative Commons has been a key contributor to the development of the Open COVID Pledge.³⁷⁶ The Creative Commons played a leadership role in taking over the mantle of the Open COVID Pledge during 2020.³⁷⁷ Peters has sought to internationalise the Open COVID Pledge – translating the pledge into all six of the official languages of the United Nations.³⁷⁸ Peters has discussed the Open COVID Pledge on the ABC on Science Friction.³⁷⁹ In

³⁶⁹ Sharif, *supra* note 1, at 11; Lemley, *supra* note 1, at 11. IP Available to End COVID-19 Pandemic, STAN. L. SCH. (Apr. 1, 2020), <https://www.stanford.edu/2020/04/01/mark-lemley-on-call-to-make-ip-available-to-end-covid-19-pandemic/>.

³⁷⁰ *Id.*

³⁷¹ *Id.*

³⁷² *Id.*

³⁷³ *Id.*

³⁷⁴ Hanae Armitage, *Stanford Postdoc Ariel Ganz Leads Movement to Free Patented Technology for COVID-19 Fight*, STAN. MED. (Oct. 5, 2020), <https://news.stanford.edu/2020/10/05/stanford-postdoc-helps-to-spearhead-movement-to-free-patented-technology-for-covid-19-fight/>.

³⁷⁵ Tech Giants- Amazon, Facebook, HP, Intel, Microsoft, and Sandia National Laboratories- Join the CC- Supported Open COVID IP Pledge, CREATIVE COMMONS (Apr. 20, 2020), <https://creativecommons.org/2020/04/20/tech-giants-join-the-cc-supported-open-covid-pledge/>.

³⁷⁶ Diane Peters, *Understanding Patents: An Overview of Legal Considerations*, PAT. COMMONS (2006), <https://patentcommons.org/publications/whitepaper-final-final-4-12-06.pdf>.

³⁷⁷ Diane Peters & Eric Stein, *Creative Commons Now Leading the Open COVID Pledge – Here’s What That Means*, CREATIVE COMMONS (Aug. 27, 2020), <https://creativecommons.org/2020/08/27/cc-ocp/>.

³⁷⁸ D. Peters, *Internationalizing the Open COVID Pledge: Translations and Outreach*, OPEN COVID PLEDGE, (Oct. 15, 2020), <https://open-covid-pledge.org/2020/10/15/internationalizing-the-open-covid-pledge-translations-asnd-outreach/>.

³⁷⁹ Natasha, *The Rise of Vaccine Nationalism – Should We Be Worried?*, ABC RADIO NATIONAL (Sept. 6, 2020), <https://abc.net.au/radionational/programs/sciencefriction/12630076>.

May 2021, the American University assumed the stewardship of the Open COVID Pledge.³⁸⁰

B. Open Science

There has also been much interest in models of open science – open access, open medicine, and open data. Sean Flynn, Aidan Hollis, and Mike Palmedo argued that there was a compelling economic justification for open access to essential medicine patents in developing countries.³⁸¹ Professor Ginny Barbour has discussed the importance of open access publishing during the coronavirus crisis.³⁸² Krishna Ravi Srinivas has been a trailblazing advocate of open source approaches in relation to biotechnology and medicine.³⁸³ He has recommended that ‘India should promote open innovation and open source drug discovery.’³⁸⁴ Amy Kapczynski has called for the establishment of an open science model to engage in research and development in respect of influenza.³⁸⁵ Open source advocates such as Professor Joshua Pearce have advocated the use of open licensing in respect of COVID-19 technologies.³⁸⁶ Henry Chesbrough has advocated open innovation models for the COVID-19 response and recovery.³⁸⁷

There has been a joint appeal for open science by a number of international organisations—including CERN, OHCHR, UNESCO, and WHO.³⁸⁸ This statement promoted models of open access, open data, open medicine, open publishing, and open innovation. The joint call emphasized the importance of open access to knowledge: “*Worldwide people need States, international bodies, science and medical institutions and practitioners to ensure the broadest possible sharing of scientific knowledge, and the broadest possible access to the benefits of scientific knowledge.*”³⁸⁹ The joint call also insisted upon recognition of the principle of benefit-sharing in respect of scientific inventions: “*The pandemic also gives new importance to the need to ensure non-discriminatory*

³⁸⁰ PIJIP Assumes Stewardship of the Open COVID Pledge, AM. U. WASH. C. OF L. (Apr. 2021), <https://www.wcl.american.edu/impact/initiatives-programs/pijip/news/pijip-assumes-stewardship-of-the-open-covid-pledge>.

³⁸¹ Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 (2) J. OF L., MED., AND ETHICS 184 (2009).

³⁸² Ginny Barbour, *How Open Access Suddenly Became the Norm*, YOUTUBE (July 29, 2020), https://www.youtube.com/watch?v=_SueRnB0uCQ.

³⁸³ Krishna Ravi Srinivas, *Intellectual Property Rights and Bio Commons: Open Source and Beyond*, 59 (188) INTERNATIONAL SOCIAL SCIENCE JOURNAL 319 (2006); Krishna Ravi Srinivas, *Open Source Drug Discovery: A Revolutionary Paradigm or a Utopian Model?*, in *INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO MEDICINES*, 263 (Thomas Pogge, Matthew Rimmer & Kim Rubenstein ed., 2010).

³⁸⁴ Krishna Ravi Srinivas, *Intellectual Property Rights and Innovation in the Times of Corona Epidemic*, 89 RIS POLICY BRIEF (April 2020), <http://infojustice.org/wp-content/uploads/2020/04/RaviSrinivas.pdf>.

³⁸⁵ Amy Kapczynski, *Order without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539 (Sept. 2017).

³⁸⁶ Joshua M Pearce, *Distributed Manufacturing of Open-Source Medical Hardware for Pandemics*, 4 (2) J. OF MANUFACTURING AND MATERIALS PROCESSING 1 (2020).

³⁸⁷ Henry Chesbrough, *To Recover Faster from Covid-19, Open Up: Managerial Implications from an Open Innovation Perspective*, 88 INDUS. MARKETING MGMT. 410 (July 2020).

³⁸⁸ U.N High Commissioner for Human Rights, A Joint Appeal for Open Science by CERN, OHCHR, UNESCO, and WHO, (Oct. 27, 2020), <https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26433&LangID=E>.

³⁸⁹ *Id.*

access to the benefits of science – such as any COVID-19 treatments and vaccines.”³⁹⁰ There has been a broader discussion of access to genetic resources and benefit-sharing in the context of pathogens and vaccines.³⁹¹ The joint statement highlighted the importance of access to essential medicines: “*Under international human rights law, States have a clear obligation to ensure international cooperation and access to a vaccine.*”³⁹² The joint call also emphasized the importance of health for all: “*Everyone, including vulnerable or marginalised individuals and groups, is entitled to enjoy the benefits of scientific progress – and when the benefits of science are managed as a purely commercial product reserved for the wealthy, everyone is harmed.*”³⁹³ This statement echoes a previous call for the adoption of open models of medical innovation by the United Nations Secretary General’s High Level Panel on Access to Medicines.³⁹⁴

The People’s Vaccine Alliance has perceived open licensing as a means of encouraging the open sharing of technology, intellectual property, and data.³⁹⁵

C. Open Innovation

Professor Richard Gold from McGill University has said that the coronavirus pandemic has shattered the status quo on drug development.³⁹⁶

Jeremy de Beer and Richard Gold have discussed the nexus of intellectual property, innovation policy, and international trade in respect of the coronavirus COVID-19 pandemic.³⁹⁷ The researchers commented: “*This COVID-19 stimulated move away from proprietary science— in which we patent everything and keep it secret until we do— to open science—where we do not clog up the system and do share research outcomes, data, materials, and tools — reflects a longer-term dissatisfaction over drug and vaccine development generally: drugs are increasingly expensive to develop, and our investments are producing less and less.*”³⁹⁸ The researchers argued that ‘Canada should seize this chance to rethink the role of intellectual property acquisition vis-à-vis other domestic and international policy levers.’³⁹⁹ The researchers concluded: “*With a more nuanced approach to intellectual property and greater emphasis on open*

³⁹⁰ *Id.*

³⁹¹ Mark Eccleston-Turner and Michelle Rourke, *Arguments Against the Inequitable Distribution of Vaccines Using the Access and Benefit Sharing Transaction*, 70 INTERNATIONAL AND COMPARATIVE LAW QUARTERLY 825-858 (2021); and Fran Humphries, Michelle Rourke, Todd Berry, Elizabeth Englezos and Charles Lawson, *COVID-19 Tests the Limits of Biodiversity Laws in a Health Crisis: Rethinking “Country of Origin” for Virus Access and Benefit sharing* 28 JOURNAL OF LAW AND MEDICINE 684-706 (2021).

³⁹² U.N High Commissioner for Human Rights, A Joint Appeal for Open Science by CERN, OHCHR, UNESCO, and WHO, (Oct. 27, 2020), <https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26433&LangID=E>.

³⁹³ *Id.*

³⁹⁴ Dreifuss, *supra* note 25.

³⁹⁵ COVID-19: We Need A People’s Vaccine, OXFAM AMERICA <https://www.oxfamamerica.org/explore/emergencies/covid-19-peoples-vaccine>.

³⁹⁶ E. Richard Gold, *The Coronavirus Pandemic Has Shattered the Status Quo on Drug Development. We Should Build on That*, FORTUNE (Mar. 26, 2020), <https://fortune.com/2020/03/26/coronavirus-vaccine-drug-development-open-science-covid-19-treatment/>.

³⁹⁷ Jeremy de Beer & E. Richard Gold, *International Trade, Intellectual Property, and Innovation Policy: Lessons from a Pandemic*, in VULNERABLE: THE LAW, POLICY AND ETHICS OF COVID-19, 591 (Colleen Flood et al. eds., 2020) at 579.

³⁹⁸ *Id.* at 586.

³⁹⁹ *Id.* at 589.

science, Canada can emerge from this pandemic with a healthier biomedical innovation ecosystem to fight or, better, prevent the next one.”⁴⁰⁰

Jeremy de Beer and Richard Gold emphasized that there is a need for an open, networked international response to pandemics – such as the coronavirus.

In a report for the Royal Society Canada, Richard Gold and his collaborators have called for the Open Drug Discovery of Anti-Virals Critical for Canada’s Pandemic Strategy.⁴⁰¹ They have recommended that Canada should develop “a flexible, open and stable non-profit, virtual drug discovery entity that coordinates and invests in a pipeline for the proactive development of anti-viral drugs (and possibly vaccines) for viruses with pandemic potential.”⁴⁰² The researchers envisaged: “The independent, non-profit should be provided with long-term, stable funding to insulate it from day-to-day politics.”⁴⁰³ The researchers maintained: “The non-profit and Canada’s pandemic innovation preparedness ought to be embedded in an international, open, effort to coordinate R&D of new products, such as the international environments in which the SGC and DNDi operate.”⁴⁰⁴ The researchers emphasized that “funding councils and other funding bodies ought to establish specific open science calls, with significant funding.”⁴⁰⁵ The report concluded: “Canada ought to lead the world in open science policymaking, for example, by supporting Health Canada (and/or other regulators) to implement regulatory mechanisms that encourage open science drug development.”⁴⁰⁶

VII. THE TRIPS WAIVER

The governments of India and South Africa have put forward a broad proposal for a TRIPS Waiver in respect of COVID-19 technologies. Meanwhile, the U.S. Government has supported a TRIPS Waiver for vaccines. A number of European countries have put forward counter-proposals to the TRIPS Waiver – focusing upon intellectual property flexibilities, such as compulsory licensing and voluntary licensing. There has been debate about the nature, scope, and duration of the proposals of the TRIPS Waiver.⁴⁰⁷ It has proven to be difficult to obtain consensus amongst nation states as to an acceptable form for a TRIPS Waiver. Given that such an approach would enable the open production and distribution of vaccines, treatments, diagnostics, and health equipment as global public goods during the coronavirus crisis, the People’s Vaccine Alliance has been a champion of the TRIPS Waiver.⁴⁰⁸

⁴⁰⁰ *Id.* at 589.

⁴⁰¹ Tania Bubela et al., *Open Drug Discovery of Anti-Virals Critical for Canada’s Pandemic Strategy*, 5 FACETS J. (Dec. 17, 2020), <https://www.facetsjournal.com/doi/pdf/10.1139/facets-2020-0079>.

⁴⁰² *Id.* at 4.

⁴⁰³ *Id.*

⁴⁰⁴ *Id.*

⁴⁰⁵ *Id.*

⁴⁰⁶ *Id.*

⁴⁰⁷ Peter Yu, *A Critical Appraisal of the COVID-19 TRIPS Waiver*, in INTELLECTUAL PROPERTY RIGHTS IN THE POST PANDEMIC WORLD: AN INTEGRATED FRAMEWORK OF SUSTAINABILITY, INNOVATION AND GLOBAL JUSTICE, (Taina E. Pihlajarinne, Jukka Mähönen and Pratyush Upreti, eds., 2021-2022).

⁴⁰⁸ *People’s Vaccine Alliance Lauds US Decision to Break Open COVID-19 Monopolies and Urges Others to Follow US Lead*, OXFAM (May 6, 2021), <https://www.oxfam.org/en/press-releases/peoples-vaccine-alliance-lauds-us-decision-break-open-covid-19-monopolies>.

A. The TRIPS Waiver

In 2020, India and South Africa have called for a waiver of parts of the *TRIPS Agreement* 1994 to enable countries to better respond to the coronavirus COVID-19.⁴⁰⁹ They have argued: “*In these exceptional circumstances, we request that the Council for TRIPS recommends, as early as possible, to the General Council a waiver from the implementation, application and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19.*”⁴¹⁰ It is worth noting Section 1 concerns copyright law; Section 4 deals with designs; Section 5 relates to patents; and Section 7 deals with confidential information and trade secrets. South Africa and India argued that the waiver should apply to all WTO members but would not prejudice “*the right of least developed country Members under paragraph 1 of Article 66 of the TRIPS Agreement.*”⁴¹¹ In their view, “*The waiver should continue until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity hence we propose an initial duration of [x] years from the date of the adoption of the waiver.*”⁴¹² Apparently, though, developed countries have resisted the adoption of the waiver.⁴¹³

Ellen t’ Hoen has discussed the importance of the TRIPS Waiver proposal.⁴¹⁴ She noted: “The concern is that the development of and equitable access to the tools – such as vaccines and treatments, needed to fight the pandemic could be limited by patents and other IP barriers.”⁴¹⁵ She suggested: “*The waiver proposal [aims to lift] the barriers posed by patents and other forms of intellectual property to local production and distribution of generic and biosimilar products.*”⁴¹⁶

In its summary of the TRIPS Council meeting, the WTO noted: “*The proponents argued that many countries - especially developing countries - may face institutional and legal difficulties when using TRIPS flexibilities, including the special compulsory licensing mechanism provided for in Article 31bis, which they saw as a cumbersome process for the import and export of pharmaceutical products.*”⁴¹⁷ Though many developing and least developed country members reacted positively to the proposal, some sought clarifications about its practical implementation and potential nationwide impact of the waiver.⁴¹⁸ The WTO commented: “*A number of developing and developed country members opposed the waiver proposal, noting that there is no indication that intellectual property rights (IPRs) have been a genuine barrier to accessing*

[and-urges.](#)

⁴⁰⁹ COMMUNICATION FROM INDIA AND SOUTH AFRICA, *supra* note 64; See also, Thiru Balasubramaniam, *WTO TRIPS Council: India and South Africa submit draft decision text on a waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19*, KNOWLEDGE ECOLOGY INT’L (Oct. 2, 2020), <https://www.keionline.org/34061>.

⁴¹⁰ *Id.*

⁴¹¹ *Id.*

⁴¹² *Id.*

⁴¹³ *Id.*

⁴¹⁴ HOEN, *supra* note 88.

⁴¹⁵ *Id.*

⁴¹⁶ *Id.*

⁴¹⁷ Press Release, World Trade Org., Members Discuss Intellectual Property Response to the COVID-19 Pandemic, (Oct. 20, 2020), https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm?utm_source=dlvr.it&utm_medium=twitter.

⁴¹⁸ *Id.*

COVID-19 related medicines and technologies.”⁴¹⁹ The developed countries apparently argued: “*The suspension of IPRs, even for a limited period of time, was not only unnecessary but it would also undermine the collaborative efforts to fight the pandemic that are already under way.*”⁴²⁰

Alongside South Africa and India, a large number of nations have become co-sponsors of the TRIPS Waiver.⁴²¹ The TRIPS Waiver has been supported by African Group, Bolivia, Egypt, Eswatini, Fiji, Indonesia, Kenya, the Least Developed Countries Group, Maldives, Mozambique, Namibia, Pakistan, Vanuatu, Venezuela, and Zimbabwe. There have been further revisions made to refine the TRIPS Waiver. India’s Prime Minister Narendra Modi has been actively lobbying other nations to support the TRIPS Waiver.⁴²²

B. The Shift of the Position of the U.S. on the TRIPS Waiver

The Trump Administration supported Operation Warp Speed in the U.S., but was unwilling to join in multilateral discussions about collaboration over COVID-19 technologies.⁴²³ There was concern that the Trump Administration adopted a “America First” approach to COVID-19 diagnostics, therapeutics, and vaccines.⁴²⁴ There has also been a debate about the transparency and accountability of this regime.

After the ‘America First’ approach taken by the Trump administration, Progressive Democrats pressed the Biden Administration to offer support for the TRIPS Waiver.⁴²⁵ In the House of Representatives, Democratic Representatives Rosa DeLauro (Connecticut) Jan Schakowsky (Illinois), Earl Blumenauer (Oregon) and Lloyd Doggett (Texas) were key supporters of the

⁴¹⁹ *Id.*

⁴²⁰ *Id.*

⁴²¹ Council for Trade-Related Aspects of Intellectual Property Rights, Communication from the African Group et al., *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 21, 2021).

⁴²² *Modi Seeks Support of G-7 Nations for TRIPS Waiver at WTO*, THE HINDU BUSINESS LINE (June 13, 2021), <https://www.thehindubusinessline.com/news/modi-seeks-support-of-g-7-nations-for-trips-waiver-at-wto/article34802793.ece>; *India Official Says There Is Widespread Support at G7 for TRIPS Waiver at WTO*, REUTERS (June 14, 2021), <https://www.reuters.com/world/india/indian-official-says-there-is-widespread-support-g7-trips-waiver-wto-2021-06-13/>; Shreya Nandi, *India Gets Wide Support on TRIPS Waiver for COVID-19 Vaccines at G-7 Meet*, BUSINESS STANDARD (June 14, 2021), https://www.business-standard.com/article/current-affairs/india-gets-wide-support-on-trips-waiver-for-covid-19-vaccines-at-g-7-meet-121061400029_1.html.

⁴²³ *Trump Administration Announces Framework and Leadership for Operation Warp Speed*, HHS (15 May, 2020), <https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html>.

⁴²⁴ MICHAEL LEWIS, *THE PREMONITION: A PANDEMIC STORY* (2021); LAWRENCE WRIGHT, *THE PLAGUE YEAR: AMERICA IN THE TIME OF COVID* (2021); ANDY SLAVITT, *PREVENTABLE: THE INSIDE OF HOW LEADERSHIP FAILURES, POLITICS, AND SELFISHNESS DOOMED THE U.S. CORONAVIRUS RESPONSE* (2021); YASMEEN ABUTALEB AND DAMIAN PALETTA, *NIGHTMARE SCENARIO: INSIDE THE TRUMP ADMINISTRATION’S RESPONSE TO THE PANDEMIC THAT CHANGED HISTORY* (2021); MICHAEL WOLFF, *LANDSLIDE: THE FINAL DAYS OF THE TRUMP PRESIDENCY* (2021).

⁴²⁵ Peter Sullivan, *Progressives Up Pressure on Biden to Back COVID Vaccine Patent Waiver*, THE HILL (March 24, 2021), <https://thehill.com/policy/healthcare/544620-progressives-up-pressure-on-biden-to-back-covid-vaccine-patent-waiver>.

TRIPS Waiver. Representative Ro Khanna (California) was also vocal about the need for the U.S. to assist India during the coronavirus crisis.⁴²⁶ The Speaker of the House Nancy Pelosi (California) also expressed her support for a TRIPS Waiver. In the Senate, former Presidential candidates Senator Bernie Sanders (Vermont) and Senator Elizabeth Warren (Massachusetts) –and other leading progressive Democrats - were champions of a TRIPS Waiver.⁴²⁷ Sanders and his colleagues pleaded with President Joe Biden: “*Your Administration has the opportunity to reverse the damage done by the Trump Administration to our nation’s global reputation and restore America’s public health leadership on the world stage*”.⁴²⁸ The Senators implored President Joe Biden to provide support for the TRIPS Waiver: “*To bring the pandemic to its quickest end and save the lives of Americans and people around the world, we ask that you prioritize people over pharmaceutical company profits by reversing the Trump position and announcing U.S. support for the WTO TRIPS waiver*.”⁴²⁹

The People’s Vaccine lobbied the new Biden Administration to support a TRIPS Waiver. Former Heads of State and Nobel Laureates called on President Joe Biden to waive intellectual property rules for COVID Vaccines.⁴³⁰ Their letter stressed that, with the leadership of the U.S. President COVID-19 vaccine technologies could be shared with the world: “*We believe this would be an unparalleled opportunity for the U.S. to exercise solidarity, cooperation and renewed leadership, one we hope will inspire many more to do the same*”.⁴³¹ The dignitaries said that Biden should “*let this moment be remembered in history as the time we chose to put the collective right to safety for all ahead of the commercial monopolies of the few*.”⁴³² This broad-based social movement has been successful in shifting the position of the Biden administration.⁴³³

After much deliberation,⁴³⁴ the new Biden Administration has agreed to support a version of the TRIPS Waiver, which is focused on vaccines. The U.S. Trade Representative Ambassador Katherine Tai commented upon the justifications for the decision to support a TRIPS Waiver for

⁴²⁶ Press Release, Congressman Ro Khanna, It’s Vital That the US Drop Barriers to Vaccine Production and Aid COVID-Ravaged India (May 7, 2021), <https://khanna.house.gov/media/in-the-news/ro-khanna-it-s-vital-us-drop-barriers-vaccine-production-and-aid-covid-ravaged>.

⁴²⁷ Letter from Senator Bernie Sanders et al., to President Joe Biden, (Apr. 17, 2021), <https://www.sanders.senate.gov/press-releases/news-senators-urge-biden-to-approve-vaccine-patent-waiver-to-boost-production-and-end-pandemic>.

⁴²⁸ *Id.*

⁴²⁹ *Id.*

⁴³⁰ Petre Agre et al., *Open Letter: Former Heads of State and Nobel Laureates Call on President Biden to Waive Intellectual Property Rules for COVID Vaccines*, PEOPLE’S VACCINE ALLIANCE (Apr. 15, 2021), <https://peoplesvaccinealliance.medium.com/open-letter-former-heads-of-state-and-nobel-laureates-call-on-president-biden-to-waive-e0589edd5704>.

⁴³¹ *Id.*

⁴³² *Id.*

⁴³³ Lev Facher & Nicholas Florio, *How David Beat Goliath: Advocacy Groups Seized A Moment, And Found Allies, In Bid to Loosen Vaccine Patent Rights*, STAT (May 7, 2021), <https://www.statnews.com/2021/05/07/how-david-beat-goliath-advocacy-groups-seized-a-moment-and-found-allies-in-bid-to-loosen-vaccine-patent-rights/>.

⁴³⁴ White House Press secretary Jen Psaki said of President Joe Biden’s decision-making process on the TRIPS Waiver: ‘He’s a details guy and he wants to dig into the pros and cons and all of the considerations for any decision.’ Patsy Widakuswara, *Biden Agrees to Waive COVID-19 Vaccine Patents, But It’s Still Complicated*, VOICE OF AMERICA NEWS (May 5, 2021), <https://www.voanews.com/covid-19-pandemic/biden-agrees-waive-covid-19-vaccine-patents-its-still-complicated>; Press Release, Jen Psaki, Press Secretary (July 9, 2021), <https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/09/press-briefing-by-press-secretary-jen-psaki-july-9-2021> (The Press Secretary has also said that President Biden has been a ‘strong proponent’ of the TRIPS Waiver).

Vaccines:

*“This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures. The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines.”*⁴³⁵

The Ambassador promised that the U.S. would actively participate in text-based negotiations over the TRIPS Waiver in the WTO – but noted that those negotiations would take time, given the consensus-based nature of the institution, and the complexity of the issues involved with intellectual property and access to essential medicines. Katharine Tai insisted: *“The Administration’s aim is to get as many safe and effective vaccines to as many people as fast as possible.”*⁴³⁶ She observed: *“As our vaccine supply for the American people is secured, the Administration will continue to ramp up its efforts – working with the private sector and all possible partners – to expand vaccine manufacturing and distribution.”*⁴³⁷ The Ambassador also said that the U.S. administration *“will also work to increase the raw materials needed to produce those vaccines.”*⁴³⁸

The Speaker of the House Nancy Pelosi commended the Biden Administration on its decision to support a TRIPS Waiver for Vaccines.⁴³⁹ She observed: *“Accelerating the production and distribution of life-saving vaccines across the globe is both a moral imperative and an urgent necessity to crush the virus pandemic and prevent the spread of more virulent coronavirus variants.”*⁴⁴⁰ Pelosi stressed: *“We cannot be fully safe from the virus anywhere until we defeat it everywhere.”*⁴⁴¹

There were a number of countries who followed the leadership of the U.S. on the TRIPS Waiver. After previously being non-committal on the topic,⁴⁴² Jacinda Ardern’s New Zealand Government said that it would support a TRIPS Waiver for vaccines.⁴⁴³ Her Trade Minister, the Hon. Damien O’Connor observed that New Zealand supported equitable access to COVID vaccines for all.⁴⁴⁴ The Minister commented: ‘New Zealand supports the waiver of IP protections on vaccines as an important part of our collective efforts to address the human catastrophe of the

⁴³⁵ Press Release, Office of the U.S. Trade Representative, Statement from Ambassador Katherine Tai on the COVID-19 TRIPS Waiver (May 5, 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>.

⁴³⁶ *Id.*

⁴³⁷ *Id.*

⁴³⁸ *Id.*

⁴³⁹ Press Release, Nancy Pelosi, Speaker, House of Representatives Pelosi Statement on Biden Administration Support for Vaccine Patents Waiver at WTO (May 5, 2021), <https://www.speaker.gov/newsroom/5521-3>.

⁴⁴⁰ *Id.*

⁴⁴¹ *Id.*

⁴⁴² (24 March 2021) 751 NZPD 1744, https://www.parliament.nz/resource/enNZ/HansD_20210324_20210324/566d2c95e499e0fab70c8bac98d8ccf0dfd1f00.

⁴⁴³ Thomas Manch, *New Zealand To Support Effort to Waive COVID-19 Vaccine Patents, After U.S. Backs WTO Bid*, STUFF NZ (May 6, 2021), <https://www.stuff.co.nz/national/health/coronavirus/125048729/new-zealand-to-support-effort-to-waive-covid19-vaccine-patents-after-united-states-backs-wto-bid>.

⁴⁴⁴ Damien O’Connor, *NZ Backs Moves To Improve Global Access to COVID Vaccines*, THE BEEHIVE (May 6, 2021), <https://www.beehive.govt.nz/release/nz-backs-moves-improve-global-access-covid-vaccines>.

pandemic.⁴⁴⁵ However, documents revealed under the Official Information Act showed that New Zealand Government had previously been frustrating efforts to promote a “People’s Vaccine”⁴⁴⁶

There remains a clutch of countries who have been non-committal about the TRIPS Waiver. The Australian Government, for instance, was equivocal for a long time about the TRIPS Waiver in public.⁴⁴⁷ While expressing enthusiasm for President Joe Biden’s stance,⁴⁴⁸ the Australian Government seems wary of offending the vaccine developer, Pfizer, and other biomedical companies that oppose the TRIPS Waiver.⁴⁴⁹ Opposition parties such as the Australian Greens have pressed the Coalition Government to support the TRIPS Waiver. Senator Penny Wong and her colleagues in the Australian Labor Party stressed that the speed of adoption of the TRIPS Waiver was urgent, especially given that “India is in a dire need of vaccines in Africa, with 16 per cent of the world’s population, has less than two per cent of vaccine supply.”⁴⁵⁰ The Australian Greens said in a speech: “The Morrison government should be following the lead of the Biden administration in discussion and supporting the waiver of intellectual property rights on COVID vaccine patents to ensure equitable access to the vaccines.”⁴⁵¹ In an impassioned speech, Senator Mehreen Faruqi, Australian Greens, urged the Australian Government: “If you have a skerrick of decency or any sense of responsibility to the people’s lives and provide your full-throated support to the TRIPS waiver now.”⁴⁵² Civil society groups including Human Rights Watch, MSF Australia, and APTF have encouraged the Australian Government to adopt the TRIPS Waiver.⁴⁵⁴ Michele

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446 Matthew Knott & Phoebe Barr, *How the ‘People’s Vaccine’ for COVID Undermines its Principled Reputation*, THE GUARDIAN (Aug. 25, 2021), <https://www.theguardian.com/world/commentisfree/2021/aug/25/new-zealands-stance-on-vaccines>.

Elias Visontay, *India Wants Access to Cheap Copies of COVID Vaccines. So Why Is Australia Holding Out?*, THE GUARDIAN (Apr. 30, 2021), <https://www.theguardian.com/world/2021/apr/30/india-wants-access-to-cheap-copies-of-covid-vaccines-so-why-is-australia-holding-out>; Lyndee Farnham, *Australia Stalls Vaccine Supply*, THE SATURDAY PAPER (Aug. 21, 2021), <https://www.thesaturdaypaper.com.au/politics/2021/08/21/australia-stalls-vaccine-supply/162946800012311#mtr>.

Matthew Knott & Phoebe Barr, *“A Moment of Moral Courage”: Australia Applauds US Push for Patent-Free COVID Vaccines*, BRISBANE TIMES (May 6, 2021), <https://www.brisbanetimes.com.au/world/north-america/biden-administration-backs-covid-vaccines-patent-waiver-20210506-p5688834d7bd089f14c%2F0014%22>.

Paul Kar, *How a COVID Vaccine Patent Waiver Could Harm Supply and Safety*, THE GUARDIAN (May 13, 2021), <https://www.theguardian.com/australia-news/2021/may/13/pfizer-warns-australia-a-covid-vaccine-intellectual-property-patent-waiver-could-harm-supply-and-safety>; *Medicines Australia Updated Position on Intellectual Property (In Light of TRIPS Waiver)*, MED. AUSTL. (May 6, 2021), <https://www.medicinesaustralia.com.au/media-release/medicines-australia-updated-position-on-intellectual-property-in-light-of-trips-waiver>.

⁴⁵⁰ Elias Visontay, *Pressure Mounts on Australia to Support COVID Vaccine Intellectual Property Waiver for Developing Nations*, THE GUARDIAN (May 6, 2021), <https://www.theguardian.com/australia-news/2021/may/06/pressure-mounts-on-australia-to-support-covid-vaccine-intellectual-property-waiver-for-developing-nations>.

⁴⁵¹ Senator Penny Wong, Mark Butler MP & Madeleine King MP, *Morrison Must Ensure Developing Nations Have Access to Vaccines*, AUSTRALIAN LABOR PARTY (Apr. 30, 2021), <https://www.pennywong.com.au/media-hub/media-statements/morrison-must-ensure-developing-nations-have-access-to-vaccines>.

⁴⁵² Commonwealth, *Parliamentary Debates*, Senate, 12 May 2021, 6 (Rachel Siewert, Senator) (Austl.), <https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22chamber%2Fhansards%2F5d7154b6-80d6-4733-ad27-6f37db4fb595%2F0014%22>.

⁴⁵³ Commonwealth, *Parliamentary Debates*, Senate, 24 August 2021, 38 (Mehreen Faruqi, Senator) (Austl.), <https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22chamber%2Fhansards%2F62d6646b-aeca-456e-9883-4d7bd089f14c%2F0105%22>.

⁴⁵⁴ Sophie McNeill, *Australia Should Back COVID-19 Waiver of Intellectual Property Rules: Waive TRIPS Amid Delta Outbreak, Vaccine Shortages*,

O'Neil of Unions Australia commented: “*The growing COVID-19 crisis in India shows the urgent need for a ramp up of the production of vaccines to enable equitable access to end this pandemic as quickly as possible.*”⁴⁵⁵ India's Deputy High Commissioner to Australia, Palaniswamy Subramanian Karthigeyan, has urged Australia to support a TRIPS Waiver: “*Given the situation we find ourselves in, time is of the greatest essence and an effective response to the pandemic requires other countries to make these products accessible, to make it equitable, to make it affordable.*”⁴⁵⁶

In the end, the Australian Government finally committed to support a TRIPS Waiver for vaccines in September 2021.⁴⁵⁷ The Australian Government, though, refused to co-sponsor the TRIPS Waiver.⁴⁵⁸ The pharmaceutical and biotechnology industries were aggrieved by the decision of the Australian Government to support a TRIPS Waiver – calling on them to reconsider their decision.⁴⁵⁹

The Liberal Government of Canada has also been rather non-committal about support the TRIPS Waiver.⁴⁶⁰ This is disappointing given that past Liberal Governments have been leaders on access to essential medicines,⁴⁶¹ and Prime Minister Justin Trudeau had previously made statements about the importance of universal access to essential medicines.⁴⁶² It has also been

HUMAN RIGHTS WATCH (July 25, 2021), <https://www.hrw.org/news/2021/07/25/australia-should-back-covid-19-waiver-intellectual-property-rules>; *Australia Must Stop Stalling Negotiations On Landmark Pandemic Monopoly Waiver*, MEDECINS SANS FRONTIERES (June 8, 2021), <https://msf.org.au/article/statements-opinion/australia-must-stop-stalling-negotiations-landmark-pandemic-monopoly>; Patricia Randal, *Rich Countries are First in Line for COVID-19 Vaccines Because A Handful of Companies Control the Price and Quantity*, THE GUARDIAN (22 July 2021), <https://www.theguardian.com/commentisfree/2021/jul/22/rich-countries-are-first-in-line-for-covid-vaccines-because-a-handful-of-companies-control-both-the-price-and-quantity>.

⁴⁵⁵ Press Release, AUSTRALIAN COUNCIL OF TRADE UNIONS, *Morrison Government Continues to Oppose Vaccine IP Waiver Despite US, NZ Support* (May 6, 2021), https://www.actu.org.au/actu-media/media-releases/2021/morrison-government-continues-to-oppose-vaccine-ip-waiver-despite-us-nz-support?utm_source=miragenews&utm_medium=miragenews&utm_campaign=news.

⁴⁵⁶ Bianca Hall, Rachel Clun & Emma Koehn, *Australia Accused of Delaying Campaign To Allow Generic COVID Vaccines*, THE SYDNEY MORNING HERALD (Apr. 29, 2021), <https://www.smh.com.au/national/australia-accused-of-delaying-campaign-to-allow-generic-covid-vaccines-20210428-p57n09.html>.

⁴⁵⁷ Paul Karp and Elias Visontay, *Australia to Support Vaccine Waiver After Months of Pressure from Human Rights Groups*, THE GUARDIAN (September 8, 2021), <https://www.theguardian.com/society/2021/sep/08/australia-to-support-vaccine-waiver-after-months-of-pressure-from-human-rights-groups>; Deborah Gleeson, *Australia has Finally Backed a Plan to Let Developing Countries Make Cheap COVID-19 Vaccines — What Matters is What it Does Next*, THE CONVERSATION (September 14, 2021), <https://theconversation.com/australia-has-finally-backed-a-plan-to-let-developing-countries-make-cheap-covid-19-vaccines-what-matters-is-what-it-does-next-167630>; and Stephanie Dalzell, *Australia Backs International Push for Generic COVID-19 Vaccines, but Several Countries Remain Unconvinced*, ABC NEWS (October 6, 2021) <https://www.abc.net.au/news/2021-10-06/cph-australia-backs-push-for-generic-covid-19-vaccines/100516060>.

⁴⁵⁸ Denham Sadler, *Australia Refuses to Co-Sponsor COVID-19 Vaccine IP Waiver*, INNOVATIONAUS, (November 4, 2021), <https://www.innovationaus.com/australia-refuses-to-co-sponsor-covid-19-vaccine-ip-waiver/>

⁴⁵⁹ Press Release, AUSBIOTECH AND MEDICINES AUSTRALIA, *COVID-19 Vaccine Patent Waiver will not Speed Up Global Vaccination*, <https://www.ausbiotech.org/news/covid-19-vaccine-patent-waiver-will-not-speed-up-global-vaccination-say-ausbiotech-and-medicines-australia>.

⁴⁶⁰ Government of Canada, Statement by Canada at WTO TRIPS Council (Feb. 23, 2021), <https://www.international.gc.ca/world-monde/international-relations-relations-internationales/wto-omc/2021-02-23-trips-adpic.aspx?lang=eng>.

⁴⁶¹ STEPHEN LEWIS, RACE AGAINST TIME: SEARCHING FOR HOPE IN AIDS-RAVAGED AFRICA (2006); Matthew Rimmer, *The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid*, 15 (7) EXPERT OPINION ON THERAPEUTIC PAT. 889 (2005); Matthew Rimmer, *Race Against Time: The Export of Essential Medicines to Rwanda* 1 (2) PUB. HEALTH ETHICS 89 (2008).

⁴⁶² TRUDEAU ET AL., *supra* note 101.

frustrating that the Liberal Government of Canada has been slow to respond to requests for compulsory licensing for the purposes of exporting medicines overseas during the coronavirus crisis. Professor Richard E. Gold of McGill University wonders whether the Canadian Government is fearful of a backlash from Big Pharma: “*Any time that the government worries about exporting or decreasing IP, they’re going to get attacked by certain sectors, including the pharmaceutical sector.*”⁴⁶³

C. Opposition to the TRIPS Waiver

In spite of the Biden administration’s support for the TRIPS Waiver, there are a range of hold-outs to the TRIPS Waiver who have been obstructing consensus on the proposal in the World Trade Organization. The European Commission has been steadfast in its opposition to the TRIPS Waiver.⁴⁶⁴ The Government of Germany has been particularly resistant to the adoption of a TRIPS Waiver.⁴⁶⁵ In 2020, Chancellor Angela Merkel maintained that vaccines for COVID-19 should be treated as global public goods. For instance, she stressed at the 73rd World Health Assembly that a “*vaccine must be accessible and affordable to everyone.*”⁴⁶⁶ In 2021, Chancellor Angela Merkel engaged in backsliding from this position, and insisted that vaccines for COVID-19 should still be subject to private intellectual property rights.⁴⁶⁷ A German government spokeswoman said: “*The protection of intellectual property is a source of innovation and this has to remain so in the future.*”⁴⁶⁸ This turnaround is perplexing and exasperating – given the previous calls for scientific collaboration and co-operation. Chancellor Angela Merkel came under particular criticism for this volte-face while she was visiting the U.S. in 2021.⁴⁶⁹ During her visit to the White House, various U.S. legislators and civil society groups engaged in vocal criticism of her stance.⁴⁷⁰ The People’s Vaccine Campaign mounted

⁴⁶³ Ahmar Khan, *Canada lacks ‘political will’ to waive COVID-19 vaccine patents, Bolivian minister says*, GLOBAL NEWS, (October 6 2021) <https://globalnews.ca/news/8243635/bolivian-minister-canada-covid-vaccine-waiver/>.

⁴⁶⁴ Andrew Green, *Europe Still Can’t Get on Board with the TRIPS Waiver*, DEVEX (May 31, 2021), <https://www.devex.com/news/europe-still-can-t-get-on-board-with-the-trips-waiver-100027>.

⁴⁶⁵ Joseph Choi, *Merkel Breaks with Biden on US Plan to Waive Patent Protections for COVID-19 Vaccines*, THE HILL (May 6, 2021), <https://thehill.com/policy/international/552171-merkel-breaks-with-biden-on-us-plan-to-waive-patent-protections-for>.

⁴⁶⁶ Matthew Rimmer (@DrRimmer), TWITTER (May 19, 2020, 5:46 PM), <https://twitter.com/DrRimmer/status/1262718696314638336?s=20>; See also, *Merkel: Coronavirus Pandemic Will Be Overcome Quicker If World Works Together*, REUTERS (May 18, 2020), <https://www.reuters.com/article/us-health-coronavirus-who-merkel/merkel-coronavirus-pandemic-will-be-overcome-quicker-if-world-works-together-idUSKBN22U1HY>; *G20: Angela Merkel Calls for Global Action to Beat Coronavirus*, DW NEWS (Nov. 21, 2020), <https://www.dw.com/en/g20-angela-merkel-calls-for-global-action-to-beat-coronavirus/a-55686409?maca=en-Twitter-sharing>.

⁴⁶⁷ Arne Delfs & Eric Martin, *Merkel Pushes Back on Vaccine Patent Waiver in Row with U.S.*, BLOOMBERG (May 7, 2021), <https://www.bloomberg.com/news/articles/2021-05-06/merkel-pushes-back-on-vaccine-patent-waiver-in-clash-with-biden>.

⁴⁶⁸ *Id.*

⁴⁶⁹ Jake Johnson, *Biden-Merkel Meeting Fails to Move Forward Vaccine Patent Waiver*, TRUTHOUT (July 16, 2021), https://truthout.org/articles/biden-merkel-meeting-fails-to-move-forward-vaccine-patent-waiver/?utm_campaign=Truthout+Share+Buttons.

⁴⁷⁰ Press Release, Rep. Jan Schakowsky, *Schakowsky, Colleagues Request Meeting with Merkel To Discuss European Union Blocking TRIPS Waiver* (12 July 2021), <https://schakowsky.house.gov/media/press-releases/schakowsky-colleagues-request-meeting-merkel-discuss-european-union-blocking>; *U.S. lawmakers ask for Meeting on WTO Waiver with Merkel during Washington Visit*, REUTERS (July 13, 2021), <https://www.reuters.com/world/us/us-lawmakers-ask-meeting-wto-waiver-with-merkel-during-washington-visit-2021->

a vigorous campaign to change the mind of German Chancellor Angela Merkel about her position on the TRIPS Waiver.⁴⁷¹

The European Parliament, in a vote, called upon the European Commission to support a TRIPS Waiver.⁴⁷² In a resolution adopted with 355 votes in favour, 263 against and 71 abstentions, the European Parliament proposed negotiations start for a temporary waiver of the WTO TRIPS Agreement on patents to improve global access to affordable COVID-19-related medical products and to address global production constraints and supply shortages.⁴⁷³

After some equivocation, French President Emmanuel Macron has also called for the European Commission to support the TRIPS Waiver.⁴⁷⁴

Other countries that have endorsed the TRIPS Waiver include the Governments of the United Kingdom, Switzerland,⁴⁷⁵ Norway,⁴⁷⁶ and South Korea.⁴⁷⁷ Somewhat indecisively, Japan has said that it would not oppose the TRIPS Waiver but would not endorse the TRIPS Waiver either.⁴⁷⁷

The Conservative Government led by Boris Johnson has resisted entreaties to support the TRIPS Waiver.⁴⁷⁸ Prime Minister Gordon Brown has pressed the current United Kingdom government and other members of the G7 to do more on access to essential medicines.⁴⁷⁹

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⁴⁷¹ Biden-Merkel Summit Fail: Pres. Biden Unable to End Germany's Blockade of COVID WTO TRIPS Waiver He Seeks to End Pandemic, PUBLIC CITY NEWS, <https://www.publiccitynews.com/biden-merkel-summit-fail-pres-biden-unable-to-end-germanys-blockade-covid-wto-trips-waiver/>.

⁴⁷² European Parliament Press Release, *European Parliament Calls for Temporary COVID-19 Vaccine Patent Waiver* (July 10, 2021), <https://www.europarl.europa.eu/media/default.do?more=downloadMedia&file=IPR05514/parliament-calls-for-temporary-covid-19-vaccine-patent-waiver>.

⁴⁷³ EUR. PARL. DOC., *supra* note 113.

⁴⁷⁴ Lotte Leicht, *European Commission Increasingly Isolated on COVID Patent Waivers: French President Emmanuel Macron and the European Parliament Endorsed Waiver, But Commission Remains Available*, HUMAN RIGHTS WATCH (June 11, 2021), <https://www.hrw.org/news/2021/06/11/european-commission-increasingly-isolated-covid-patent-waivers>.

⁴⁷⁵ IGE, *Suspension of the TRIPS Agreement in the COVID-19 Pandemic?* (2020) <https://www.ige.ch/en/intellectual-property/ip-and-society/swiss-health-foreign-policy-and-access-to-therapeutic-products/suspension-of-the-trips-agreement>.

⁴⁷⁶ Norway in Geneva, Statement by Norway at WTO TRIPS Council (Oct. 16, 2020), <https://www.norway.no/en/missions/wto-un/nig/latest-news/trips1610>.

⁴⁷⁷ Human Rights Watch, *Quad Leaders Should Back Covid-19 Intellectual Property Waiver*, (September 23, 2021) <https://reliefweb.int/report/world/quad-leaders-should-back-covid-19-intellectual-property-waiver>.

⁴⁷⁸ Hannah Summers, *Britain in Talks to Waive Covid Vaccine Patents to Improve Global Access to Jabs*, THE GUARDIAN (May 20, 2021), <https://www.theguardian.com/global-development/2021/may/20/britain-in-talks-to-waive-covid-vaccine-patents-to-improve-global-access-to-jabs>; Larry Elliott, *Labour says UK must "Get off the Fence" over Global Covid Vaccine Access*, THE GUARDIAN (May 20, 2021), <https://www.theguardian.com/world/2021/may/20/labour-uk-global-covid-vaccine-access-patent-waiver>; Aubrey Allegretti, *MPs Tell Johnson: You Have A Duty to Help Vaccinate the World*, THE GUARDIAN (June 1, 2021), <https://www.theguardian.com/society/2021/may/31/mps-boris-johnson-donate-vaccines-poorer-countries>.

⁴⁷⁹ Gordon Brown, *The G7 must push for Global Vaccination. Here's How it Could Do It*, THE GUARDIAN (Apr. 12, 2021), <https://www.theguardian.com/commentisfree/2021/apr/12/g7-global-vaccination-covid>; Gordon Brown, *Despite the Grand Words, This G7 Falls Devastatingly Short On Vaccines*, THE GUARDIAN (June 14, 2021), <https://www.theguardian.com/commentisfree/2021/jun/14/grand-words-g7-vaccines-summit-failure-gordon-brown>; Gordon Brown, *The World Is Making Billions of COVID Vaccine Doses, So Why Is Africa Not Getting Them*, THE GUARDIAN (Aug. 16, 2021), <https://www.theguardian.com/commentisfree/2021/aug/16/world-billions-covid-vaccine-doses-africa>.

80 Members of Parliament signed a petition on Intellectual Property and the COVID-19 response.⁴⁸⁰ The co-sponsors included Caroline Lucas from the Green Party, Navendu Mishra and Clive Lewis of the British Labour Party, Layla Moran and Wendy Chamberlain of the Liberal Democrats, and Independent Claudia Webbe. The petition “*urges the Government to recognise that intellectual property barriers are hindering equitable access to COVID-19 health technologies, reconsider its position and support the waiver proposal at upcoming TRIPS Council and WTO General Council Meetings.*”⁴⁸¹ Navendu Mishra has lamented: “*It was incredibly short-sighted of the UK to oppose the TRIPS waiver at the WTO last October and it must now reconsider its position and heed the calls of more than 150 former heads of state (including Gordon Brown) and Nobel laureates for a people’s vaccine, which would help to overcome Covid vaccine inequality.*”⁴⁸² Richard Burgon MP has also called for the United Kingdom to support a ‘People’s Vaccine.’⁴⁸³

The Gates Foundation has a history of supporting intellectual property maximalist positions in the debate over access to essential medicines.⁴⁸⁴ The Gates Foundation was initially supportive of private intellectual property holders being in charge of the distribution of vaccines, treatments, and diagnostics. However, there have been major challenges and barriers to the delivery of COVID-19 technologies. Bill Gates has warned of a “*longer, more unjust, deadlier pandemic*” if market forces are left to distribute medicines.⁴⁸⁵ The Gates Foundation was a reluctant, late supporter of the TRIPS Waiver.⁴⁸⁶ There is a need to set in place mechanisms to ensure the fair and equitable distribution of COVID-19 technologies in the U.S. and elsewhere.

Big pharmaceutical companies and vaccine developers are clearly seeking to delay, frustrate, and block the passage of the TRIPS Waiver.⁴⁸⁷ There has been an extensive lobbying campaign by intellectual property owners to nation governments against the adoption of the TRIPS Waiver.⁴⁸⁸ Vaccine

[unprotected](#); GORDON BROWN, SEVEN WAYS TO CHANGE THE WORLD: HOW TO FIX THE MOST PRESSING PROBLEMS WE FACE (2021).

⁴⁸⁰ EDM 1451 - Intellectual Property and COVID-19 Response, UNITED KINGDOM PARLIAMENT (08 Feb. 2021), <https://edm.parliament.uk/early-day-motion/58063/intellectual-property-and-covid19-response>.

⁴⁸¹ *Id.*

⁴⁸² Navendu Mishra, *India’s COVID Spiral is Nothing Short of Horrifying – And The UK Must Act*, MIRROR (Apr. 30, 2021), <https://www.mirror.co.uk/news/politics/indias-covid-spiral-nothing-short-24015159>; See also, Navendu Mishra, *There Should Be No Monopolies in a Pandemic*, POLITICS (Nov. 20, 2020), <https://politics.co.uk/comment-analysis/2020/11/20/there-should-be-no-monopolies-in-a-pandemic>.

⁴⁸³ Richard Burgon, *A Vaccine That Serves All of Humanity – Not Private Profit*, MORNING STAR, <https://morningstaronline.co.uk/article/f/vaccine-serves-all-humanity-not-private-profit>.

⁴⁸⁴ Matthew Rimmer, *The Lazarus Effect: The (RED) Campaign, and Creative Capitalism*, in *INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO MEDICINES*, 313 (Thomas Pogge, Matthew Rimmer & Kim Rubenstein ed., 2010).

⁴⁸⁵ John Miller, *Bill Gates calls for COVID-19 Meds to Go to People Who Need Them, Not “Highest Bidder”*, THE SYDNEY MORNING HERALD (June 10, 2020), <https://t.co/pAp3e9QXgT?amp=1>.

⁴⁸⁶ Catherine Cheney, *Gates Foundation Reverses Course on COVID-19 Vaccine Patents*, DEVEX (May 7, 2021), <https://www.devex.com/news/gates-foundation-reverses-course-on-covid-19-vaccine-patents-99810>.

⁴⁸⁷ Paul Karp, *Pfizer Warns Australia a COVID Vaccine Patent Waiver Could Harm Supply and Safety*, THE GUARDIAN (May 13, 2021), <https://www.theguardian.com/australia-news/2021/may/13/pfizer-warns-australia-a-covid-vaccine-intellectual-property-patent-waiver-could-harm-supply-and-safety>.

⁴⁸⁸ Lee Fang, *Pharmaceutical Industry Dispatches Army of Lobbyists to Block Generic COVID-19 Vaccines*, THE INTERCEPT (Apr. 23, 2021), <https://theintercept.com/2021/04/23/covid-vaccine-ip-waiver-lobbying>; Lee Fang, *Hollywood Lobbyists Intervene*

developers have also been placing great pressure upon nation states during negotiations to acquire vaccines.⁴⁸⁹ It remains to be seen whether the TRIPS Waiver proposed by South Africa and India will be realized in a timely fashion – if it all.

If the TRIPS Waiver does get up, many countries will also have to consider their commitments under TRIPS+ and TRIPS++ agreements like the bilateral trade agreement, the *Australia-U.S. Free Trade Agreement* 2004⁴⁹⁰ and the regional trade agreement, the *Trans-Pacific Partnership*.⁴⁹¹ It may well be complicated seeking additional waivers in respect of the obligations and commitments under TRIPS+ and TRIPS ++ agreements.

D. Community Support for the TRIPS Waiver

Human rights bodies have made supporting statements about the need for universal, affordable vaccination for COVID-19.⁴⁹²

There has been an open petition by over 100 academics, scholars, and researchers, calling for the adoption of the TRIPS Waiver.⁴⁹³ The letter stressed: “*The temporary TRIPS waiver - as proposed by India and*

Against Proposal to Share Vaccine Technology, THE INTERCEPT (Apr. 28, 2021), <https://theintercept.com/2021/04/27/covid-vaccine-copyright-hollywood-lobbyists>; Lee Fang, *Documents Reveal Pharma Plot to Stop Generic COVID-19 Vaccine Waiver*, THE INTERCEPT (May 15, 2021), <https://theintercept.com/2021/05/14/covid-vaccine-waiver-generic-pharma-lobby>; Brett Wilkins, *Big Pharma Plotting to Derail Biden's COVID Vaccine Waiver: Report*, SALON (May 17, 2021), https://www.salon.com/2021/05/17/big-pharma-plotting-to-derail-covid-vaccine-waiver-report_partner.

⁴⁸⁹ Madlen Davies et al., “*Held to Ransom*”: *Pfizer Demands Governments Gamble with State Assets to Secure Vaccine Deal*, THE BUREAU OF INVESTIGATIVE JOURNALISM (Feb. 23, 2021), <https://www.thebureauinvestigates.com/stories/2021-02-23/held-to-ransom-pfizer-demands-governments-gamble-with-state-assets-to-secure-vaccine-deal>; Investigation: *Drugmaker “Bullied” Latin American Nations*, AL JAZEERA (Mar. 11, 2021), <https://www.aljazeera.com/news/2021/3/11/investigation-pfizer-bullied-latin-american-nations>; Zain Rizvi, *Pfizer's Power*, PUBLIC CITIZEN, (October 19, 2021), <https://www.citizen.org/article/pfizers-power/>; Adam Taylor, *In Secret Vaccine Contracts with Governments, Pfizer took Hard Line in Push for Profit*, Report says, THE WASHINGTON POST, (October 19, 2021) <https://www.washingtonpost.com/world/2021/10/19/secret-vaccine-contracts-with-governments-pfizer-took-hard-line-push-profit-report-says/> and Zain Rizvi, *Public Citizen Blasts Pfizer for Putting Corporate Profit Over Increasing Access to COVID Vaccines*, DEMOCRACY NOW!, (October 22, 2021), https://www.democracynow.org/2021/10/22/public_citizen_researcher_exposes_pfizer_vaccines.

⁴⁹⁰ Australia-U.S. Free Trade Agreement, Austl.-U.S., May 18, 2004, 118 Stat. 919; See generally, Matthew Rimmer, *Robbery Under Arms: Copyright Law and the Australia-U.S. Free Trade Agreement* 11 (3) FIRST MONDAY (March 2006), <http://firstmonday.org/ojs/index.php/fm/article/view/1316> and Ken Harvey et al., *Will the Australia-U.S. Free Trade Agreement Undermine the Pharmaceutical Benefits Scheme?*, 181 (5) MED. J. OF AUS. 256 (October 2004).

⁴⁹¹ Trans-Pacific Partnership (TPP), 4 Feb. 2016, and *Comprehensive and Progressive Agreement for Trans-Pacific Partnership* (2018), <https://www.dfat.gov.au/sites/default/files/tpp-11-treaty-text.pdf>; See generally, Matthew Rimmer, *The Trans-Pacific Partnership: Intellectual Property, Public Health, and Access to Essential Medicines* 29 INTELL. PROP. J. 277 (2017); DEBORAH GLEESON, & RONALD LABONTE, *TRADE AGREEMENTS AND PUBLIC HEALTH: A PRIMER FOR HEALTH POLICY MAKERS, RESEARCHERS AND ADVOCATES* (2020); MATTHEW RIMMER, *THE TRANS-PACIFIC PARTNERSHIP: INTELLECTUAL PROPERTY AND TRADE IN THE PACIFIC RIM* (2020).

⁴⁹² Statement by Committee on Economic, Social and Cultural Rights on Universal Affordable Vaccination for COVID-19, International Cooperation and Intellectual Property, E/C.12/2021/1 (March 12, 2021) <https://t.co/YbLQw8bq3G?amp=1>; U.N. Human Rights Council, *Ensuring Equitable, Affordable, Timely and Universal Access for All Countries to Vaccines in Response to the Coronavirus Disease (COVID-19) Pandemic*, A/HRC/46/L.25/Rev.1 (March 17, 2021).

⁴⁹³ Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal (July 2021), <https://docs.google.com/forms/d/e/1FAIpQLSfS497EZW5oNf2tk46rzdUAYswABW91OT91QarsaFTvoBLHvQ/vie>

South Africa and supported by more than 100 countries - is a necessary and proportionate legal measure towards the clearing of existing intellectual property barriers to scaling up of production of COVID-19 health technologies in a direct, consistent and effective fashion."⁴⁹⁴

The community of scholars demanded: "*We call on the governments of the United Kingdom of Great Britain and Northern Ireland, Australia, Brazil, Japan, Norway, Switzerland and the European Union to drop their opposition to the TRIPS Waiver proposal at the World Trade Organisation and to support the waiver.*"⁴⁹⁵ In addition to the passage of the TRIPS Waiver, the academics called for the adoption of a package of measures – including the "*global co-ordination of supply chains; streamlining regulatory approval processes and sharing exclusive data from regulatory dossiers; and investment in the WHO's C-TAP and the mRNA technology transfer hub in South Africa.*"⁴⁹⁶

In July 2021, MSF has complained that opposing countries have been filibustering negotiations on the TRIPS Waiver at the WTO.⁴⁹⁷ Dr Tom Ellman, director of MSF's Southern Africa Medical Unit, despaired: "*It is outrageous to see countries blocking the TRIPS Waiver that is desperately needed as an important tool to remove legal barriers and allow production to be scaled up by multiple manufacturers for critical COVID-19 drugs, diagnostics and vaccines.*"⁴⁹⁸ Ellman commented: "*At a moment when we are in race against time to save lives and control the spread of unchecked transmission and development of new dangerous variants, pharmaceutical corporation's business-as-usual approach is intolerable.*"⁴⁹⁹ Ellman called for a broad version of the TRIPS Waiver to be adopted, which covered not just vaccines, but also treatments, diagnostics, and other health technologies.⁵⁰⁰ The surge of the Delta strain of the coronavirus in 2021 has made the need for an effective response to global need for access to essential medicines all the more urgent.

In November 2021, the International Commission of Jurists issued an opinion, calling for the waiver of global intellectual property rights for COVID-19 vaccines and therapeutics.⁵⁰¹ The International Commission of Jurists recognised "*that for the pandemic to end, or at least be brought under control, urgent access to vaccines is crucial, even if they are not the only determinant of the rights to health, science, equality and life*".⁵⁰² The Opinion observed:

[wform](https://www.lse.ac.uk/News/Latest-news-from-LSE/2021/g-July-21/Waive-intellectual-property-protection-for-COVID-vaccines.aspx); *Waive Intellectual Property Protection for COVID Vaccines urge over 100 IP Academic Experts*, THE LONDON SCH. OF ECON. AND POL. SCI. (July 13, 2021), <https://lse.ac.uk/News/Latest-news-from-LSE/2021/g-July-21/Waive-intellectual-property-protection-for-COVID-vaccines.aspx>.

⁴⁹⁴ *Id.*

⁴⁹⁵ *Id.*

⁴⁹⁶ *Id.*

⁴⁹⁷ *Opposing Countries Must Stop Filibustering Negotiations on 'TRIPS Waiver' at WTO*, MEDECINS SANS FRONTIERES ACCESS CAMPAIGN (July 26, 2021), <https://msfaccess.org/opposing-countries-must-stop-filibustering-negotiations-trips-waiver-wto>.

⁴⁹⁸ *Id.*

⁴⁹⁹ *Id.*

⁵⁰⁰ *Id.*

⁵⁰¹ International Commission of Jurists, *Global Jurists call for Waiver of Global Intellectual Property Rights for COVID-19 Vaccines and Therapeutics*, (November 8, 2021), <https://www.icj.org/global-jurists-call-for-waiver-of-global-intellectual-property-rights-for-covid-19-vaccines-and-therapeutics/>; and International Commission of Jurists, *Human Rights Obligations of States to not Impede the Proposed COVID-19 TRIPS Waiver*, (November 2021) <https://www.icj.org/wp-content/uploads/2021/11/Human-Rights-Obligations-States-Proposed-COVID-19-TRIPS-Waiver.pdf>.

⁵⁰² International Commission of Jurists, *Human Rights Obligations of States to not Impede the Proposed COVID-19 TRIPS Waiver*, (November 2021), 1, <https://www.icj.org/wp-content/uploads/2021/11/Human-Rights-Obligations-States-Proposed-COVID-19->

“Failing to implement legitimate and legal, public health safeguards, as provided in the TRIPS Agreement, including by creating obstacles to the TRIPS waiver negotiations, constitutes a failure on the part of States parties to fulfil their human rights obligations under the rights to health, equality, science and life.”⁵⁰³

VIII. CONCLUSION

This paper has told the story of the People’s Vaccine Alliance – a ragtag group of advocates, activists, and rebels who have challenged the status quo in respect of intellectual property and access to essential medicines. This social movement has questioned profiteering by pharmaceutical companies, vaccine developers, and medical diagnostics entities who have sought to maximise their intellectual property rights related to COVID-19 technologies. The Alliance has also highlighted that vaccine nationalism has been raging during the public health coronavirus crisis. There have been profound inequities in the distribution of COVID-19 vaccines, treatments, diagnostics, and other technologies.

There have been a variety of alternative models of intellectual property advanced in the public policy debates – but they have been slow to reach a critical mass, and have faced considerable opposition and resistance from established biomedical industries. Susi Geiger and Aisling McMahon have questioned the proliferation of proposals for vaccine equity for COVID-19.⁵⁰⁴ It is true that many of the proposals for intellectual property sharing are still at an immature stage of development. The campaign for a People’s Vaccine is a new social movement – although it has had some early successes, it still has much work to do. The ACT-Accelerator, and its constituent parts like COVAX have struggled to obtain sufficient health financing to achieve its goals to promoting research, development, and deployment of COVID-19 technologies. The Medicines Patent Pool and C-TAP have had to contend with uncooperative intellectual property holders. Compulsory licensing and crown use have been mooted by various nation states in response to the demands of vaccine developers and other intellectual property rights holders. Although there have been massive public investments in COVID-19 technologies, public sector licensing has been patchy. There has been experimentation with patent pledges. But so far, the take-up has been largely by private information technology companies, and public sector research organisations. The TRIPS Waiver advanced by South Africa and India has made some progress in the WTO with the Biden Administration expressing a willingness to support a TRIPS Waiver for Vaccines. However, there remains entrenched resistance to a TRIPS Waiver from established developed nations like Germany, Switzerland, and Norway, with close ties to biomedical industries.

[TRIPS-Waiver.pdf](#).

⁵⁰³ *Id.*, 17.

⁵⁰⁴ Susi Geiger & Aisling McMahon, *Too Many Cooks or Too Many Recipes? An Analysis of the Institutional Landscape and Proliferation of Proposals for Global Vaccine Equity* (Geary Inst., U. C. Dublin, Working Paper No. 202108, 2021).

By its nature, this study is a provisional overview of a panoply of policy proposal, rather than an in-depth, exhaustive study of a single particular option. No doubt future research by this author and other scholars in the field of access to essential medicines will delve further into the evolution of these particular policy options, and evaluate the success or otherwise of these endeavours and ventures in their own right and through combinations. Ellen 't Hoen and her collaborators have noted: 'Several initiatives have been proposed that begin to address key challenges of scaling up vaccine production capacity, but so far in limited or piecemeal ways.'⁵⁰⁵ The background paper concludes: 'What is ultimately needed is a cohesive global action plan that addresses the legal, technical and financial barriers to rapid scale-up of vaccine production.'⁵⁰⁶ The research and development of vaccines, treatments, and diagnostics has also been proceeding apace. Successful COVID-19 technologies will no doubt be in high demand, and will raise complex questions about intellectual property and access to medicines. The nature of the coronavirus public health crisis has also been evolving, particularly with the appearance of new variants.

The coronavirus public health crisis may well lead to a realignment of international intellectual property law. Reflecting upon the coronavirus crisis, the novelist Arundhati Roy has observed that there is an opportunity for a reform of economic and social structures: *"Historically, pandemics have forced humans to break with the past and imagine their world anew."*⁵⁰⁷ It is certainly the case that there is scope to reimagine intellectual property in the wake of the coronavirus crisis. Professor Myra Tawfik from Windsor Law School from Canada has argued that *"the worldwide COVID-19 public health crisis highlights the inequities and biases within the international and domestic intellectual property (IP) legal orders that were already being scrutinized prior to this extraordinary global upheaval."*⁵⁰⁸ She contends: *"If countries hoard medical supplies and IP rights holder extract usurious prices for access to treatments and supplies, then the fallout from these individualistic actions will compel an alternative IP future the next time around."*⁵⁰⁹ Otherwise Tawfik suggests: *"If, on the other hand, the global community emerges from the COVID-19 pandemic having adopted collaborative IP strategies that ensure equitable and fair access to COVID-19 treatments and supplies, the success of this approach and the global co-operation it will have engendered will carry forward into the future."*⁵¹⁰ Tawfik imagines: *"A post-pandemic IP legal order will be built on greater collaboration, balance and inclusion."*⁵¹¹ She is hopeful that the intellectual property regime will find a new equilibrium: *"By imposing checks and balances on individualistic and maximalist approaches, it will curb the abuses of the current IP environment, which privileges the dominant players"*.⁵¹²

⁵⁰⁵ HOEN ET AL., *supra* note 163.

⁵⁰⁶ HOEN ET AL., *supra* note 163.

⁵⁰⁷ Arundhati Roy, *The Pandemic is a Portal*, FINANCIAL TIMES (Apr. 4, 2020), <https://www.ft.com/content/10d8f5e8-74eb-11ea-95fe-fcd274e920ca>.

⁵⁰⁸ Myra Tawfik, *The Post-Pandemic IP Legal Order: Collaborative, Balanced and Inclusive*, Center for International Governance Innovation (July 8, 2020), <https://www.cigionline.org/articles/post-pandemic-ip-legal-order-collaborative-balanced-and-inclusive>.

⁵⁰⁹ *Id.*

⁵¹⁰ *Id.*

⁵¹¹ *Id.*

⁵¹² *Id.*

Susi Geiger and Aisling McMahon have expressed concern about the complicated, fragmented nature of the institutional landscape.⁵¹³ There are a host of institutions – some well-established, others new, which have been grappling with the question of access to medicines during the COVID-19 crisis. The WHO has been engaged with a range of public policy issues as part of the COVID-19 crisis. It has also been instrumental in setting up new institutions such as the ACT-Accelerator, COVAX, and C-TAP to address various aspects of the COVID-19 crisis. The Independent Panel has made a number of recommendations as to the reformation of WHO.⁵¹⁴ After being paralysed by conflict between the superpowers of China and the U.S., the WTO has appointed a new director, and has sought to progress the debate over access to essential medicines. As well as providing technical information,⁵¹⁵ the WTO has hosted debates in the TRIPS Council over proposals such as the TRIPS Waiver.⁵¹⁶ The new WTO Director-General Ngozi Okonjo-Iweala has promised to advance discussions on the topic in the TRIPS Council, observing “*we need to respond urgently to COVID-19 because the world is watching and people are dying*”.⁵¹⁷ With the changeover of Director-Generals, WIPO has been relatively quiet in respect of the debate over intellectual property and access to medicines during the coronavirus crisis. WHO, WTO, and WIPO have previously worked together on intersections between intellectual property, public health, and trade.⁵¹⁸ In 2021, the directors of WHO, WTO, and WIPO agreed to engage in intensified co-operation in support of access to medical technologies worldwide to tackle the COVID-19 pandemic.⁵¹⁹ The leaders of the international institutions stressed: “*We underscored our commitment to universal, equitable access to COVID-19 vaccines, therapeutics, diagnostics, and other health technologies – a commitment anchored in the understanding that this is an urgent moral imperative in need of immediate practical action.*”⁵²⁰ The upheaval of the coronavirus crisis has certainly underlined the need for an overhaul of the multilateral system to ensure that it is better prepared for global crises – such as the coronavirus pandemic. It is also a

⁵¹³ Geiger and McMahon, *Supra* note 504.

⁵¹⁴ THE INDEPENDENT PANEL FOR PANDEMIC PREPAREDNESS AND RESPONSE, *supra* note 23.

⁵¹⁵ *Members Discuss Intellectual Property Response to the COVID-19 Pandemic* (Oct. 20, 2020), WORLD TRADE ORG., https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm?utm_source=dlvr.it&utm_medium=twitter.

⁵¹⁶ COVID-19: Measures Regarding Trade-Related Intellectual Property Rights, WORLD TRADE ORG. (Aug. 31, 2021), https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm; World Trade Organization, Information Note on the TRIPS Agreement and COVID-19 (Oct. 15, 2020), https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf.

⁵¹⁷ *WTO Chief Lays Out Global Action To Increase Vaccine Access*, REUTERS (Apr. 15, 2021), <https://www.reuters.com/article/us-trade-wto-vaccines-idUSKBN2C12YU>; *Statement of Director-General Ngozi Okonjo-Iweala on USTR Tai's statement on the TRIPS Waiver*, WORLD TRADE ORGANIZATION (May 6, 2021) https://www.wto.org/english/news_e/news21_e/dgno_06may21_e.htm.

⁵¹⁸ WORLD HEALTH ORGANIZATION, WORLD INTELLECTUAL PROPERTY ORGANIZATION & WORLD TRADE ORGANIZATION, PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION - INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE (Charlotte Beauchamp et al., eds., 2nd ed. 2020).

⁵¹⁹ Press Release, WHO, Directors General of WHO, WIPO and the WTO agree on intensified cooperation in support of access to medical technologies worldwide to tackle the COVID-19 pandemic (June 24, 2021), <https://www.who.int/news/item/24-06-2021-directors-general-of-who-wipo-and-the-wto-agree-on-intensified-cooperation-in-support-of-access-to-medical-technologies-worldwide-to-tackle-the-covid-19-pandemic>.

⁵²⁰ *Id.*

shame that the previous recommendations of the United Nations Secretary-General High Level Panel report on access to medicines about the need to build up the global infrastructure for public health were not heeded.⁵²¹ There is certainly a pressing need to ensure better financing for global public health.⁵²²

There has also been discussion as to whether there should be an international pandemic treaty to better protect the world from future health crises.⁵²³ 25 heads of government and international agencies made a joint call for more robust international health architecture.⁵²⁴ The joint statement noted: “*The COVID-19 pandemic has been a stark and painful reminder that nobody is safe until everyone is safe.*”⁵²⁵ The joint statement called for access to essential medicines: “*We are, therefore, committed to ensuring universal and equitable access to safe, efficacious and affordable vaccines, medicines and diagnostics for this and future pandemics.*”⁵²⁶ The joint statement stressed that vaccines should be treated as global public goods: “*Immunization is a global public good and we will need to be able to develop, manufacture and deploy vaccines as quickly as possible.*”⁵²⁷

There is certainly a need to consider the role that intellectual property law, policy, and practice will play not only in the COVID-19 response, but in the COVID-19 recovery. United Nations Secretary-General Antonio Guterres has called for a COVID-19 recovery plan, which upholds the Sustainable Development Goals and human rights: “*By respecting human rights in this time of crisis, we will build more effective and inclusive solutions for the emergency of today and the recovery for tomorrow.*”⁵²⁸

There have been a host of proposals for COVID-19 recovery plans.⁵²⁹ There has been a call for a reinvestment in public health, sustainable development, and climate action as part of a successful COVID-19 recovery.⁵³⁰ Guterres has said: “*For too long, we have undervalued and underinvested in global public goods*

⁵²¹ Dreifuss et al., *supra* note 25.

⁵²² Ilona Kickbush, *The COVID-19 Crisis Is A Signal – Need To ‘Reset’ Global Health Financing*, HEALTH POLICY WATCH (Nov. 11, 2020), <https://healthpolicy-watch.news/the-covid-19-crisis-is-a-signal-to-reset-global-health-financing>.

⁵²³ *Global Leaders Unite In Urgent Call for International Pandemic Treaty*, WORLD HEALTH ORGANIZATION (Mar. 30, 2021), <https://www.who.int/news/item/30-03-2021-global-leaders-unite-in-urgent-call-for-international-pandemic-treaty>.

⁵²⁴ *COVID-19 Shows Why United Action is Needed for More Robust International Health Architecture*, WORLD HEALTH ORGANIZATION (30 Mar., 2021), <https://www.who.int/news-room/commentaries/detail/op-ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture>.

⁵²⁵ *Id.*

⁵²⁶ *Id.*

⁵²⁷ *Id.*

⁵²⁸ U.N. Sec. Gen., *We are all in this Together: Human Rights and COVID-19 Response and Recovery*, (Apr. 23, 2020), <https://www.un.org/en/un-coronavirus-communications-team/we-are-all-together-human-rights-and-covid-19-response-and-recovery>.

⁵²⁹ For a discussion of COVID-19 recovery policies, see TANYA PLIBERSEK, *A BETTER NORMAL AFTER COVID-19* (2020); KLAUS SCHWAB & THIERRY MALLERET, *COVID-19: THE GREAT RESET* (2020); ROSS GARNAUT, *RESET: RESTORING AUSTRALIA AFTER THE GREAT CRASH OF 2020* (2021).

⁵³⁰ *Beyond Recovery: Towards 2030*, UNITED NATIONS DEV. PROGRAMME (2020), https://global.undp.acsitefactory.com/sites/g/files/zskgke326/files/publications/undp-COVID-19_UNDP_2.0_Offer.pdf; *The OECD Green Recovery Database: Examining the Environmental Implications of COVID-19 Recovery Policies*, OECD (Apr. 19, 2021), <https://www.oecd.org/coronavirus/policy-responses/the-oecd-green-recovery-database-47ae0f0d/#section-d1e334>.

— *a clean environment, cyber security, peace, the list goes on.*”⁵³¹ He emphasizes that there is “*one vital lesson of this pandemic: the need for new urgency in support of global public goods and universal health coverage.*”⁵³²

⁵³¹ U.N. Sec. Gen., Secretary-General's remarks at the launch of the Statement of Commitment and Call for Support for the Global Collaboration to Accelerate the Development, Production and Equitable Access to New COVID-19 Tools, (Apr. 24, 2020), <https://www.un.org/sg/en/content/sg/statement/2020-04-24/secretary-generals-remarks-the-launch-of-the-statement-of-commitment-and-call-for-support-for-the-global-collaboration-accelerate-the-development-production-and>.

⁵³² *Id.*

HALFWAY ON THE “STAIRWAY TO HEAVEN”: AN ANALYSIS OF COPYRIGHT PROTECTION FOR MUSICAL WORKS IN THE NINTH CIRCUIT

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Abstract

Music is pleasing to the ears of the consumers but is confusing to a judge. There exist difficulties in differentiating the protectable elements of musical works from the unprotectable elements. The Ninth Circuit has constantly erred by protecting elements of musical works that ought not to be protected. Judges with no musical knowledge cannot analyse if infringement has taken place or not. However, in the Ninth Circuit, adjudicating power is primarily provided to the judges and the juries, despite expert opinions being taken. Nevertheless, some positive steps have been taken. In 2020, the Ninth Circuit abrogated the controversial inverse ratio rule. Further, the confusing tests undertaken to find infringement were clarified. Such decisions have been welcomed. However, these steps have only brought the Ninth Circuit halfway to an ideal copyright regime, as various problems still exist in the tests themselves. The tests demand for expert opinions but expect the judges to make their own subjective analysis as an ordinary observer by ignoring the expert opinions. The judges are expected to determine infringement based on the “feel and groove” of a song but, such similarity in the feel and groove can be a result of the unprotected elements. Further, the courts sometimes fail to acknowledge the inherent limitations in the playing field when it comes to musical compositions and that similarity to some extent is inevitable. Such shortcomings can result in the protection of ideas and goes against the copyright law. The shortcomings are intertwined and the article attempts to explain them and provide a viable solution. This article highlights the journey that has been taken by the Ninth Circuit and the journey that is still left to be taken. It discusses the problems prevalent in the Ninth Circuit, while also bringing observations and analysis propounded by other circuits and judgments.

I. INTRODUCTION

The very first copyright law of the United States of America (“US”) did not protect musical works until its revision in 1831.¹ Currently, in the US, the purpose of copyright law has been described in economic terms.² While economic gain is not the only consideration of copyright protection,³ we can observe that music has today become a commodity bought and sold in the marketplace.⁴ Courts, while dealing with infringement cases, have also seen “*whether the secondary use usurps*

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¹ Maria Scheid, *When does music enter the public domain in the United States?*, Ohio State University (July 27, 2020), <https://library.osu.edu/site/publicdomain/2020/07/27/when-does-music-enter-the-public-domain-in-the-united-states/>.

² See Jean-Luc Piotraut, *An Authors' Rights-Based Copyright Law: The Fairness and Morality of French and American Law Compared*, 24 CARDOZO ARTS & ENT. L.J. 549, 554 (2006).

³ See *Mazer v. Stein*, 347 U.S. 201, 219 (1954).

⁴ STEVEN MILES, CONSUMERISM AS A WAY OF LIFE 107 (1998).

the market of the original work".⁵ In the case of *Oyewole*, the court decided in favour of the defendants, as one of the factors that it observed was that, it was unlikely that the target audience of the defendant and the plaintiff were the same, which therefore did not affect the potential market value of the song.⁶ Therefore, copyright protects a composer's market interest. "*The plaintiff's legally protected interest is not, as such, his reputation as a musician but his interest in the potential financial returns from his compositions, which is derived from the lay public's approbation of his efforts.*"⁷ Later, it was further clarified that it is not just monetary gain of the author that is seen but also if the user of the work profits from the use of the copyrighted work without payment of the customary price to the author.⁸ This further puts a light on the economic value that the copyright regime seeks to protect.

Different circuits in the US have different approaches to determine copyright infringement in the case of musical compositions.⁹ There exists a lot of confusion and shortcomings in the judicial system when it comes to the determination of infringement, especially in the case of musical works. For example, it can be observed that the inverse ratio rule (See, **II (B)**), as earlier adopted by the Ninth Circuit, disproportionately protected popular musical works. However, it is largely observed that the rule has been plaintiff-centric as the rule has helped in establishing infringement even against popular musical works, where its artist(s) were the defendants.¹⁰ It can also be observed that even in cases of dissimilarities between the musical works, courts in the Ninth Circuit have found infringement.¹¹ Further, given the monetary stake at hand, along with the shortcomings that exist, cases of infringement are filed invariably against popular songs,¹² thus depriving the artists of the monetary value of their works.

Western music and the litigation on it suffer from a lack of familiarity with music theory, unhelpful contribution by music experts, failure to acknowledge inherent constraints in the western tonality and, difficulty in differentiating between the plaintiff's work from the music in the public domain.¹³ While some confusions have been clarified by the Ninth Circuit, the copyright regime, when it comes to the protection of musical works, is still halfway from an ideal copyright

⁵ *Blanch v. Koons*, 467 F.3d 244, 258 (2d Cir. 2006).

⁶ *Oyewole v. Ora*, 291 F. Supp. 3d 422, 436 (S.D.N.Y. 2018).

⁷ *Arnstein v. Porter*, 154 F.2d 464, 473 (2d Cir. 1946).

⁸ *Harper & Row, Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 562 (1985).

⁹ Eric Rogers, *Substantially Unfair: An Empirical Examination of Copyright Substantial Similarity Analysis among the Federal Circuits*, 2013 MICH. ST. L. REV. 893, 911 (2013) [hereinafter "Rogers"].

¹⁰ See *Williams v. Gaye*, 895 F.3d 1106, 1138 (9th Cir. 2018).

¹¹ See Alex Abad-Santos, *A jury said Katy Perry's "Dark Horse" copied another song. The \$2.8 million verdict is alarming*, Vox (Aug. 2, 2019, 2:02 PM), <https://www.vox.com/culture/2019/7/30/20747100/katy-perry-dark-horse-joyful-noise-copyright-2-8-million>.

¹² See *Arnstein v. Edward B. Marks Music Corp.*, 82 F.2d 275, 277 (2d Cir. 1936); see also *Fred Fisher, Inc. v. Dillingham*, 298 F. 145, 147-148 (S.D.N.Y. 1924); see also *Hein v. Harris*, 175 F. 875, 876 (C.C.S.D.N.Y. 1910); see also *Williams v. Gaye*, 895 F.3d 1106 (9th Cir. 2018).

¹³ Margit Livingston & Joseph Urbanato, *Copyright Infringement of Music: Determining Whether What Sounds Alike Is Alike*, 15 VAND. J. ENT. & TECH. L. 227, 275 (2013) [hereinafter "Livingston"].

regime.

A. Tests Undertaken by the Ninth Circuit: A Brief History

Methods used by the courts to analyse and decide cases of copyright infringement are different among different circuits.¹⁴ The Second Circuit, as provided in *Arnstein v. Porter*, follows a three- step requirement of; (a) proof of access, (b) substantial similarity, and (c) improper appropriation. It is essentially a two-part test where the plaintiff has to prove “copying” and “illicit copying”.¹⁵ However, the Ninth Circuit has taken a slightly different stance, since, to prove infringement, it requires; (a) valid copyright, (b) proof of access along with similarity, and (c) substantial similarity.¹⁶ One must prove that he has valid copyright on the work and that the other copied the protected elements of the copyright.¹⁷ The question as to whether the copying amounts to improper appropriation is not explicitly considered by the Ninth Circuit, but is implicit in the courts’ consideration of the similarities among the works.¹⁸

The extrinsic-intrinsic (two-prong-test) approach was pioneered in the Ninth Circuit¹⁹ and later adopted by the Fourth and the Eighth Circuits.²⁰ Until 1977, the Ninth Circuit essentially followed the ordinary observer test developed by the Second Circuit.²¹ In 1977, the case of *Sid & Marty Krofft Television Productions, Inc. v. McDonald's Corp.*, in the Ninth Circuit, developed the concept of the extrinsic and intrinsic test.²² It was decided that, in the first part, i.e. the extrinsic test, only the work’s ideas are compared. *Krofft*’s reasoning was questionable. Similarities in ideas are often found but are not a ground for infringement. *Krofft* largely eliminated the possibility of the case being won by a defendant on summary judgment grounds.²³ (See, **VI (B)**) *Krofft* created more problems than it solved, as it misread *Arnstein*’s two-part test as an idea-expression dichotomy.²⁴ Finally, in *Shaw v. Lindheim*,²⁵ the Ninth Circuit corrected itself²⁶ and held that the extrinsic test should be used to determine similarity of expressions. The extrinsic test and the intrinsic test are now more sensibly

¹⁴ Rogers, *supra* note 9.

¹⁵ See *Arnstein v. Porter*, 154 F.2d 464, 468 (2d Cir. 1946).

¹⁶ See Darian Hogan, *Stairway To Inverse Ratio Rule Abrogation*, The Biederman Blog (Mar. 16, 2020), <https://www.biedermanblog.com/stairway-to-inverse-ratio-rule-abrogation/>.

¹⁷ *Apple Computer, Inc. v. Microsoft Corp.*, 35 F.3d 1435, 1442 (9th Cir. 1994).

¹⁸ Aaron M. Broaddus, *Eliminating the Confusion: A Restatement of the Test for Copyright Infringement*, 5 DEPAUL-LCA J. ART & ENT. L. 43, 46 n.18 (1994-1995) [hereinafter “Broaddus”].

¹⁹ See *Sid & Marty Krofft Television Productions, Inc. v. McDonald's Corp.*, 562 F.2d 1157, 1164 (9th Cir. 1977).

²⁰ See *Towler v. Sayles*, 76 F.3d 579, 583–84 (4th Cir. 1996); see also *Hartman v. Hallmark Cards, Inc.*, 833 F.2d 117, 120 (8th Cir. 1987).

²¹ Rogers, *supra* note 9, at 907.

²² See *Sid & Marty Krofft Television Productions, Inc. v. McDonald's Corp.*, 562 F.2d 1157, 1164 (9th Cir. 1977).

²³ Broaddus, *supra* note 18, at 53.

²⁴ Montgomery Frankel, *From Krofft to Shaw, and Beyond - The Shifting Test for Copyright Infringement in the Ninth Circuit*, 40 COPYRIGHT L. SYMP. 429, 434 (1990-1991) [hereinafter “Frankel”].

²⁵ See *Shaw v. Lindheim*, 908 F.2d 531, 535 (9th Cir. 1990).

²⁶ Christopher Jon Springman & Samantha F. Hednik, *The Filtration Problem in Copyright's “Substantial Similarity” Infringement Test*, 23 LEWIS & CLARK L. REV. 571, 579 (2019) [hereinafter “Springman”].

termed as “objective test” and “subjective test”, respectively.²⁷ While in *Shaw* the use of the extrinsic test was limited to literary works, the case of *Brown Bag Software v. Symantec Corp.*²⁸ made it clear that the expansive reading of the extrinsic test was not limited to literary works.

B. Tests Undertaken by the Ninth Circuit in the Present

Initially, other circuits adopted the tests propounded in these two circuits (i.e., the Ninth and the Second Circuit), some with their own modifications.²⁹ It has been observed that the two circuits’ analyses have converged together in the present.³⁰ However, some differences do exist. Currently, the steps to establish infringement in the Ninth Circuit have been provided in the flowchart below:

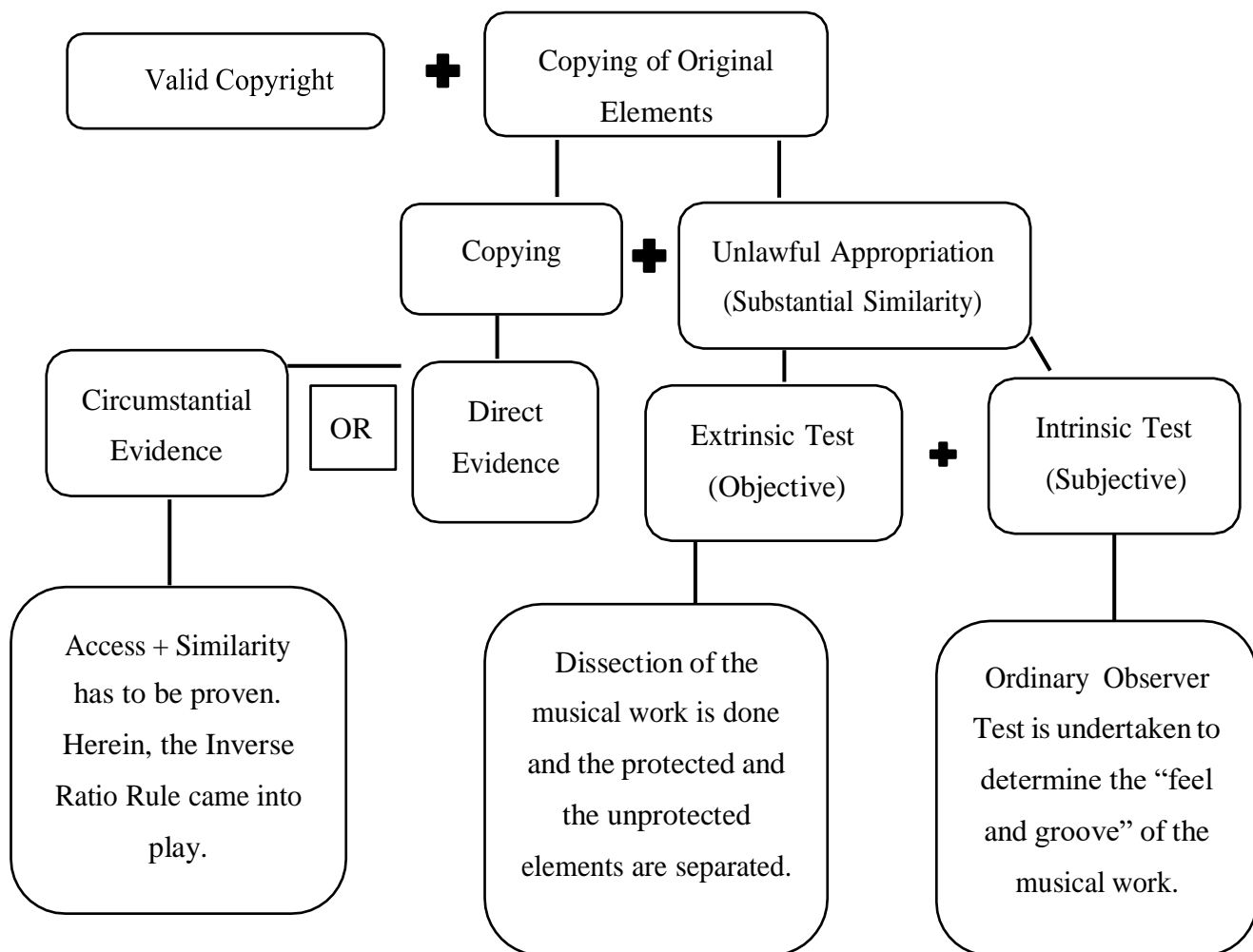


Figure-1: Tests Undertaken in the Ninth Circuit to Determine Infringement of Musical Copyright

While the Ninth Circuit has moved closer to the Second Circuit in its approach towards

²⁷ See *Antonick v. Elec. Arts, Inc.*, 841 F.3d 1062, 1066 (9th Cir. 2016).

²⁸ See *Brown Bag Software v. Symantec Corp.*, 960 F.2d 1465, 1476 (9th Cir. 1992).

²⁹ *Livingston*, *supra* note 13, at 262.

³⁰ See Jenny Small, *The Illusion of Copyright Infringement Protection*, 12 CHI-KENT J. INTELL. PROP. 217, 221-222 (2013).

infringement cases, especially with respect to the extrinsic test, there still exist loopholes in the approach taken by the Ninth Circuit.³¹

There is a large discussion on the usage of the words like “copying”, “similarity” and “substantial similarity”,³² which must be clarified before studying infringement analysis by the Ninth Circuit. The terms have a distinct meaning but have been used incorrectly in various judgments. Further, the procedure for determining substantial similarity is clouded.³³ This adds to the already existing problems in analysing infringement in musical compositions.³⁴

The Ninth Circuit considers a two-part extrinsic-intrinsic test in determining substantial similarity.³⁵ The Second Circuit has clarified that “probative similarity” is a threshold matter in showing “copying”, while “substantial similarity” is a comprehensive test to determine “actionable copying”.³⁶ While the Ninth Circuit has also recently accepted such differentiation,³⁷ it is important to note that, historically the term “substantial similarity” has been used in literature and numerous cases,³⁸ while dealing with “copying”, which is incorrect. Therefore, for the purpose of clarity, while dealing with “copying” or the “inverse ratio rule”, (even for the purpose of this article) one must remember that it deals with “probative similarity”, even though other terms might have been used. Courts in the US have used the terms “probative similarity”, “striking similarity” and “substantial similarity”, which are not on a sliding scale. The terms “probative similarity” and “striking similarity”, are analytical tools to determine factual copying while the term “substantial similarity” is used to determine if the factual copying is legally actionable i.e., if the protected elements of a song have been infringed. Therefore, while dealing with “copying”, factual copying is established and while dealing with “substantial similarity”, actionable copying is established. (See further, the case of *Skidmore v. Led Zeppelin* at III, which has clarified the confusion.)

II. DIRECT AND CIRCUMSTANTIAL EVIDENCE

Earlier, Courts recognised the importance of the two elements i.e., access,³⁹ and similarity.⁴⁰ It also

³¹ *Id.* at 261.

³² See Broaddus, *supra* note 18, at 46-52.

³³ Joshua M. Dalton & Sara Cable, *The Copyright Defendant's Guide to Disproving Substantial Similarity on Summary Judgment*, 3 LANDSLIDE 26, 26 (2011) [hereinafter “Dalton”].

³⁴ See Jamie Lund, *An Empirical Examination of the Lay Listener Test in Music Composition Copyright Infringement*, 11 VA.SPORTS & ENT. L.J. 137, 175 (2011) [hereinafter “Lund”].

³⁵ *Smith v. Jackson*, 84 F.3d 1213, 1218 (9th Cir. 1996).

³⁶ Sergiu Gherman, *Harmony and Its Functionality: A Gloss on the Substantial Similarity Test in Music Copyrights*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 483, 488 (2009) [hereinafter “Gherman”].

³⁷ See *Skidmore v. Led Zeppelin*, 952 F.3d 1051, 1064 (9th Cir. 2020).

³⁸ See *Three Boys Music Corp. v. Bolton*, 212 F.3d 477, 486 (9th Cir. 2000).

³⁹ See *Arnstein v. Edward B. Marks Music Corp.*, 82 F.2d 275, 275-76 (2d Cir. 1936); see also *Wilkie v. Santly Bros.*, 13F. Supp. 136, 136 (S.D.N.Y. 1935).

⁴⁰ See *Fred Fisher v. Dillingham*, 298 F. 145, 147 (S.D.N.Y. 1924); see also *Haas v. Leo Fiest*, 234 F. 105, 107 (S.D.N.Y. 1916); see also *Boosey v. Empire Music*, 224 F. 646, 647 (S.D.N.Y. 1915); *Hein v. Harris*, 175 F. 875, 877 (C.C.N.Y. 1910).

recognised that direct evidence of copying is rarely available.⁴¹ Since actual copying is rarely, if ever, witnessed,⁴² circumstantial evidence is sought to prove copying, which entails plaintiffs showing that the defendant had access to their works.⁴³ Then, plaintiffs establish that there is probative similarity⁴⁴ (as observed by the Fifth Circuit) which means, defendant's work contains similarity with the plaintiff's work, which can only be a result of copying and not a result of the use of public domain materials or coincidence.⁴⁵ In the Ninth Circuit as well, the plaintiffs are required to prove similarity between the works probative of copying, in addition to proving access, in absence of direct evidence.⁴⁶ However, the Circuit used to require a lower standard of proof of similarity if high access is shown (inverse ratio rule) while determining similarity.⁴⁷ The rule was rightly abrogated by the Ninth Circuit in 2020. (See, **III**)

A. Access

Courts have used the "chain of events theory", the "wide-dissemination theory" and the theory of "striking similarity" to establish access.⁴⁸ These theories have been acknowledged by the Ninth Circuit as well.⁴⁹ Under the chain of events theory, the plaintiff is required to prove that the musical copy had passed through one or more hands and had reached the defendant.⁵⁰ Courts have even found the possibility of access of the plaintiff's work based on the fact that the plaintiff, the defendant, and the producer "[ran] in the same musical circles".⁵¹ In the modern world, such a judgment can have a negative impact, as a single producer can be involved in the production of multiple musical works.

Additionally, access has been construed where there was wide dissemination of work,⁵² and objective factors like record sales and radio performances have also been looked upon to prove access.⁵³ Similarly, the number of plays on MySpace and YouTube have also been considered.⁵⁴ However, with the emergence of music streaming apps and websites, it has been questioned if it is

⁴¹ *JCW Invs., Inc. v. Novelty, Inc.*, 482 F.3d 910, 915 (7th Cir. 2007); *Smith v. Jackson*, 84 F.3d 1213, 1218 (9th Cir. 1996); *Lipton v. Nature Co.*, 71 F.3d 464, 471 (2d Cir. 1995).

⁴² *Roth Greeting Cards v. United Card Co.*, 429 F.2d 1106, 1110 (9th Cir. 1970).

⁴³ Sarah Burstein, *Not (Necessarily) Narrower: Rethinking the Relative Scope of Copyright Protection for Designs*, 3 IP THEORY 114, 119 (2013) [hereinafter "Burstein"].

⁴⁴ See *Armour v. Knowles*, 512 F.3d 147, 152 (5th Cir. 2007).

⁴⁵ See Alan Latman, *Probative Similarity as Proof of Copying: Toward Dispelling Some Myths in Copyright Infringement*, 90 COLUM. L. REV. 1187, 1204 (1990).

⁴⁶ See *Rentmeester v. Nike, Inc.*, 883 F.3d 1111, 1117 (9th Cir. 2018).

⁴⁷ *Sid & Marty Krofft Television Productions, Inc. v. McDonald's Corp.*, 562 F.2d 1157, 1172 (9th Cir. 1977).

⁴⁸ See *Selle v. Gibb*, 741 F.2d 896, 901 (7th Cir. 1984); see also *Peters v. West*, 776 F. Supp. 2d 742, 748 (N.D. Ill. 2011); see also Alyssa Chavers, *Williams v. Gaye: Further Blurring the Lines between Inspiration and Infringement*, 50 GOLDEN GATE U. L. REV. 3, 14 (2020) [hereinafter "Chavers"].

⁴⁹ See *Three Boys Music Corp. v. Bolton*, 212 F.3d 477, 482-485 (9th Cir. 2000).

⁵⁰ See *id.* at 482; see also *Gaste v. Kaiserman*, 863 F.2d 1061, 1067 (2d Cir. 1988).

⁵¹ *Straughter v. Raymond*, CV 08-2170 CAS (CWx), 19 (C.D. Cal. Aug. 19, 2011).

⁵² See *L.A. Printex Indus. Inc. v. Aeropostale, Inc.* 676 F.3d 841, 846-47 (9th Cir. 2012).

⁵³ *Three Boys Music Corp. v. Bolton*, 212 F.3d 477, 482 (9th Cir. 2000).

⁵⁴ *Gray v. Perry*, No. 2:15-cv-05642-CAS(JCx), 2019 WL 2992007, 13-15 (C.D. Cal. 2019).

reasonable to assume access to such a large quantity of videos that are present in such platforms, even if their views are taken into consideration.⁵⁵ Logically, the answer should be negative.

Where a work is widely disseminated (for example, where the original work's DVD had earned \$7,000,000 in the first two years since its release), its access by the defendant has been presumed.⁵⁶ In the case of *Rice v. Fox Broadcasting*, it was decided that since only 17,000 copies had been sold from 1986 to 1999, it could not be considered as widely disseminated.⁵⁷ In the internet world, it can be observed that if the musical work has an online presence and ease of access, access must be presumed. In this regard, it has been suggested that the defendants can rebut by showing improbability of access.⁵⁸ However, such a shift in the burden on the defendant further helps the plaintiff and can give rise to frivolous cases. Failure to evolve infringement standards with evolving technology poses a great risk.⁵⁹ Further, such finding of access based on wide dissemination is often accompanied by the issue of sub-conscious copying,⁶⁰ which adds to the problem. (See **VI (C)**)

It can be seen that popularity and wide distribution of work are elements that can result in an infringement being established easily.⁶¹ The alleged infringer is also presumed to have access if the songs are so similar that the alleged copied work replaces the need for the original in the marketplace.⁶² However, as observed in the Second and the Fifth Circuit, mere speculation or conjecture would not amount to access.⁶³ Access must be proved with significant, affirmative and probative evidence.⁶⁴ However, in the Ninth Circuit, the requirement is that there must be a reasonable opportunity of viewing the plaintiff's work by the defendant, not just a bare possibility.⁶⁵ It has been observed that, while previously, access was mostly a defence available to the defendant, the access requirement has become a plaintiff's tool in the modern world.⁶⁶ Therefore, there is a need to create a balance in the test to find access, by considering the aspects that direct evidence is rarely available as well as that dissemination is easily possible in the modern world.

B. Inverse Ratio Rule

The inverse ratio rule is a common law doctrine that was used by many courts in infringement

⁵⁵ See Jeanne C. Fromer, *The New Copyright Opportunist*, 67 J. COPYRIGHT SOC'Y U.S.A. 1, 12 (2020).

⁵⁶ *Capcom Co. v. MKR Group, Inc.*, No. C 08-0904 RS, 2 (N.D. Cal. 2008).

⁵⁷ *Rice v. Fox Broadcasting*, 330 F.3d 1170, 1178 (9th Cir. 2003).

⁵⁸ Livingston, *supra* note 13, at 291.

⁵⁹ *Metro-Goldwyn-Meyer Studios, Inc. v. Gorkster, LTD.* - Brief of Professors Peter S. Menell, David Nimmer, Robert P. Merges, and Justin Hughes, as Amici Curiae in Support of Petitioners, 20 BERKELEY TECH. L.J. 511, 514 (2005).

⁶⁰ *Three Boys Music Corp. v. Bolton*, 212 F.3d 477, 482 (9th Cir. 2000).

⁶¹ See *ABKCO Music, Inc. v. Harrisongs Music, Ltd.*, 722 F.2d 988, 998 (2d Cir. 1983); see also *L.A. Printex Indus. Inc. v. Aeropostale, Inc.* 676 F.3d 841, 846-47 (9th Cir. 2012).

⁶² See *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 587-88 (1994).

⁶³ *Armour v. Knowles*, 512 F.3d 147, 153 (5th Cir. 2007); *Intersong-USA v. CBS*, 757 F. Supp. 274, 281 (S.D.N.Y. 1991).

⁶⁴ *Intersong-USA v. CBS*, 757 F. Supp. 274, 281 (S.D.N.Y. 1991).

⁶⁵ *Three Boys Music Corp. v. Bolton*, 212 F.3d 477, 482 (9th Cir. 2000).

⁶⁶ Karen Beville, *Copyright Infringement and Access: Has the Access Requirement Lost Its Probative Value*, 52 RUTGERS L. REV. 311, 331 (1999).

analysis.⁶⁷ The rule is that, for strong proof of access, weak proof of similarity is enough to prove copying.⁶⁸ Nimmer asserts that “*since a very high degree of similarity is required in order to dispense with proof of access, it must logically follow that where proof of access is offered, the required degree of similarity may be somewhat less than would be necessary in the absence of such proof.*”⁶⁹ However, the Ninth Circuit finally did away with the rule in 2020, in the case of *Skidmore v. Led Zeppelin*⁷⁰ (See, III). This highly controversial rule severely impacted the copyright regime, especially with respect to musical works in today’s world. The Ninth Circuit has historically used the inverse ratio rule in infringement cases.⁷¹ Currently, it is only in the Sixth Circuit that the rule remains as a valid law.⁷²

1. Access does not imply Similarity

A wide distribution of the work often allows inferring of access.⁷³ To prove access, the plaintiff only has to prove that the defendant had an opportunity to view the work. The plaintiff is not required to prove that the defendant actually viewed his or her work. Again, access may be inferred in cases of striking similarity among the two works.⁷⁴ Therefore, the requirement to prove access has been made easy, especially due to wide dissemination of work through the internet, thus correctly contradicting what Nimmer had stated. Further, access to musical work is not the same as access to other artistic expressions as many of the fundamental concepts of music are accessible to anyone. Based on this argument, it was suggested that the inverse ratio rule needs revision.⁷⁵

While the concept of inverse ratio has been supported in principle (and also by some courts),⁷⁶ in practice, it has been unsound. According to Justice Clark in the case of *Music Corp. v. Lee*,⁷⁷ “*the logical outcome of the claimed principle is obviously that proof of actual access will render a showing of similarities entirely unnecessary.*” Furthermore, he stated the rule to be “*a superficially attractive apophthegm which upon examination confuses more than it clarifies*”. The Second Circuit further referred to the rule as an “*ingeniously fabricated principle of law*”.⁷⁸

⁶⁷ Steven Shonack, *Postmodern Piracy: How Copyright Law Constrains Contemporary Art*, 14 Loy LA Ent. L.J. 281, 313 n.256 (1994) [hereinafter “Shonack”].

⁶⁸ See *Three Boys Music Corp. v. Bolton*, 212 F.3d 477, 486 (9th Cir. 2000).

⁶⁹ *Sid & Marty Krofft Television Productions, Inc. v. McDonald’s Corp.*, 562 F.2d 1157, 1172 (9th Cir. 1977).

⁷⁰ *Skidmore v. Led Zeppelin*, 952 F.3d 1051 (9th Cir. 2020).

⁷¹ See *Three Boys Music Corp. v. Bolton*, 212 F.3d 477, 485 (9th Cir. 2000); see also *Shaw v. Lindheim*, 919 F.2d 1353, 1361-62 (9th Cir. 1990); see also *Sid & Marty Krofft Television Productions, Inc. v. McDonald’s Corp.*, 562 F.2d 1157, 1172 (9th Cir. 1977).

⁷² See David A. Steinberg & James Berkley, *Appeals Court Rules In Favor Of Zeppelin*, 10 NAT’L L. REV. 71 (2020).

⁷³ *Selle v. Gibb*, 741 F.2d 896, 901 (7th Cir. 1984).

⁷⁴ Broaddus, *supra* note 18, at 47.

⁷⁵ Nicholas Booth, *Backing down: Blurred Lines in the Standards for Analysis of Substantial Similarity in Copyright Infringement for Musical Works*, 24 J. INTELL. PROP. L. 99, 127 (2016).

⁷⁶ See *Sid & Marty Krofft Television Productions, Inc. v. McDonald’s Corp.*, 562 F.2d 1157, 1172 (9th Cir. 1977); see also *Teinberg v. Columbia Pictures Indus., Inc.* 663 F. Supp. 706, 714 (S.D.N.Y. 1987).

⁷⁷ *Music Corp. v. Lee*, 296 F.2d 186, 187 (2d Cir. 1961).

⁷⁸ *Id.* at 187.

If there is no similarity, no amount of evidence of access will prove copying.⁷⁹ If due to a high level of access, a lower level of similarity suffices to establish infringement, it can lead to improper infringements based on similarity of ideas or unoriginal expressions.⁸⁰ Regardless of the quantum of proof of access, the requirement to show similarity is a matter of threshold.⁸¹ The requirement to show similarities does not vary as proof of access increases or decreases. No amount to access amounts to copying where the works are devoid of similarity.⁸² However, the inverse ratio rule accepted a lower degree of similarity if there was evidence of a high amount of access.⁸³ Therefore, the inverse ratio rule, which suggests a decrease in requirement to prove similarity is flawed.⁸⁴

2. Plaintiff Centric Rule

The inverse ratio rule significantly impaired a defendant's case and has been said to be logically infirm.⁸⁵ This rule made it easier for the plaintiff-owner, whose copyright is well-known and successful, to prove copying on the part of the defendant.⁸⁶ In the case of *Three Boys Music Corp v. Bolton*,⁸⁷ the court found similarity between the works despite the claims that the defendant's song contained a mere similar combination of unprotected elements.⁸⁸ The court further stated that "we have never held, however, that the inverse ratio rule says a weak showing of access requires a stronger showing of substantial similarity."⁸⁹ Therefore, according to the case, if there is a weak showing of access, it is not required for the plaintiff to prove a stronger similarity. However, in the case of the presence of high proof of access, low proof of similarity suffices to prove copying. This further puts a light on the plaintiff-centric nature of the rule.

In *Metcalf v. Bochco*, it was observed that the defendant had seen the work more than once, and thus, the case largely favoured the plaintiff, although not expressly dealing with the rule.⁹⁰ In an increasingly small world, the inverse ratio rule becomes largely misleading, often inapplicable and, in some cases, useless.⁹¹ The rule led to infringement being established even in a minimal degree of similarity. The rule must not be applied to reduce the burden of proof on the plaintiff. Rather the

⁷⁹ Jones v. Supreme Music Corp., 101 F. Supp. 989, 990 (S.D.N.Y. 1951).

⁸⁰ David Aronoff, *Exploding the Inverse Ratio Rule*, 55 J. COPYRIGHT SOC'Y USA 125, 126 (2008) [hereinafter "Aronoff"].

⁸¹ Gherman, *supra* note 36.

⁸² Arnstein v. Porter, 154 F.2d 464, 468 (2d Cir. 1946).

⁸³ Rice v. Fox Broadcasting, 330 F.3d 1170, 1178 (9th Cir. 2003).

⁸⁴ See Broaddus, *supra* note 18, at 48-49.

⁸⁵ Dalton, *supra* note 33, at 31.

⁸⁶ See Burstein, *supra* note 43, at 122.

⁸⁷ See *Three Boys Music Corp. v. Bolton*, 212 F.3d 477, 486 (9th Cir. 2000).

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ See *Metcalf v. Bochco*, 294 F.3d 1069, 1075 (9th Cir. 2002).

⁹¹ See Karlyn Ruth Meyer, *Doctrine of the Dead: How Capcom v. MKR Exposes the Decreasing Fit between Modern Copyright Infringement Analysis and Modern Video Games*, 9 CHI-KENT J. INTEL. PROP. 132, 141 (2010).

plaintiff must provide independent proof to establish similarity.⁹²

The case of *Williams v. Gaye*⁹³ (See, **VI (G) (2)**) caused an uproar as it disproportionately favoured Gaye, whose work was said to have been infringed. However, in this case, in the first opinion published by the court on March 21, 2018, it was stated that the court was “*bound to apply [the inverse ratio rule]*” but, in a modified opinion published on July 11, 2018, all the discussions on the inverse ratio rules were gone.⁹⁴ Therefore, while the Ninth Circuit in this case (i.e. before the case of *Skidmore v. Led Zeppelin*) did not highlight any weakness, it certainly implied that an infringement case can be settled without the application of the rule.⁹⁵ While the court did favour Gaye, its silence on its second opinion is of significance.

3. Additional Shortcomings of the Rule

The majority have taken a contrary position to the inverse ratio rule.⁹⁶ The rule is deleterious and lacks any analytical benefit.⁹⁷ Further, it has been pertinently asked, with respect to the nomenclature of the rule that, “*if the rule is genuinely a ratio, what quantum of additional strong access excuses what measure of weak similarity? Does 15% greater access excuse 15% less similarity?*”⁹⁸

The rule entails an inherent bias against commercial use.⁹⁹ While the economic objective of copyright law does secure payment to the author, another reason for the existence of copyright law is to motivate creativity.¹⁰⁰ The inverse ratio rule instead discourages creativity. Because of the vague nature of the rule,¹⁰¹ it incurred a significant risk when litigating similarity and access issues.¹⁰² The problem starts with proving access itself. While access should be denied if the proof is too far-fetched,¹⁰³ courts have had trouble establishing a minimum threshold to establish access.¹⁰⁴ Proving the defendant’s access to the plaintiff’s work is a requirement,¹⁰⁵ but the inverse ratio rule that is applied along with this requirement has been unreasonable. Therefore, its abrogation has been a welcomed step.

⁹² Jamie Busching, *Shaw v. Lindheim: The Ninth Circuit's Attempt to Equalize the Odds in Copyright Infringement*, 11 LOY. ENT. L.J. 67, 85 (1991).

⁹³ *Williams v. Gaye*, 885 F.3d 1150 (9th Cir. 2018).

⁹⁴ Chavers, *supra* note 48, at 8-10.

⁹⁵ *See id.* at 20.

⁹⁶ James S. Altman, *Copyright Protection of Computer Software*, 5 COMPUTER/L.J. 413, 420 n.42 (1985).

⁹⁷ Aronoff, *supra* note 80, at 143.

⁹⁸ *Id.* at 140.

⁹⁹ Shonack, *supra* note 67, at 313.

¹⁰⁰ *Fogerty v. Fantasy, Inc.*, 510 U.S. 517, 526-527 (1994).

¹⁰¹ Robert S. Gawthrop III, *An Inquiry into Criminal Copyright Infringement*, 20 COPYRIGHT L. SYMP. 154, 162 (1970).

¹⁰² Stephen P. Anway, *Mediation in Copyright Disputes: From Compromise Created Incentives to Incentive Created Compromises*, 18 OHIO ST. J. DISP. RESOL. 439, 449 n.57 (2003) [hereinafter “Anway”].

¹⁰³ *See Selle v. Gibb*, 741 F.2d 896, 905 (7th Cir. 1984).

¹⁰⁴ Michael Landau & Donald E Biederman, *The Case for a Specialized Copyright Court: Eliminating the Jurisdictional Advantage*, 21 HASTINGS COMM. & ENT. L.J. 717, 726-727 (1998) [hereinafter “Landau and Biederman”].

¹⁰⁵ *See Rice v. Fox Broadcasting*, 330 F.3d 1170, 1178 (9th Cir. 2003).

III. CLARIFICATIONS PROVIDED BY SKIDMORE V. LED ZEPPELIN

In 2014, Micheal Skidmore, as a trustee for the estate of Randy Craig Wolfe, filed an action against Led Zeppelin's famous song "Stairway to Heaven" alleging that the opening notes¹⁰⁶ were copied from Spirit's song named "Taurus".¹⁰⁷ In this case, the requirements for infringement were finally clarified by the Ninth Circuit and the circuit joined the majority of other circuits by abrogating the controversial inverse ratio rule.¹⁰⁸

Wolfe was a guitarist, a singer, and a songwriter to the band Spirit and wrote the song "Taurus" in 1967. In this case, there was evidence that the band Led Zeppelin had performed on the same day, in the same festival in which Spirit had also played, in at least three separate instances. Further, the band Led Zeppelin had also performed a cover version of one of the Spirit's songs titled "Fresh Garbage".¹⁰⁹ However, there was no evidence that any members of Led Zeppelin had ever heard "Taurus" prior to the release of their hit song "Stairway to Heaven". The case was brought forty-three years after the release of the song "Stairway to Heaven" and nearly two decades after the passing away of Wolfe.¹¹⁰

The trial court ruled that the Copyright Act of 1909 was applicable rather than the 1976 Act since the songs were released prior to the 1976 Act. Since the Act of 1909 protects musical compositions in the form of sheet music and such protection is not provided to sound recordings, only the sheet music was used to enquire on substantial similarity. Further, the trial court did not provide the jury with inverse ratio rule instructions. The jury returned a verdict in favour of Led Zeppelin as it was found that there was no substantial similarity despite Led Zeppelin having access to the song "Taurus".¹¹¹ Skidmore appealed and challenged the trial court's decision to deny providing the jury with inverse ratio rule instruction. Eventually, the court again reinstated the trial court's ruling.¹¹²

In the appeal, the court analysed the test for copyright infringement. A plaintiff must prove ownership of copyright and that the defendant has copied protected aspects of the copyrighted work.¹¹³ So as to prove copying of protected aspects, a plaintiff must prove both "actual copying" and "unlawful appropriation". The court further clarified that these tests are

¹⁰⁶ Sean O'Connor, *Why Stairway to Heaven Doesn't Infringe Taurus Copyright: Analysis & Demo of "Scène à faire" Motif Common to Both*, SpicyIP (June 19, 2016), <https://spicyip.com/2016/06/why-stairway-to-heaven-doesnt-infringe-taurus-copyright-analysis-demo-of-scenes-a-faire-motif-common-to-both.html>.

¹⁰⁷ Skidmore v. Led Zeppelin, 952 F.3d 1051, 1057 (9th Cir. 2020).

¹⁰⁸ Alexander R. Wolfe, *Skidmore v. Led Zeppelin: Changing Music Infringement Analysis in the Ninth Circuit*, 23 U. DENV. SPORTS & ENT. L.J. 1, 1 (2020).

¹⁰⁹ Skidmore v. Led Zeppelin, 952 F.3d 1051, 1057 (9th Cir. 2020).

¹¹⁰ Joseph A. Greene, *Skidmore v. Led Zeppelin: Extraordinary Circumstances and Perpetual Statute of Limitations in Copyright Infringement*, 69 ME. L. REV. 307, 311-316 (2017).

¹¹¹ See Skidmore v. Led Zeppelin, 952 F.3d 1051, 1059 (9th Cir. 2020).

¹¹² *Id.* at 1060.

¹¹³ *Id.* at 1064.

independent despite incorrectly and collectively, being referred to as “substantial similarity test”.¹¹⁴ The court provided that actual copying can be proven by circumstantial evidence of access and by establishing that the works share similarities probative of copying.

The second requirement of unlawful appropriation can be proven by showing that the protected elements of the work share “substantial similarity”.¹¹⁵ Now, the extrinsic-intrinsic test is undertaken to prove substantial similarity. The extrinsic test looks at what is protectable and what is not in the copyrighted work. Further, the test compares similarities of “specific expressive elements in the two works.”¹¹⁶ The intrinsic test looks at similarities between the works from the view of an “ordinary reasonable observer”. Finally, if all these requirements are fulfilled, it amounts to infringement. (See, **Figure-1**)

The court noted the inverse ratio rule, which requires a “*lower standard of proof of substantial similarity when a high degree of access is shown*”.¹¹⁷ The trial court had denied Skidmore’s proposal for an application of the controversial rule. Upon appeal, it was decided that the rule is a judge-made law and is “*not part of the copyright statute, defies logic, and creates uncertainty for the courts and the parties.*” The court cited the confusion created by previous cases as to which part of the test — copying or unlawful appropriation — the rule was applied upon.¹¹⁸ Further, the rule was subjective and did not provide what amount of access and similarity is needed to invoke the rule.¹¹⁹ It decided that the rule disproportionately favoured popular works which have been widely disseminated through the internet and the media. The court stated that “*the constellation of problems and inconsistencies in the application of the inverse ratio rule prompts us to abrogate the rule.*”¹²⁰

Upon appeal, three jury instructions were in issue; (a) failure to give an inverse ratio rule instruction, (b) insufficiency of the court’s originality instructions and, (c) failure to give selection and arrangement instruction.¹²¹ (Jury instructions have been further discussed below, see **VI (A)**) Jury instruction no. 16 highlighted the essence of the “common musical elements”. The instruction was found to have correctly listed the unprotectable elements.¹²² Jury instruction no. 20 correctly highlighted that original expressions can be a result of borrowing from previous works or from the public domain since it is well accepted that the “original” parts of the work need not be new

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.* at 1066.

¹¹⁸ *Id.*

¹¹⁹ *Id.* at 1067.

¹²⁰ *Id.* at 1069.

¹²¹ *Id.* at 1065.

¹²² *Id.* at 1070.

or novel.¹²³ However, it was also found that while the jury instructions provided were correct statements, they were misleading when it came to instructions for differentiation of protectable and unprotectable elements of the works (See **VI (C-F)**), as it omitted the principle that combinations of unprotected elements can be protected.¹²⁴ Judge Ikuta and Judge Bae, concurring in part and dissenting in part, stated that such originality instruction, coupled with failure to instruct the jury on selection and arrangement, amounted to a miscarriage of justice.¹²⁵ This highlights the importance of jury instructions in differentiating protectable and unprotectable elements of musical works.

The judgment abrogated the controversial inverse ratio rule and provided clarifications to remove confusion with regard to the tests undertaken. However, the journey is only halfway done. Inherent problems lie in the tests undertaken by Ninth Circuit itself which should be corrected.

IV. EXTRINSIC TEST (OBJECTIVE TEST)

The “extrinsic test” relies on expert analysis to determine substantial similarity, unlike the “intrinsic test” where substantial similarity is determined based on the reactions of a “reasonable audience” for whom the works would normally be directed.¹²⁶ It is seen that only the extrinsic test deals with the matter of law.¹²⁷ Under the extrinsic test, the works are dissected into their elements for the determination of protected elements and their comparison. The “extrinsic test” relies on expert analysis to determine substantial similarity, unlike the “intrinsic test” where substantial similarity is determined based on the reactions of a “reasonable audience” for whom the works would normally be directed.

A. Dissection

Plaintiffs must prove that the defendants copied the protected elements of the copyrighted work.¹²⁸ Here, courts would determine the protected subject matter by dissecting melody, rhythm, and accompaniment of the musical works. For instance, Judge Learned Hand conducted an analytical dissection of musical works with an almost note-by-note comparison of the two songs in dispute.¹²⁹ The Ninth Circuit provided criteria like plot, theme, dialogue, mood, setting, pace,

¹²³ *Id.* at 1071.

¹²⁴ Elizabeth Sawyer, *Dazed and Confused: Copyright Limitation*, 29 DEPAUL J. ART, TECH. & INTELL. PROP. L. 93, 107 (2019); *Id.* at 1085.

¹²⁵ *Intellectual Property - Copyright in Musical Compositions - Ninth Circuit Confines the Scope of Copyright in Compositions under the 1909 Act to the Deposit Copy. - Skidmore v. Led Zeppelin*, 952 F.3d 1051 (9th Cir. 2020), 134 Harv. L. Rev. 1543, 1547 (2021).

¹²⁶ See *Sid & Marty Krofft Television Productions, Inc. v. McDonald's Corp.*, 562 F.2d 1157, 1164-1166 (9th Cir. 1977).

¹²⁷ *Rentmeester v. Nike, Inc.*, 883 F.3d 1111, 1118 (9th Cir. 2018).

¹²⁸ Emily Miao & Nicole E. Grimm, *The Blurred Lines of What Constitutes Copyright Infringement of Music: Robin Thicke v. Marvin Gaye's Estate*, 20 WESTLAW J. INTELL. PROP. 1, 3-4 (2013).

¹²⁹ See *Arnstein v. Edward B. Marks Music Corp.*, 82 F.2d 275, 277 (2d Cir. 1936); see also *Fred Fisher, Inc. v. Dillingham*,

sequence of events, and characters for the extrinsic test with regards to literary works.¹³⁰ However, it has failed to provide such elements for musical compositions,¹³¹ which has made the extrinsic test face a difficult application in the courts, even if expert assistance is used.

B. Experts

Similarity is generally established through expert opinion after dissection of the disputed works. While some courts have recognised the need for experts, some courts (in some cases) had discounted them.¹³² Courts have in the late nineteenth and early twentieth century, relied on their own musical knowledge¹³³ and did not use expert testimony, and thus the juries seemed absent.¹³⁴ In the case of musical works, experts have gotten greater importance since the technical aspects that musical works have, are unfamiliar to the judge and the jury.¹³⁵ Courts, very early on, had addressed the need for expert opinion in cases of disputes regarding musical works.¹³⁶ However, it can be seen that before such a need was realised, judges took an egoistic step and relied upon their own musical knowledge to analyse the works.¹³⁷ Nevertheless, in the present, the requirement of an expert for the purpose of dissection of work, cannot be denied.

An expert can dissect musical works into its melody, harmony, rhythm, texture, and formal structure for comparison between the works.¹³⁸ However, even if there are several elements to musical construction, it is seen that similarities in melody have been the most probative of copying.¹³⁹ Further, while musicologists might have the required knowledge and database for search before composing a musical work, others do not. Therefore, the musicologists can sometimes establish similarities, despite the authors not being aware of it.¹⁴⁰ Additionally, there exists a problem of hyper-dissection wherein “overlooking the forest for the trees” takes place.¹⁴¹ Such issues must be made aware to the experts.

Further, the very nature of popular music is the reason why many works share common elements. Musicians work within a limited boundary of musical elements to make a popular

298 F. 145, 148-150 (S.D.N.Y. 1924); *see also* *Hein v. Harris*, 175 F. 875, 876 (C.C.S.D.N.Y. 1910).

¹³⁰ *Shaw v. Lindheim*, 919 F.2d 1353, 1356-57 (9th Cir. 1990); *Litchfield v. Spielberg*, 736 F.2d 1352, 1356 (9th Cir. 1984).

¹³¹ *Swirsky v. Carey*, 376 F.3d 841, 849 (9th Cir. 2004).

¹³² *See Overman v. Loesser*, 205 F.2d 521, 524 (9th Cir. 1953); *see also* *Supreme Records, Inc. v. Decca Records, Inc.*, 90 F. Supp. 904, 912 (S.D. Cal. 1950).

¹³³ *See Haas v. Leo Feist, Inc.*, 234 F. 105, 107 (S.D.N.Y. 1916); *see also* *Boosey v. Empire Music Co.*, 224 F. 646, 647 (S.D.N.Y. 1915).

¹³⁴ *Livingston*, *supra* note 13, at 256.

¹³⁵ *Id.* at 239.

¹³⁶ *See Marks v. Leo Feist, Inc.*, 290 F. 959, 960 (2d Cir. 1923).

¹³⁷ *See Livingston*, *supra* note 13, at 271.

¹³⁸ *See M. Fletcher Reynolds, Selle v. Gibb and the Forensic Analysis of Plagiarism*, 32 C. MUSIC SYMP. 55 (1992).

¹³⁹ *See Johnson v. Gordon*, 409 F.3d 12, 21 (1st Cir. 2005); *see also* *Swirsky v. Carey*, 376 F.3d 841, 846-847 (9th Cir. 2004); *see also* *Calhoun v. Lillenas Publ'g*, 298 F.3d 1228, 1232-1233 (11th Cir. 2002).

¹⁴⁰ *See Landau and Biederman*, *supra* note 104, at 734.

¹⁴¹ *Johnson v. Gordon*, 409 F.3d 12, 25 (1st Cir. 2005).

musical composition, as there are limited patterns of such musical elements that the consumers prefer (See, **VI (D)** and **VI (E)**). The requirement of familiar chord progression and lyrical themes are some of the reasons for common elements in music. Therefore, the experts should establish which elements used in the work of the plaintiff cannot be protected, taking these limitations into account. The music experts can analyse both the works and provide an opinion as to whether the patterns of notes and chords in the work are likely works of independent creation, works created from common public domain sources, or works created by copying the work of the plaintiff.¹⁴² The experts can dissect the musical compositions and analyse if there is any similarity among the elements of melody, harmony, rhythm, etc. Further, they should also be able to look into the historical context and describe the music's public domain antecedents.¹⁴³ Since musical works are largely based on the historical development and prior arts in the field, the greater the knowledge and understanding that one has, the greater the perception of what is original and what is not.¹⁴⁴

It is also important to note that while expert evaluation is important, experts have reached faulty conclusions.¹⁴⁵ Experts often aggregate their objective findings to come to a subjective conclusion. Thus, while hyper-dissection should be prevented, an expert must also not cross the boundary of the extrinsic test to analyse the “total concept and feel” of the work, which is a part of the intrinsic analysis.¹⁴⁶

Additionally, courts have also been of the opinion that a party can buy an expert opinion. Therefore, a doubtful functioning of experts can be seen.¹⁴⁷ Further, a musicologist, while may understand and analyse the composition based on music theory, might lack an understanding of the particular nuances of a genre.¹⁴⁸ Therefore, it is of the utmost importance to assure the independence of the experts and that the experts' expertise aligns with the subject matter (genre) of the work, while also making them aware of the boundaries of the extrinsic test. Such expert opinion should be given importance in infringement analyses, even during the intrinsic test. (See, **V (A) (2)**)

V. INTRINSIC TEST (SUBJECTIVE TEST)

¹⁴² See *Repp v. Webber*, 132 F.3d 882, 886-87 (2d Cir. 1997); see also *Straughter v. Raymond*, CV 08-2170 CAS (CWx) 23, (C.D. Cal. Aug. 19, 2011).

¹⁴³ *Livingston*, *supra* note 13, at 271.

¹⁴⁴ *Id.* at 241.

¹⁴⁵ See *id.* at 279.

¹⁴⁶ See *Shaw v. Lindheim*, 919 F.2d 1353, 1356 (9th Cir. 1990).

¹⁴⁷ See *Baron v. Leo Feist, Inc.*, 78 F. Supp. 686, 686-87 (S.D.N.Y. 1948); *Livingston*, *supra* note 13, at 273.

¹⁴⁸ See Yvette Joy Liebesman, *Using Innovative Technologies to Analyze for Similarity Between Musical Works in Copyright Infringement Disputes*, 35 AIPLA Q.J. 331, 345 (2007) [hereinafter “Liebesman”].

Both the intrinsic and the extrinsic tests need to be fulfilled to establish substantial similarity.¹⁴⁹ The subjective intrinsic test is necessary because it helps in determining “*whether the ordinary, reasonable person would find the total concept and feel of the works to be substantially similar.*”¹⁵⁰ Herein, it is seen if there are similarities in the “total concept and feel” of the works.¹⁵¹ Accordingly, an analytical dissection and expert testimonies are said to be inappropriate in this test. In *Shaw*, the Ninth Circuit made it clear that in the intrinsic test, substantial similarity in expression is to be determined depending on the response of an ordinary reasonable person. It does not depend on the type of external criteria and analysis which marks the extrinsic test.¹⁵²

It is important to note that, as decided by the Second Circuit, “... *infringement analysis is not simply a matter of ascertaining similarity between components viewed in isolation.*”¹⁵³ Similarly, the Ninth Circuit, in *Seth Swirsky v. Mariah Carey* provided that “*to pull these elements out of a song individually, without looking at them in combination, is to perform an incomplete and distorted musicological analysis.*”¹⁵⁴ It was further stated that elements of a musical work might not be protected individually, but they may be protected when combined.¹⁵⁵ Thus, the extrinsic test is not enough. A musical work consists of elements like rhythm, harmony, and melody.¹⁵⁶ However, similarities between the songs are to be seen in overall sound, groove, and vibe rather than within melody, lyrics, or harmony.¹⁵⁷ For instance, in the case of *Three Boys*, substantial similarity was found due to “*a combination of five unprotectable elements: (1) the title hook phrase (including the lyric, rhythm, and pitch); (2) the shifted cadence; (2) the instrumental figures; (4) verse/chorus relationship; (5) the fade ending.*”¹⁵⁸

However, in the case of *Williams v. Gaye*,¹⁵⁹ (See, **(VI) (G) (2)**) the jury found infringement simply because the groove of the two songs sounded similar, despite there being several compositional differences.¹⁶⁰ This decision has not considered the history of art and musical composition,¹⁶¹ as the genre of the music has not been given much consideration. Even if a

¹⁴⁹ See *Funky Films, Inc. v. Time Warner Entm't Co.*, 462 F.3d 1072, 1076-1077 (9th Cir. 2006).

¹⁵⁰ *Three Boys Music Corp. v. Bolton*, 212 F.3d 477, 485 (9th Cir. 2000).

¹⁵¹ *Cavalier v. Random House, Inc.*, 297 F.3d 815, 822 (9th Cir. 2002); *Sid & Marty Krofft Television Productions, Inc. v. McDonald's Corp.*, 562 F.2d 1157, 1165 (9th Cir. 1977); *Roth Greeting Cards Co. v. United Card Co.*, 429 F.2d 1106, 1110 (9th Cir. 1970).

¹⁵² *Shaw v. Lindheim*, 919 F.2d 1353, 1356 (9th Cir. 1990).

¹⁵³ *Tufenkian Import/Export Ventures, Inc. v. Moomjy*, 338 F.3d 127, 134 (2d Cir. 2003).

¹⁵⁴ *Swirsky v. Carey*, 376 F.3d 841, 848 (9th Cir. 2004).

¹⁵⁵ *Id.* at 848; *Satava v. Lowry*, 323 F.3d 805, 811 (9th Cir. 2003).

¹⁵⁶ *Bridgeport Music, Inc. v. UMG Recordings, Inc.*, 585 F.3d 267, 273 (6th Cir. 2009).

¹⁵⁷ See David Post, *Blurred Lines and Copyright Infringement*, WASHINGTON POST (Mar. 12, 2015), <https://www.washingtonpost.com/news/voлокх-conspiracy/wp/2015/03/12/blurred-lines-and-copyright-infringement/>.

¹⁵⁸ *Three Boys Music Corp. v. Bolton*, 212 F.3d 477, 485 (9th Cir. 2000).

¹⁵⁹ *Williams v. Gaye*, 885 F.3d 1150 (9th Cir. 2018).

¹⁶⁰ See John Quagliarello, *Blurring the Lines: The Impact of Williams v. Gaye on Music Composition*, 10 HARV. J. SPORTS & ENT. L. 133, 138 (2019).

¹⁶¹ See Tim Wu, *Why the “Blurred Lines” Copyright Verdict Should Be Thrown Out*, NEW YORKER (Mar. 12, 2015), <https://www.newyorker.com/culture/culture-desk/why-the-blurred-lines-copyright-verdict-should-be-thrown-out>.

subjective test is being undertaken, similarities in feel or groove should not solely result in infringement, because such element of “groove” can be fundamental to a specific musical style (genre).¹⁶² Thus, the judgment has been heavily criticised in the musical and the legal world.

Additionally, the intrinsic test is problematic because it requires the jury to analyse the musical work, by disregarding the expert opinion taken during the extrinsic test. It is difficult for a juror to forget what has been explained to him during the extrinsic test, and make a new analysis.¹⁶³ In the case of *Williams v. Gaye*, it has been said that the jurors were most likely influenced by Gaye’s expert musicologist, while the best source for evaluation of similarity would have been the songs themselves.¹⁶⁴ This decision by the Ninth Circuit was said to definitely lessen outputs from artists.¹⁶⁵

Further, the requirement to inquire about the “total concept and feel” of the works makes the matter worse. It requires the courts to look into “total concept”, although “concepts” are not protected under Section-102 (b) of the Copyright Act.¹⁶⁶ Now, observation of an ordinary observer to determine substantial similarity is the least likely to respect such a boundary.¹⁶⁷ Further, the “feel” of a work can be a result of such elements of the work which are *scène à faire* (See, **VI (G)**), and are outside the scope of copyright protection. Thus, the dissection that takes place in the extrinsic test should not be entirely ignored, but should not be entirely relied upon either.

A. SUBSTANTIAL SIMILARITY

As already mentioned, to establish substantial similarity, both the intrinsic and the extrinsic test needs to be fulfilled. To prove substantial similarity, it should be shown that (a) the defendant copied from the plaintiff’s work and (b) that the copying constituted improper appropriation.¹⁶⁸ While the work of the defendant once needed to be virtually similar to the work of the plaintiff,¹⁶⁹ the current view is that significant parts of the work are also protected by copyright.¹⁷⁰ Exact copying of the work is not required to establish infringement.¹⁷¹

1. Qualitative, not Quantitative

¹⁶² Olivia Lattanza, *The Blurred Protection for the Feel or Groove of a Song under Copyright Law: Examining the Implications of Williams v. Gaye on Creativity in Music*, 35 TOURO L. REV. 723, 751 (2019) [hereinafter “Lattanza”].

¹⁶³ Lisa Field, *Copyright Infringement and Musical Expression: Creating Specific Jury Instructions for Comparing Music* 38 T. JEFFERSON L. REV. 152, 171 (2016) [hereinafter “Field”].

¹⁶⁴ Lattanza, *supra* note 162, at 725-726.

¹⁶⁵ See Randy Lewis, *More Than 200 Musicians Rally Behind Appeal of 'Blurred Lines' Verdict*, L.A. TIMES (Aug. 31, 2016), <https://www.latimes.com/entertainment/music/la-et-ms-blurred-lines-appeal-musicians-20160831-snap-story.html>.

¹⁶⁶ Springman, *supra* note 26, at 580.

¹⁶⁷ *Id.* at 574.

¹⁶⁸ *Stillman v. Leo Burnett Co., Inc.*, 720 F. Supp. 1353, 1357 (N.D. Ill. 1989).

¹⁶⁹ Mark A. Lemley & Mark P. McKenna, *Is Pepsi Really a Substitute for Coke? Market Definition in Antitrust and IP*, 100 GEO. L. J. 2055, 2105 (2012).

¹⁷⁰ Jay Dalter, Jr., *Trademark Protection for Industrial Designs*, U. ILL. L. REV. 887, 912-913 (1988).

¹⁷¹ See *Arnstein v. Porter*, 154 F.2d 464, 469 (2d Cir. 1946).

Substantial similarity is based on the qualitative aspect of copying, as has been affirmed by courts of various jurisdictions within the US. The question is not “how much” has been copied but rather “what” has been copied.¹⁷² As Judge Learned Hand has rightly remarked, “*no plagiarist can excuse the wrong by showing how much of his work he did not pirate.*”¹⁷³ In the case of *Universal Pictures Co. v. Harold Lloyd Corp.*,¹⁷⁴ it was decided that copyright infringement need not arise due to copying of the entire work or even a large portion of the work, in form or substance. However, it is important to note that there have been attempts by other Courts to set a quantitative ground to determine copying.¹⁷⁵ In the case of *Marks v. Leo Feist, Inc.*¹⁷⁶ (the case is responsible for the “six-bar rule”) number of bars that were copied was looked upon by the Second Circuit and it was decided that taking of six bars is not actionable per se. However, courts have moved away from this finding as lesser copying of bars were also found to be actionable.¹⁷⁷ Copying of six-note chorus with similar melodies has been held to infringe copyright protection since the chorus formed the heart of the composition.¹⁷⁸ Copying of “the meritorious part of a song” can amount to infringement.¹⁷⁹ Some portion of musical works can contribute to or showcase the success of the work, and such substantial components, if copied, can easily amount to infringement.¹⁸⁰

Similarly, in *Newton v. Diamond*, the Ninth Circuit found that a three-note segment melody was not quantitatively or qualitatively significant to give rise to an infringement.¹⁸¹ Substantial taking includes qualitative substantial taking, as can be seen in the case of *Harper & Row Publishers, Inc. v. Nation Enterprises*,¹⁸² wherein the Supreme Court found that copying 300 words of a 20,000 words article amounts to substantial taking as it was considered as the “heart of the matter”. Qualitative analysis is favoured because signature-type sounds can have large commercial value. As largely observed in the Second Circuit, it is important to note that a “demands test” has been propounded. It sees if the copied work will lead to a decrease in demand of the plaintiff’s work.¹⁸³ This highlights that the test is a qualitative test.

However, commentators have criticised the court’s reliance upon outdated notions of melody, harmony, and rhythm, which are not reflective of the contemporary musical expression.¹⁸⁴

¹⁷² See Maura Giannini, *The Substantial Similarity Test and Its Use in Determining Copyright Infringement through Digital Sampling*, 16 RUTGERS COMPUTER & TECH. L.J. 509, 520 (1990).

¹⁷³ *Sheldon v. Metro-Goldwyn Pictures Corp.*, 81 F.2d 49, 56 (2d Cir. 1936).

¹⁷⁴ *Universal Pictures Co. v. Harold Lloyd Corporation*, 162 F.2d 354, 361 (9th Cir. 1947).

¹⁷⁵ See Molly McGraw, *Sound Sampling Protection and Infringement in Today’s Music industry*, 4 HIGH TECH. L. J. 147, 163 (1989).

¹⁷⁶ *Marks v. Leo Feist, Inc.*, 290 F. 959 (2d Cir. 1923).

¹⁷⁷ See *Northern Music Corp. v. King Record Distributing Co.*, 105 F. Supp. 393, 399 (S.D.N.Y. 1952); see also *Robertson v. Batten, Barton, Durstine & Osborn, Inc.*, 146 F. Supp. 795, 798 (S.D. Cal. 1956).

¹⁷⁸ *Boosey v. Empire Music*, 224 F. 646 (S.D.N.Y. 1915).

¹⁷⁹ *Northern Music Corp. v. King Record Distributing Co.*, 105 F. Supp. 393, 397 (S.D.N.Y. 1952).

¹⁸⁰ See *Fred Fisher, Inc. v. Dillingham*, 298 F. 145, 147 (S.D.N.Y. 1924).

¹⁸¹ *Newton v. Diamond*, 388 F.3d 1189, 1194-96 (9th Cir. 2004).

¹⁸² *Harper & Row v. Nation Enterprises*, 471 U.S. 539, 565 (1985).

¹⁸³ *Rosemont Enters., Inc. v. Random House, Inc.*, 366 F.2d 303, 307 (2d Cir. 1966).

¹⁸⁴ See Alan Korn, *Issues Facing Legal Practitioners in Measuring Substantiality of Contemporary Musical Expression*, 6 J.MARSHALL REV. INTELL.

Further, it has been criticised that, application of the tests have arisen the problem of subjective and inconsistent results.¹⁸⁵ Therefore courts should see what “actually is” of qualitative significance rather than “what they think actually is” of qualitative significance. Now, to determine which part of the work has qualitative significance, the court must have some musical knowledge and should not completely ignore the extrinsic test.

2. Ordinary Observer Test

While dealing with the ordinary observer test, the Seventh Circuit provided that the test is to find out if the works are so similar that a lay observer can conclude that the defendant appropriated the protectable aspects of the plaintiff's work by taking that material of substance and value.¹⁸⁶ As provided by the Second Circuit, the test is used to determine “*whether defendant took from the plaintiff's work, so much of what is pleasing to the ears of lay listeners, who comprise the audience for whom such popular music is composed, that defendant wrongfully appropriated something which belongs to the plaintiff.*”¹⁸⁷ Similarity is determined based on whether an ordinary person can recognize copying of the plaintiff's work in the defendant's work.¹⁸⁸ For instance, the audience test (or the ordinary observer test)¹⁸⁹ was undertaken by the Ninth Circuit to determine if a film infringed a novel.¹⁹⁰ However, such a test remains in use across all circuits while analysing different kinds of work.¹⁹¹

The ordinary observer test identifies which work of infringement may act as a market substitute to the copyrighted work, thus taking profits away from the owner of the copyrighted work.¹⁹² In infringement of musical works, the test becomes an ordinary listener test.¹⁹³ However, articulation of a listener's experience after listening to the musical work is difficult due to the abstractness that aural perception holds.¹⁹⁴ This demands for a side-by-side comparison of the competing works.¹⁹⁵

The ordinary observer test has caused confusion and prejudice amongst the jury.¹⁹⁶ Courts play sound recordings to jurors, for them to assess if there is any substantial similarity.¹⁹⁷ Judges can be

PROP. L. 489, 489-91 (2007).

¹⁸⁵ See Liebesman, *supra* note 148, at 333-35.

¹⁸⁶ Atari, Inc. v. North American Philips Consumer Electronics Corp., 672 F.2d 607, 614 (7th Cir. 1982).

¹⁸⁷ Arnstein v. Porter, 154 F.2d 464, 473 (2d Cir. 1946).

¹⁸⁸ See Warner Bros. Inc. v. American Broadcasting Cos., 654 F.2d 204, 208 (2d Cir. 1981).

¹⁸⁹ Carl Sundholm, *Computer Copyright Infringement: Beyond the Limits of the Iterative Test*, 3 SANTA CLARA HIGH TECH. L.J. 369, 373 (2012).

¹⁹⁰ See Harold Lloyd Corp. v. Witwer, 65 F.2d 1, 19 (9th Cir. 1933).

¹⁹¹ See Dalton, *supra* note 33 at 27.

¹⁹² Jeanne C. Fromer & Mark A. Lemley, *The Audience in Intellectual Property Infringement*, 112 MICH. L. REV. 1251, 1254-1255 (2014).

¹⁹³ See Springman, *supra* note 26, at 574.

¹⁹⁴ See W. JAY DOWLING, PERCEPTION OF MUSIC, BLACKWELL HANDBOOK OF PERCEPTION 470-71 (E. Bruce Goldstein ed.) (2001).

¹⁹⁵ Gherman, *supra* note 36, at 504.

¹⁹⁶ See Lund, *supra* note 34, at 140.

¹⁹⁷ *Id.* at 147.

both over-inclusive and under-inclusive in the assessment of infringement.¹⁹⁸ Judges and jury may find similarities in musical works merely because there exist similarities in performance and basic characteristics of the genre. Further, performances might cover up the similarity that lies in the protected musical components, thus easily fooling a judge.¹⁹⁹

If a listener does not belong to the audience of the musical work, the listener is less likely to remember and recognize the presence or absence of key original elements.²⁰⁰ Therefore, jurors are not able to recognize the elements since the songs may not be directed to their usual taste which they are familiar with. Where a listener is not able to draw elements of musical works into familiar structures, the listener's musical memory declines and the person is unable to recognize the expressive content of the composition to determine similarity.²⁰¹ In the case of *Dawson v. Hinshaw Music Inc.*, the Fourth Circuit stated that “only a reckless indifference to common sense would lead a court to embrace a doctrine that requires a copyright case to turn on the opinion of someone who is ignorant of the relevant differences and similarities between the two works.”²⁰² Therefore, it is important to determine the narrow-audience for whom the music is made i.e. the “intended audience”, rather than simply going with a “lay observer” test.²⁰³

It is important to note that a lay listener cannot be given so much power that *scène à faire* (See, VI(G)) becomes a copyrightable element, as can be seen in the case of *Kroft* where there was sub-conscious inclusion of *scène à faire* as a copyrightable element. Thus, expert testimony is required so that lay listeners can conduct their subjective test with full knowledge and context.²⁰⁴ Since the ordinary observer test was not able to differentiate the unprotected elements of the work, the Second Circuit came up with the “more discerning ordinary observer test”.²⁰⁵ Further, successive filtering test has been suggested as an addition to the doctrines used by the circuits, during which, elements of the works are determined and further, it is determined if such elements are protected by the copyright laws.²⁰⁶ However, when it comes to the Ninth Circuit, it might appear that such an additional step is not required as filtration of unprotected elements would already have been done in the extrinsic test, by an expert. Nevertheless, while undertaking the intrinsic test, only subjective analysis is undertaken and the extrinsic test is ignored. Therefore, the possibility of an

¹⁹⁸ Alice J. Kim, *Expert Testimony and Substantial Similarity: Facing the Music in (Music) Copyright Infringement Cases*, 19 COLUM.-VLA J.L. & ARTS 109, 128 (1994).

¹⁹⁹ See Livingston, *supra* note 13, at 274.

²⁰⁰ JANE O'DEA, VIRTUE OR VIRTUOSITY? EXPLORATION IN THE ETHICS OF MUSICAL PERFORMANCE 4-17 (2000).

²⁰¹ Gherman, *supra* note 36, at 513.

²⁰² *Dawson v. Hinshaw Music Inc.*, 905 F.2d 731, 735 (4th Cir. 1990).

²⁰³ See *Arnstein v. Porter*, 154 F.2d 464, 473 (2d Cir. 1946).

²⁰⁴ Torreon Edwards, *Scène à faire in Music: How an Old Defense Is Maturing, and How It Be Improved*, 23 MARQ. INTELL.PROP. L. REV. 105, 110 (2019) [hereinafter “Edwards”].

²⁰⁵ *Laureyssens v. Idea Group, Inc.*, 964 F.2d 131, 141 (2d Cir. 1992).

²⁰⁶ See David Nimmer, Richard L. Brenacchi & Gary N. Frischling, *A Structured Approach to Analyzing the Substantial Similarity of Computer Software in Copyright Infringement Cases*, 20 ARIZ. ST. L.J. 625, 651 (1988).

unprotected element being protected can be observed, like in the case of *Williams v. Gaye*.²⁰⁷ However, in *Williams v. Gaye*, the problem was with over-reliance upon the extrinsic test. Therefore, while undertaking the intrinsic test, the court should not entirely ignore the findings made in the extrinsic test. However, the court should also not completely depend on the findings of the extrinsic test. Such a situation arises because unprotected elements, together, can form a protectable work²⁰⁸ and further because, similarity in “feel” of the work alone, while ignoring compositional differences, *scène à faire*, etc., cannot amount to infringement.²⁰⁹

VI. ADDITIONAL ISSUES

Additional issues which are general in nature and (mostly) not specific to the Ninth Circuit have also plagued the infringement analysis. For example, even if the tests have been satisfied on the face of it, there might exist justified grounds for copying which the court must also examine. Similarly, there exist issues with jury instructions and summary judgments, which are specific to the Ninth Circuit. Such issues add to the above-mentioned shortcomings within the tests undertaken by the Ninth Circuit.

A. Jury Instructions

As discussed above, the case of *Skidmore v. Led Zeppelin* (See **III**) highlighted the importance of jury instructions. Jury instructions provide guidance regarding the protected elements of a work. However, this is not the case in the Ninth Circuit when it comes to cases concerning musical infringement, because of the lack of a set of specific jury instructions with regards to musical infringement. This lacking leaves the test in the Ninth Circuit open to interpretation by jurors and courts, which results in confusion and chaos. Therefore, a model jury instruction needs to be added, which instructs the jury on the test, identification of protectable musical elements, etc.²¹⁰ Typical jury instructions as provided in the Ninth Circuit, in cases of alleged infringement, has disadvantaged the jurors due to the exclusion of specificity with regard to musical elements which forms the basis for their analysis.²¹¹

B. Issues with Summary Judgments

Plea for summary judgment can be observed in a lot of copyright disputes. A summary judgment can be provided in favour of both the defendants or the plaintiffs. It must be noted that to grant a summary judgment, only the extrinsic test is important as the subjective test is left to the jury.²¹²

²⁰⁷ *Williams v. Gaye*, 885 F.3d 1150 (9th Cir. 2018).

²⁰⁸ *See Swirsky v. Carey*, 376 F.3d 841, 848 (9th Cir. 2004); *see also Satava v. Lowry*, 323 F.3d 805, 811 (9th Cir. 2003).

²⁰⁹ *See Lattanza*, *supra* note 162, at 750-751.

²¹⁰ *Field*, *supra* note 163, at 168-169.

²¹¹ *Id.* at 175.

²¹² *Seth Swirsky v. Mariah Carey*, 376 F.3d 841, 845 (9th Cir. 2004); *see also Brown Bag Software v. Symantec Corp.*, 960 F.2d 1465,

Summary judgement is granted to the plaintiff where the works are overwhelmingly similar. It is granted to the defendant when the works are so dissimilar that an infringement claim would be without merit.²¹³ A summary judgment can be allowed in favour of the defendant where the defendant has copied mere ideas. Also, where copying of *scène à faire*, copying of mere facts, or the expressions which are obviously dissimilar have occurred, summary judgment can be provided in favour of the defendant.²¹⁴ In the case of *Narell v. Freeman*,²¹⁵ it was decided that “...summary judgment is appropriate [in favour of the non-moving party (defendant)] if...no reasonable juror could find substantial similarity of ideas and expression.” Summary judgment should only be provided (in favour of the plaintiff) only in cases where the similarities are too obvious.²¹⁶ Here again, the problems observed in the case of extrinsic test comes into play. Further, courts should be careful not to look into subjective determination of similarity or dissimilarity.²¹⁷ However, courts have dealt with the findings of a reasonable juror as a ground to grant or dismiss summary judgment.²¹⁸

However, summary judgment on the issue of substantial similarity is said to be unusual.²¹⁹ It is not favoured while dealing with substantial similarity issue.²²⁰ Summary judgment has been frowned upon since the examination of substantial similarity is a question of fact.²²¹ But, the extrinsic test is largely a legal test rather than factual. The fact-based nature of the issue of substantial similarity, makes summary judgments rare.²²² Despite this, summary judgments in cases of substantial similarity have been pleaded substantially.

Defending a copyright action has become more expensive as cases which could have once ended in summary judgment itself, goes on to trial and appeal.²²³ Thus summary judgment holds importance. On practical grounds, rather than disfavouring summary judgments completely, courts should provide such judgments in cases where there is absolute obviousness or non-obviousness of similarity or non-similarity, based on both legal and factual analysis. Such judgments should however, be rare.

C. Subconscious/Unconscious Copying

The terms “subconscious copying” and “unconscious copying” have been used synonymously in

1477 (9th Cir. 1992).

²¹³ *Twentieth Century-Fox Film Corp. v. MCA, Inc.*, 715 F.2d 1327, 1330 (9th Cir. 1983).

²¹⁴ Frankel, *supra* note 24, at 441.

²¹⁵ *Narell v. Freeman*, 872 F. 2d. 907, 909 (9th Cir. 1989).

²¹⁶ *See Peter Pan Fabrics, Inc. v. Dan River Mills, Inc.*, 295 F. Supp. 1366, 1369 (S.D.N.Y. 1969); Shonack, *supra* note 67, at 307.

²¹⁷ *See Kouf v. Walt Disney Pictures & Television*, 16 F.3d. 1042, 1045 (9th Cir. 1994).

²¹⁸ *Narell v. Freeman*, 872 F. 2d. 907, 910 (9th Cir. 1989); *Id.*

²¹⁹ *T-Peg, Inc. v. Vermont Timber Works, Inc.*, 459 F.3d 97, 112 (1st Cir. 2006).

²²⁰ *Berkic v. Crichton*, 761 F.2d 1289, 1292 (9th Cir. 1985); *see also Shaw v. Lindheim*, 919 F.2d 1353, 1355 (9th Cir. 1990).

²²¹ *Hoehling v. Universal City Studios, Inc.*, 618 F.2d 972, 977 (2d Cir. 1980).

²²² *Axelrod Cherveney Architects v. Winmar Homes*, 2:05-cv-711-ENV-ETB, 14 (E.D.N.Y. Mar. 6, 2007).

²²³ Landau and Biederman, *supra* note 104, at 725-726.

infringement cases.²²⁴ Musicians and people are exposed to a large number of music every day, which gets stored in their memory consciously and subconsciously.²²⁵ Further, contemporary music is consciously or subconsciously influenced by the previous generation of composers.²²⁶ Subconscious copying occurs when a musician makes use of a combination of sounds that would be pleasing to the listeners because “his subconscious [mind] knew that [such combination] had already worked in a song his conscious mind did not remember.”²²⁷ However, such copying would not escape infringement liability.²²⁸ The doctrine of unconscious copying provides that if one produces from memory, a thing that his mind has been familiar with, it amounts to infringement. It is not relevant if the defendant unconsciously followed the plaintiff’s work.²²⁹

While independent creation is a complete defence against copyright infringement,²³⁰ subconscious copying is not.²³¹ Now, herein, it is important to note that the theory of subconscious copying is largely seen in musical works.²³² Relative simplicity, commonality within the genre, rich shared musical heritage and daily exposure to music, can lead to the creation of two similar works.²³³

Implicit memories, which are a part of the “unconscious”, can affect behaviours even though the person is not aware of their influence.²³⁴ However, subconscious copying being put on the same pedestal as deliberate copying is wrong. Courts treat unconscious copying as deliberate copying, making the unconscious copier liable for infringement.²³⁵ Further, lack of awareness of copying is immaterial while determining infringement.²³⁶ Such practices will negatively affect creative expressions and moral fairness.²³⁷

1. Plaintiff-Centric-Rule

The doctrine of sub-conscious copying might lead to a denial of the fact that copying does not

²²⁴ Christopher Brett Jaeger, *Does That Sound Familiar: Creators' Liability for Unconscious Copyright Infringement*, 61 VAND. L. REV. 1903, 1905 n.9 (2008) [hereinafter “Jaeger”].

²²⁵ Livingston, *supra* note 13, at 269-70.

²²⁶ Livingston, *supra* note 13, at 290.

²²⁷ Bright Tunes Music Corp. v. Harrisongs Music, Ltd., 420 F. Supp. 177, 180 (S.D.N.Y. 1976).

²²⁸ *Id.* at 180-181; Fred Fisher, Inc. v. Dillingham, 298 F. 145, 148 (S. D.N.Y. 1942).

²²⁹ Edwards & Deutsch Lithographing Co. v. Boorman, 15 F.2d 35, 37 (7th Cir. 1926); Fred Fisher, Inc. v. Dillingham, 298 F. 145, 148 (S.D.N.Y. 1942).

²³⁰ See Nichols v. Universal Pictures Corp., 45 F.2d 119, 122 (2d Cir. 1930).

²³¹ ABKCO Music, Inc. v. Harrisongs Music, Ltd., 722 F.2d 988, 998 (2d Cir. 1983).

²³² See Rebecca Tushnet, *Worth A Thousand Words: The Image of Copyright*, 125 HARV. L. REV. 683, 729 n.209 (2012).

²³³ Livingston, *supra* note 13, at 282.

²³⁴ See Howard Shevrin & Scott Dickman, *The Psychological Unconscious: A Necessary Assumption for All Psychological Theory?*, 35 AM. PSYCHOLOGIST 421, 423 (1980).

²³⁵ See Olufunmilayo B. Arewa, *The Freedom to Copy: Copyright, Creation, and Context*, 41 U.C. DAVIS L. REV. 477, 479-81 (2007).

²³⁶ See Fred Fisher, Inc. v. Dillingham, 298 F. 145, 148 (S.D.N.Y. 1942).

²³⁷ Jaeger, *supra* note 224, at 1927; see also Kimberly Shane, *The Unconscious Erosion of Copyright Legitimacy by the Unconscious Copying Doctrine*, 13 U. DENV. SPORTS & ENT. L.J. 53, 67 (2012) [hereinafter “Shane”].

always amount to infringement in the contemporary world.²³⁸ The doctrine puts a substantial burden on the defendants.²³⁹ For instance, in *Fred Fisher, Inc. v. Dillingham* in the US Court for the Southern District of New York, Judge Hand agreed with the defendant's argument of not having copied the work consciously but the court was constrained to find infringement due to the virtual identity of the works and lack of a common prior source.²⁴⁰ Additionally, despite long gaps of time between access and subconscious copying, courts have held the defendant liable.²⁴¹

In *ABKCO*, where sub-conscious copying was established by the Second Circuit, it was held that "*the similarity was so striking and where access was found, the remoteness of that access provides no basis for reversal [of the finding of subconscious copying]*"²⁴² Similarly, in *Three Boys Music*, it was decided that the defendants must have subconsciously copied the plaintiff's work, even if there was a weak case of access.²⁴³ The court held the defendant liable for infringement. The jury's finding of access was based on the defendant's admitted admiration of the plaintiff's music, and radio and television airplay in the mid-1960s. The defendant's exposure to the plaintiff's song was twenty- five years before his own song was written. Further, the defendant had no recollection of having heard the song, unlike in the case of *ABKCO Music*.²⁴⁴

Subconscious copiers might raise the argument of independent creation as a defence, as they believe that they have created the work independently.²⁴⁵ Subconscious copying is difficult to be distinguished from the defence of independent creation.²⁴⁶ Further, evidence of widespread dissemination may also support the theory of subconscious copying.²⁴⁷ Therefore, the doctrine weakens even the defence of independent creation that is available to the defendant. Further, since wide dissemination can be easily done in the present, subconscious copying can be easily established as well.

Currently, subconscious copying can merely lessen the damages liability of the defendant.²⁴⁸ Courts should allow subconscious copying as a defence, and should allow a rebuttable presumption that all copying is conscious. It has been argued that such defence should either be an entirely separate defence or a sub-set defence to the defence of independent creation.²⁴⁹ Such

²³⁸ Jonathan Lethem, *The Ecstasy of Influence: A Plagiarism*, HARPER'S MAGAZINE (Feb. 2007), <https://harpers.org/archive/2007/02/the-ecstasy-of-influence/>.

²³⁹ See Landau and Biederman, *supra* note 104, at 733 n.74.

²⁴⁰ See *Fred Fisher, Inc. v. Dillingham*, 298 F. 145, 152 (S.D.N.Y. 1924).

²⁴¹ See *Three Boys Music Corp. v. Bolton*, 212 F.3d 477, 483 (9th Cir. 2000).

²⁴² *ABKCO Music, Inc v. Harrisongs Music, Ltd.*, 722 F.2d 988, 998 (2d Cir. 1983).

²⁴³ See *Three Boys Music Corp. v. Bolton*, 212 F.3d 477, 484-486 (9th Cir. 2000).

²⁴⁴ See *ABKCO Music, Inc. v. Harrisongs Music, Ltd.*, 722 F.2d 988, 998-999 (2d Cir. 1983).

²⁴⁵ Jaeger, *supra* note 224, at 1912-1913.

²⁴⁶ See Jessica Litman, *The Public Domain*, 39 EMORY L.J. 965, 1008-12 (1990).

²⁴⁷ *Three Boys Music Corp. v. Bolton*, 212 F.3d 477, 482 (9th Cir. 2000).

²⁴⁸ Livingston, *supra* note 13, at 268.

²⁴⁹ Jaeger, *supra* note 224, at 1925.

defence should be allowed because it is unreasonable for courts to punish some artists, while blindly accepting that the artists who have been awarded the copyright (plaintiffs) have created their works independent of any borrowing, influence, and their sub-consciousness.²⁵⁰ Additionally, subconscious copying, if taken as a defence, serves the economic and moral aims of the copyright law itself.²⁵¹ However, “defence” as referred in this paragraph means “absolute defence from punishment” and not that the subconscious copier should be provided with copyright as well, because intention is irrelevant while determining if infringement has taken place. Again, however, it must be noted that the defence of subconscious copying should also be rare. Else, every defendant would take the defence of subconscious copying and intentional copying would go unpunished.

D. Limited Scope of Originality

While dealing with elements of musical work like rhythms and tempos, it has been observed that “...these appear to have been long since exhausted; originality of rhythm is a rarity, if not an impossibility.”²⁵² Therefore, such limitations decrease the likelihood that similarities alone can prove copying, as common prior source can justify the similarity among the two works.²⁵³ The tonality to the western music limits composition to finite boundaries and thus, similarity is inevitable. Further, although independent creation negates plagiarism, there exists an inevitable possibility of similarity among music based on the same genre.²⁵⁴ Musical styles like country-western, hip hop, rock, blues, etc. have certain rhythms and musical motives. Therefore, a musical work is limited to some compositional choices, so as to comply with the expectations and requirements of the genre that the music intends to be based on.²⁵⁵ This issue can be observed in the *Williams v. Gaye* judgment (See, **VI (G) (2)**). The Ninth Circuit as well has used this idea of “limited-ness” in the case of *Ets-Hokin v. Skyy Spirits*, wherein it decided that there are limited ways to photograph a vodka bottle and thus no copyright infringement can be made.²⁵⁶

Every artist is a finite source.²⁵⁷ While considering the highly controversial issue of self-plagiarism, it has been argued that there exists only limited ways in which a single personality expresses himself. Therefore, repetition within his works is inevitable.²⁵⁸ Thus, an artist is largely limited due to the limited elements available for composition of a music and by his own abilities. This further validates an artist being inspired by the works of other musicians. Thus, courts must

²⁵⁰ Shane, *supra* note 237, at 66.

²⁵¹ Jaeger, *supra* note 224, at 1928.

²⁵² Northern Music Corp. v. King Record Distributing Co., 105 F. Supp. 393, 400 (S.D.N.Y. 1952).

²⁵³ See Strachborneo v. Arc Music Corp., 357 F. Supp. 1393, 1403 (S.D.N.Y. 1973).

²⁵⁴ Livingston, *supra* note 13, at 227.

²⁵⁵ *Id.* at 262.

²⁵⁶ See *Ets-Hokin v. Skyy Spirits, Inc.*, 255 F.3d 1068, 1082 (9th Cir. 2000).

²⁵⁷ See *Esquire v. Varga Enters. Inc.*, 81 F. Supp. 306, 307-08 (N.D. 111. 1948).

²⁵⁸ See Laurie Stearns, *Copy Wrong: Plagiarism, Process, Property, and the Law*, 80 CAL. L. REV. 513, 543-44 (1992).

recognise the limited scope of originality that exists for musical works.

E. Pleasing to the Ear

Judge Learned Hand once famously observed that “*it must be remembered that while there are an enormous number of possible permutations of the musical notes of the scale, only a few are pleasing; and much fewer still suit the infantile demands of the popular ear. Recurrence is not therefore an inevitable badge of plagiarism.*”²⁵⁹ There is an inherent limitation to the combination of notes that will sound pleasing or acceptable to a listener due to the conventional tonal practices in western musical works. It is universal human nature to prefer certain sounds, which again limits the scope of the combination of notes.²⁶⁰ The restriction on the key signatures in music exists because they are what is pleasing to the ear.²⁶¹ Since musical compositions are based on common vocabulary and must be pleasing to one’s sense of hearing, subconscious copying might exist in almost all works.²⁶² Further, popular music follows well-worn grooves, which again limits invention and variety in musical works.²⁶³

In copyright cases, one can observe that while the protection provided is broad, there are only a limited number of ways in which ideas can be expressed.²⁶⁴ Only a limited number of chords and notes are available for the composition of musical works.²⁶⁵ The Second Circuit, in the case of *Marks v. Leo Feist*, shows how the inherent limitations in musical components and the need for compliance with the consumer’s preference (and their ability to sing and perform the song) can create similarity among musical works. It was decided that “*To be successful, it must be a combination of tones that can be played as well as sung by almost anyone. Within these limits, there will be some similarity of tone succession.*”²⁶⁶ When it comes to pop songs, the public seeks simple tonal-functional harmony, and the number of possible variations to the system is scarce.²⁶⁷ Therefore, even for compliance with the consumer’s need, repetition is inevitable.

F. Looking into the Past

It is important to note that earlier works inevitably influence an artist. Today, songs are inspired in parts by some musical genre, or artists, or even previous songs.²⁶⁸ Composers from the US were,

²⁵⁹ *Darrell v. Joe Morris Music Co.*, 113 F.2d 80 (2d Cir. 1940).

²⁶⁰ See Edward Lee, *Fair Use Avoidance in Music Cases*, 59 B.C. L. REV. 1873, 1895-96 (2018).

²⁶¹ See Grant Beiner, *Copyright in Music in U.S. Interpretation: The Case for Moving away from Easy and Nonsensical Findings of Copyright Infringement*, 60 S. TEX. L. REV. 459, 493 (2019) [hereinafter “Beiner”].

²⁶² Livingston, *supra* note 13, at 270.

²⁶³ David W. Melville, *An Author’s Right to Return to a Theme: Protecting Artistic Freedom in Visual, Musical and Literary Works*, 14 LOY. L.A. ENT. L. J. 427, 454 (1993-1994).

²⁶⁴ See Emily Ranger-Murdock, “*Blurred Lines*” to “*Stairway to Heaven*”: Applicability of Selection and Arrangement Infringement Actions in Musical Compositions, 67 UCLA L. REV. 1066, 1099 (2020).

²⁶⁵ *Gaste v. Kaiserman*, 863 F.2d 1061, 1068 (2d Cir. 1988).

²⁶⁶ *Marks v. Leo Feist, Inc.*, 290 F. 959, 960 (2d Cir. 1923).

²⁶⁷ Gherman, *supra* note 36, at 497-98.

²⁶⁸ Taylor Turville, *Emulating vs. Infringement: The “Blurred Lines” of Copyright Law*, 38 WHITTIER L. REV. 199, 218 (2018).

by the end of the 19th century, generating their musical works based on the European models.²⁶⁹ Different pitch organisations, whether melodic, harmonic, or contrapuntal, and corresponding rhythms, beats, accents, and formal structure, are based on organisation of eight notes on or around one principle of tone (tonality).²⁷⁰ In the 20th Century, the predominant style of contemporary music like country, folk, jazz, etc. followed the tenets of traditional tonality.²⁷¹ Therefore, historically, musical elements have been borrowed and composed within a narrow boundary of tonality.

Borrowing from past works is necessary in the music industry,²⁷² as it is a pervasive part of producing music.²⁷³ Given the narrow field for the composition of musical works, musicians step on each other's toes for "creative necessity"²⁷⁴ and borrow from other works of music.²⁷⁵ Therefore, courts should acknowledge that borrowing from past musical works should be allowed to some reasonable extent especially given the fact that historically, music has developed through part-borrowings. Such argument is even more true considering the inherent limitation of elements faced when composing a musical work. However, such observations were not made in the highly criticised case of *Williams v. Gaye*. (See, **VI (G) (2)**)

G. Scène à faire

Not all copying amounts to copyright infringement,²⁷⁶ as not all elements of musical work can be copyright protected.²⁷⁷ "The mere fact that a work is copyrighted does not mean that every element of the work may be protected."²⁷⁸ Elements of musical works like a key, meter, tempo, common song structures, common chord progressions, common melodies and, common percussive rhythms should be unprotected.²⁷⁹

Scène à faire, is a French expression that literally means "scene which 'must' be done".²⁸⁰ Judge Yankwich introduced the doctrine of *scène à faire* to the US copyright law in 1942.²⁸¹ It is a theatre

²⁶⁹ RICHARD CRAWFORD, AMERICA'S MUSICAL LIFE 372-82 (2001).

²⁷⁰ Livingston, *supra* note 13, at 239-240.

²⁷¹ *Id.* at 250.

²⁷² Carys J. Craig & Guillaume Laroche, *Out of Tune: Why Copyright Law Needs Music Lessons*, 10 OSGOODE LEGAL STUDIES RESEARCH PAPER SERIES 43, 48 (2014).

²⁷³ Olufunmilayo B. Arewa, *From J.C. Bach to Hip Hop: Musical Borrowing, Copyright and Cultural Context*, 84 N.C. L.REV. 547, 571-72 (2006).

²⁷⁴ See Robert Rogoyski, *The Melody Machine: How to Kill Copyright, and Other Problems with Protecting Discrete Musical Elements*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 347, 409 (2006).

²⁷⁵ See J. Michael Keyes, *Musical Musings: The Case for Rethinking Music Copyright Protection*, 10 MICH. TELECOMM. & TECH. L. REV. 407, 429 (2004).

²⁷⁶ See *Feist Publ'n, Inc. v. Rural Tel. Serv. Co., Inc.*, 499 U.S. 340, 361 (1991).

²⁷⁷ See Jeffrey Cadwell, *Expert Testimony, Scenes a Faire, and Tonal Music: A (Not So) New Test for Infringement*, 46 SANTA CLARA L. REV. 137, 166-67 (2005).

²⁷⁸ *Feist Publ'n, Inc. v. Rural Tel. Serv. Co., Inc.*, 499 U.S. 340, 348 (1991).

²⁷⁹ *Griffin v. Sheeran*, 351 F. Supp. 3d 492, 497 (S.D.N.Y. 2019).

²⁸⁰ *Schwarz v. Universal Pictures Co.*, 85 F. Supp. 270, 275 (S.D. Cal. 1945).

²⁸¹ Leslie A. Kurtz, *Copyright: The Scenes a faire Doctrine*, 41 FLA. L. REV. 79, 80 (1989).

term which means “the most important scenes in a play or opera, made inevitable by the action which leads up to it.”²⁸² However, courts struggle to determine which elements form *scène à faire*.²⁸³

Scène à faire can be a defence even in the presence of substantial similarity.²⁸⁴ In the case of *Cain v. Universal Pictures Co.*,²⁸⁵ it was decided that no infringement can be made out because the thematic commonality of the “scenes” was “common faire”. In the legal world, it signifies that new works can come from a common idea which is germane to the genre.²⁸⁶ *Scène à faire* flows from the theme itself and not from minds. Thus, they should not be copyright protected.²⁸⁷ However, for instance, it is again important to note that the larger genre of “hip-hop” cannot be said to be a *scène à faire*.²⁸⁸ *Scène à faire* prevents ownership of such elements of work that must not be owned.²⁸⁹ Works under Section 102 (b) of the Copyright Act and *scène à faire* are placed outside the scope of copyright protection.²⁹⁰ Since, infringement can arise only if there are similarities in protected elements of the works,²⁹¹ similarity of *scène à faire* among two works, does not amount to infringement. Further, Adorno’s theory provides that the two essential elements of popular music are standardization and pseudo-individualization.²⁹² Therefore, protecting essential material of any composition would hinder the ability of the other composer.

Contemporary musical works are similar to each other, particularly when both are in the same genre.²⁹³ Taking the example of the blues genre, the “walking” bass line might as well be a *scène à faire*. Further, the genre is based on the same “1/4/5” chord structure.²⁹⁴ Now, for the jurors to accept such similarity, they must hold some musical knowledge.²⁹⁵ Based on the similarities observed in a genre, it has been observed that, in some way, “feel” and “groove” are analogous to the *scène à faire* in a musical work.²⁹⁶ This poses a large difficulty because, while dealing with alleged infringement cases, courts undertake a subjective test, wherein such elements are analysed. Specifically talking about the Ninth Circuit, the court considers the “feel” of the work in its intrinsic test, and has also

²⁸² Edwards, *supra* note 204, at 108; see also *Bucklew v. Hawkins, Ash, Baptie & Co.*, 329 F.3d 923, 929 (7th Cir. 2003).

²⁸³ See Edwards, *supra* note 204, at 110.

²⁸⁴ See *id.* at 106.

²⁸⁵ See *Cain v. Universal Pictures Co.*, 47 F. Supp. 1013, 1017 (S.D. Cal. 1942).

²⁸⁶ See *ETS-Hokin v. Skyy Spirits, Inc.*, 255 F.3d 1068, 1082 (9th Cir. 2000).

²⁸⁷ *MyWebGrocer, LLC v. Hometown Info, Inc.*, 375 F.3d 190, 194 (2d Cir. 2004).

²⁸⁸ *Swirsky v. Carey*, 376 F.3d 841, 850 (9th Cir. 2004).

²⁸⁹ See Patrick Metzger, *The Millennial Whoop: The Simple Melodic Sequence That's Showing Up All Over Contemporary Pop*, *Brow Beat Slate's Culture Blog*, (Aug. 29, 2016, 09:45 AM), <https://slate.com/culture/2016/08/the-millennial-whoop-the-simple-wa-oh-ing-melodic-sequence-showing-up-all-over-pop.html>; see also *Walker v. Time Life Films, Inc.*, 784 F.2d 44, 50 (2d Cir. 1986); see also *Gates Rubber Co. v. Bando Chemical Indus., Ltd.*, 9 F.3d 823, 838 (10th Cir. 1993).

²⁹⁰ *Springman*, *supra* note 26, at 572-573

²⁹¹ See *Gates Rubber Co. v. Bando Chemical Indus., Ltd.*, 9 F.3d 823, 834 (10th Cir. 1993).

²⁹² See RICHARD MIDDLETON, *STUDYING POPULAR MUSIC* 34-63 (1990).

²⁹³ *Moore v. Columbia Pictures Industries, Inc.*, 972 F.2d 939, 946 (8th Cir. 1992).

²⁹⁴ See *How to Play the Blues: Chords, Patterns and Fills for Major and Minor Blues*, *Guitar Player* (April 14, 2020), <https://www.guitarplayer.com/lessons/how-to-play-the-blues-chords-patterns-and-fills-for-major-and-minor-blues>.

²⁹⁵ See *Springman*, *supra* note 26, at 590.

²⁹⁶ *Lattanza*, *supra* note 162, at 750.

found infringement based on similarity of the “groove” of the musical work. Judges must hold knowledge regarding such issues to correctly analyse infringement cases.

Courts have used the “useful article doctrine” and separated useful features from aesthetic features, in the context of copyright. Using this doctrine, courts provide protection to aesthetic features that are separable from the subject matter’s useful application. However, such doctrine has largely been limitedly used for pictorial, graphical, and sculptural works.²⁹⁷

1. *Smith v. Micheal Jackson*

Micheal Jackson as well had to defend himself in an alleged copyright infringement case (*Smith v. Jackson*).²⁹⁸ In an appeal to the Ninth Circuit by the plaintiffs, the court applied the extrinsic-intrinsic test to determine substantial similarity. In this case, the plaintiff forwarded the argument that there is a “presumption of originality” established by the certificate of copyright registration, even in case of a question as to whether certain motives constitute *scène à faire*. The lower court had held that “motives” from the song were unprotected *scène à faire* since they were so common. The court, during appeal, referred to the case of *Apple Computer, Inc.*,²⁹⁹ wherein, the originality inquiry and *scène à faire* inquiry were dealt with separately. Thus, the Ninth Circuit, in the appeal, stated that the presumption of originality as accorded by a registration certificate cannot determine if some elements are copyrightable or not. It only validates the ownership of copyrightable work. The court in *Smith v. Micheal* also noted that proof of access is irrelevant for determining whether the similarity is due to unprotected *scène à faire*.³⁰⁰

2. *Williams v. Gaye*

The case of *Williams v. Gaye*³⁰¹ was unique because the two-musical works in dispute did not have similar melodies. The songs did not even share the same melodic phrase. The songs did not have any sequence of chords (not even two), played in the same order, for the same duration. The songs had differences in song structures and had no common lyrics.³⁰² The Ninth Circuit in the case improperly expanded the scope of copyright protection to the groove or feel of the song. To say that something “sounds like” the other, does not amount to copyright infringement.³⁰³ The judgment in *Gaye* has essentially has protected ideas, which clearly goes against the intent of copyright

²⁹⁷ Gherman, *supra* note 36, at 500-501.

²⁹⁸ *Smith v. Jackson*, 84 F.3d 1213 (9th Cir. 1996).

²⁹⁹ *See Apple Computer, Inc. v. Microsoft Corp.*, 35 F.3d 1435, 1444-45.

³⁰⁰ *Smith v. Jackson*, 84 F.3d 1213, 1220 (9th Cir. 1996).

³⁰¹ *Williams v. Gaye*, 895 F.3d 1106 (9th Cir. 2018).

³⁰² Edwin F. McPherson, *Crushing Creativity: The Blurred Lines Case and Its Aftermath*, 92 S. CAL. L. REV. 67, 67-68 (2018) [hereinafter “McPherson”].

³⁰³ Tim Wu, *Why the “Blurred Lines” Copyright Verdict Should Be Thrown Out*, NEW YORKER (Mar. 12, 2015), <https://www.newyorker.com/culture/culture-desk/why-the-blurred-lines-copyright-verdict-should-be-thrown-out>.

protection, as provided in Section 102(b) of the Copyright Act.³⁰⁴ The phrases with six consecutive eight notes in “Blurred Lines” (a song by William and others) and “Got to Give it up” (a song by Marvin Gaye) should have been considered as *scène à faire*, as such notes can also be found, for example, in the song “Thrift Shop” by Macklemore, Fetty Wap’s “Trap Queen”, Selena Gomez’s “Bad Liar” and Ariana Grande’s “breathin”.³⁰⁵

In this case, Pharrell Williams, Robin Thicke, and others were sued by the family of Marvin Gaye for appropriation of a melody present in one of the Marvin Gaye’s songs. Infringement was established based on groove and melody of the songs. However, the court was unable to distinguish between what is protected and what is not under the *scène à faire* doctrine. Attorneys of Thicke stated that the jury blurred the lines between what is protected and what is not, and that the musical style (genre) and the groove in Marvin Gaye’s song were unprotected. The parties had accepted that their musical work was inspired by Marvin Gaye. However, such acceptance should not have influenced the court’s decision because, as has been mentioned above, there is a large difference between “being inspired” and “infringement”. Further, it is said that Gaye’s song “Got to Give it Up” was itself inspired by Johnnie Taylor’s “Disco Lady”.³⁰⁶ Therefore, the judgment is largely faulty. The protection provided to the groove of the song was inappropriate as protectable elements like melody and lyrics were completely different.³⁰⁷ Lack of proper instruction, or understanding of *scène à faire*, perhaps lead to an improper holding of infringement.³⁰⁸ However, *Skidmore v. Zeppelin*, is thought to mark an end to the curse of “Blurred Lines”.³⁰⁹

H. Functional Feature, Creativity and, Originality Requirement

Individual elements such as notes or scales should not be protected by copyright.³¹⁰ Basic musical harmonies are too unoriginal to provide them with copyright protection.³¹¹ A twelve-bar blues harmonic progression should be unprotectable because of the functional feature that it lacks.³¹² It has been argued that the doctrine of functionality, as can be seen in trademark laws, are to be applied so as to determine if protection to basic harmonic progression is to be provided or not.³¹³

Unlike in cases of infringement of melodies, cases on infringement of lyrics are not confusing. In the

³⁰⁴ Copyright Act of 1976, 17 U.S.C. § 102(b); McPherson, *supra* note 302, at 68.

³⁰⁵ Paymaneh Parhami, *Williams v. Gaye: Blurring the Lines of Copyright Infringement in Music*, 34 BERKELEY TECH. L.J. 1113, 1141 (2019).

³⁰⁶ McPherson, *supra* note 302, at 74-76.

³⁰⁷ David Post, *Blurred Lines and Copyright Infringement*, WASHINGTON POST (Mar. 12, 2015), <https://www.washingtonpost.com/news/voxxh-conspiracy/wp/2015/03/12/blurred-lines-and-copyright-infringement/>.

³⁰⁸ See Edwards, *supra* note 204, at 112.

³⁰⁹ See Ben Sisario, *The 'Blurred Lines' Case Scared Songwriters. But Its Time May Be Up.*, N.Y. TIMES (Mar. 24, 2020), <https://www.nytimes.com/2020/03/24/arts/music/blurred-lines-led-zeppelin-copyright.html>.

³¹⁰ *Skidmore v. Zeppelin*, 905 F.3d 1116, 1126 (9th Cir. 2018).

³¹¹ Gherman, *supra* note 36, at 489.

³¹² *Id.* at 484.

³¹³ *Id.* at 489.

case of *Hall v. Swift*, the chorus of Taylor Swift's Song "Shake It Off" was alleged to have infringed the song "Playas Gon' Play". The case concerned allegation of infringement based on the chorus which uses two three-word phrases i.e., "haters gonna hate" and "players gonna play". However, the district court found that the short phrases were unprotected as they were not sufficiently creative. It was further decided that while the amount of creative input required to be paid is low, it is not negligible. However, upon appeal to the Ninth Circuit, the decision of the district court was reversed and remanded. Nevertheless, what needs to be noted is that the Ninth Circuit did not state that there was a copyright infringement. It merely stated that "*because the absence of originality is not established either on the face of the complaint or through the judicially noticed matters, we reverse the district court's dismissal.*" Currently (after the remand), the case can go to trial, because Taylor's request for a summary judgement has been denied.³¹⁴ Similarly, it has been decided in another case that the use of the phrase "party and bullshit" is not enough to amount to infringement.³¹⁵

Musical composition consists of musical notes, chord progression, lyrics, melodies, and anything with a spark of creativity and originality.³¹⁶ In the case of *Newton v. Diamond*,³¹⁷ the Ninth Circuit decided that "*C-D[b]--C, over a held C note..., lacked sufficient originality to merit copyright protection.*" However, where a sequence of notes becomes protectable cannot be pinpointed. Further, the court's analysis of originality while dealing with melodies appears to lack formal guidelines.³¹⁸ Therefore, due to the very nature of musical compositions, there is difficulty in drawing the line from where "creativity" begins and with it, copyright protection. Thus, experts and judges should inquire together.

VII. SUGGESTIONS AND CONCLUSION

Led Zeppelin has faced many infringement allegations.³¹⁹ It can be observed that artists like Michael Jackson and Lionel Richie (Prince) were sued for copyright infringement half a dozen times or more, per year. Most of them were based on an outlandish accusation of access. Further, given the monetary stake at hand, copyright disputes are brought to court against popular music which creates the problem of "hits bring writs". However, the accusations, however far-fetched, consume the defendant's time and money. In the English Legal System, there are far fewer copyright infringement cases than in the US. This might be because of the requirement on the

³¹⁴ *Hall v. Swift*, No. 18-55426, 2-3 (9th Cir. 2019); Amanda Holpuch, *Taylor Swift Copyright Lawsuit May Go to Trial Judge Rules*, N.Y. Times (December 10, 2021), <https://www.nytimes.com/2021/12/10/arts/music/taylor-swift-lawsuit-shake-it-off.html>.

³¹⁵ Oyewole v. Ora, 291 F. Supp. 3d 422, 436 (S.D.N.Y. 2018).

³¹⁶ Coe W. Ramsey & Amanda M. Whorton, *Music Law 101: What Does Copyright Law Protect?*, ReverbNation Blog (April 25, 2018), <https://blog.reverbNation.com/2018/04/25/music-law-101-what-does-copyright-law-protect>.

³¹⁷ *Newton v. Diamond*, 349 F.3d 591, 592 (9th Cir. 2003).

³¹⁸ Johannes Hoffman, *Breaking up Melodic Monopolies: A New Approach to Originality, Substantial Similarity, and Fair Use for Melodies in Pop Music*, 28 J.L. & POL'Y 762, 780 (2020).

³¹⁹ See *Skidmore v. Zeppelin*, Plaintiff's Complaint, (U.S. Dist. Court, Eastern Dist. of PA), <http://business.cch.com/ipld/zeppelincomplaint.pdf>.

losing party to pay the other party's court costs and attorney's fees.³²⁰ In the US as well, it has been decided in a case concerning infringement of musical work, that "*blatant disregard for the law warrants an award of cost and attorney's fee.*"³²¹ If such an approach can be a practise, it can help in reducing frivolous litigations in the first place.

A consolidated test was developed by the Second Circuit³²² and has been adopted by many other circuits as well. This approach combines the extrinsic-intrinsic approach to one single inquiry. While the lay observer test is similar to that of the Ninth Circuit, one distinct advantage of the consolidated approach is that there is no loss of information as can be observed while moving from the extrinsic test to the intrinsic test.³²³ Such a system can be adopted by the Ninth Circuit to deal with the issue of information flow between extrinsic and intrinsic tests. While the intrinsic test is said to be independent of the extrinsic test, there remains a need to communicate some findings from the extrinsic test to the next stage of intrinsic test. Similarly, there remains an issue with the court's analysis being entirely clouded by the extrinsic test. A simple consolidated approach can help resolve such issues. Further, a logical end-all solution to the problems explained above might be to consolidate extrinsic-intrinsic test to a single inquiry such that the judges and the experts can work together.

While the latest decision on the *Skidmore v. Zeppelin* has helped the Ninth Circuit to come halfway on the "stairway to better copyright protection", we can observe from the above texts that there are other shortcomings as well. Lack of court's experience and familiarity with musical copyright issues, along with unpredictability and biases of juries³²⁴ has led to contradictory and confusing results at the district court level. Judge Learned Hand had mentioned (although in relation to patent dispute) that "*I cannot stop without calling attention to the extraordinary condition of the law which makes it possible for a man without any knowledge of even the rudiments of chemistry to pass upon such questions as these.*"³²⁵ A similar situation can be seen in musical works, where juries and judges, unfamiliar with musical elements, have the authority to make decisions regarding their originality. Nearly all jurors face difficulty in separating and identifying protected and unprotected elements in a musical work's melody, harmony, genre, rhythm, chord structure, progression, etc.³²⁶ Therefore, the requirement of musical knowledge among judges and juries is important to decide on a copyright case. For example, in England, such cases were routinely put before Mr. Justice Whitford, who was an experienced musician, with

³²⁰ Landau and Biederman, *supra* note 104, at 729-731.

³²¹ *Tempo Music, Inc. v. Christenson Food & Mercantile Co.*, 806 F. Supp. 816, 821 (D. Minn. 1992).

³²² *Arnstein v. Porter*, 154 F.2d 464, 468 (2d Cir. 1946).

³²³ Springman, *supra* note 26, at 581.

³²⁴ Landau and Biederman, *supra* note 104, at 737.

³²⁵ *Parke Davis & Co. v. H.K. Mulford Co.*, 189 F.95, 115 (S.D.N.Y. 1911).

³²⁶ Springman, *supra* note 26, at 575.

knowledge both in law and music.³²⁷ Thus, education of music to a juror is a solution.³²⁸ In line with this suggestion, it can be said that the jury should be replaced with a panel of musicologists and music theorists.³²⁹ In addition, the “more discerning ordinary observer test” and consolidated approach can be introduced in the Ninth Circuit.

Establishing a uniform approach throughout the nation, for the determination of infringement of musical works is a logical solution.³³⁰ This further prevents the issue of forum shopping among the circuits.³³¹ The paramount goal of copyright law is to enhance predictability and certainty of copyright ownership,³³² and such uniformity can help towards this goal. The outcome of a copyright dispute was said to be difficult to predict when the inverse ratio rule and the idea-expression dichotomy came into play.³³³ Overruling such confusing judge-made law (i.e., the inverse ratio rule) has been welcomed. Even the Sixth Circuit has recently questioned the application of the inverse ratio rule.³³⁴ However, again, more clarity and certainty need to be brought in other tests and practices of the courts. Due to the presence of such unascertained practices in the courts, it can be observed that while the originality requirement for copyright protection is quite low, in the musical world, the requirement for originality is quite high which is akin to legal novelty,³³⁵ thus violating the basic principle of copyright law. However, it must also be noted that absolute test for infringement can only be a myth due to the very nature of musical works and thus, the aim should be to make the tests as certain as possible rather than aiming for absolute certainty.

³²⁷ Landau and Biederman, *supra* note 104, at 731.

³²⁸ See Maureen Baker, *La[w]: A Note to Follow So: Have We Forgotten the Federal Rules of Evidence in Music Plagiarism Cases?*, 65 S. CAL. L. REV. 1583, 1619 (1992).

³²⁹ Beiner, *supra* note 261, at 495.

³³⁰ Jamie Walsh, *No Justice for Johnson? A Proposal for Determining Substantial Similarity in Pop Music*, 16 DEPAUL-LCA J. ART & ENT. L. 261, 306 (2006).

³³¹ Nicole K. Roodhuyzen, *Do We Even Need a Test? A Reevaluation of Assessing Substantial Similarity in a Copyright Infringement Case*, 15 J.L. & POL'Y 1375, 1418 (2007).

³³² *Community for Creative Non-Violence v. Reid*, 490 U.S. 730, 749 (1989).

³³³ Anway, *supra* note 102, at 465 n.129.

³³⁴ Craig B. Whitney, *The Inverse Ratio Rule Maybe On Its “Last Legs” in the Sixth Circuit*, Mondaq (June 2, 2020), <https://www.mondaq.com/unitedstates/copyright/944892/the-inverse-ratio-rule-may-be-on-its-last-legs-in-the-sixth-circuit>.

³³⁵ See CRAIG JOYCE ET AL., COPYRIGHT LAW 84-86 (7th ed. 2007).

CIVIL LIABILITY IN THE PROCESSING AND PROTECTION OF PERSONAL DATA
BY AI APPLICATIONS IN EUROPE AND BRAZIL

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Abstract

Data processing operations can already be performed by AI (Artificial Intelligence) applications. Currently, the phenomenon of “robotic bosses” is already considered i.e., AI applications that are effectively responsible for managing customer data and deciding the best course of action for a given company or association. With the addition of data protection laws such as the Brazilian General Law on Personal Data Protection (LGPD) and the European General Data Protection Regulation (GDPR) this type of operation already fits into the functions of controllers and operators, who can be held legally responsible for their acts. In this sense, this article aims to verify, first of all, what these AI applications would be and, what are the attributions of data controllers and operators according to LGPD and GDPR. Soon afterwards, it will be verified the Civil Liability regime in Europe and Brazil regarding the topic in order to finally address what would be the civil liability of a non-human data processing agent. As a conclusion, it is clear that an AI application is just a tool and that the liability would fall on the natural person operator or controller, especially on the second.

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I. INTRODUCTION

By providing for significant administrative sanctions, such as fines of up to fifty million reais per violation in the case of the LGPD, the civil liability of data processing agents becomes the subject of relevant debate.

Regardless of the field, the use of artificial intelligence applications is growing considerably. However, when used for processing personal data, the application of AI brings with it not only the facilities of innovation but also the legal uncertainties of what is still considered a novelty.

Thus, since the law requires dialogue with other areas of science, it is imperative to understand what artificial intelligence is and how it works, and the first chapter will be dedicated to this subject. Next, we will address the data processing agents according to the Brazilian LGPD (Lei Geral de Proteção de Dados) and the GDPR (General Data Protection Regulation) of the European Union, thus exploring the roles and responsibilities of the controller and operator of personal data. In the third chapter, in a comparative analysis, we will seek to verify how civil liability occurs in Brazil and in European legislation, taking German law as a reference, considering the lack of a European civil law. Then, considering the previously exposed topics, we will present reflections about civil liability in cases which artificial intelligence appears as an agent of personal data treatment.

II. THE THREE ESSENTIAL ELEMENTS THAT MAKE UP AN AI APPLICATION: SOFTWARE, HARDWARE, AND DATA

In order to explore how an AI application could be used in personal data processing operations, it is necessary to first understand how such a program operates and what elements make its operation possible. A precise understanding of what Artificial Intelligence technology is all about is of fundamental importance to understanding some of the challenges its regulation presents.

Russell and Norvig, authors of one of the most cited books on AI,¹ define Artificial Intelligence as being “the study and design of intelligent agents, where an intelligent agent is a system that perceives its environment and performs actions that maximize its chances of success.”² Following this same line of thought, Kurzweil, a renowned American inventor and futurist, approaches this technology as being “the art of creating machines that perform functions that require

¹ STUART RUSSEL & PETER NORWIG, *ARTIFICIAL INTELLIGENCE: A MODERN APPROACH*, 4 PEARSON (2021).

² STUART J. RUSSELL & PETER NORWIG, *ARTIFICIAL INTELLIGENCE: A MODERN APPROACH*, 3 PRENTICE HALL (2010).

intelligence when performed by people.”³

These are just two of several definitions that this concept has and that has been gaining even more fame in recent times. However, the concept of Artificial Intelligence to be adopted for the purposes of the present paper is as follows:

It is an area of study focused on solving problems (or creating machines that perform this function) that previously only the human mind could answer. Thus, it is not possible to say that there is “one” or “the” Artificial Intelligence. What does exist is a number of different applications that make use of advanced technology in order to supplement the human reasoning capacity in one use or another.⁴

In other words, an Artificial Intelligence application is a program that runs on some kind of computer and emulates human reasoning based on the information it receives. We will see more about the elements that compose this type of application in the items below.

Within this area of study, there is also an important discussion about the distinction between the existing modalities of AI applications. In the existing literature on the subject, four types are popularly found: *narrow* as opposed to *general AI* and *weak* as opposed to *strong AI* (also called AGI: *Artificial General Intelligence*).

Teemu Roos says that *Narrow* refers to an AI application capable of performing a single task. *General*, on the other hand, would be a machine capable of handling any activity of the intellect. All Artificial Intelligence methods used today are characterized as *Narrow*.⁵ That is, they are applications that are programmed for a single purpose and can only execute that single purpose. *General AI*, which can perform any task regardless of whether it has been programmed or not, is in the realm of science fiction.

The dichotomy between *weak* and *strong*, on the other hand, can be narrowed down to the philosophical distinction between appearing intelligent through your actions and actually being intelligent, as problematized by the ‘Turing Test’.⁶ According to Teemu Roos, *strong AI* would amount to a genuinely intelligent and self-aware mind. *Weak AI*, on the other hand, would be what effectively exists, namely systems that exhibit intelligent behaviour despite being just computer applications.⁷

³ RAYMOND KURZWEIL, *THE AGE OF INTELLIGENT MACHINES* (MIT Press 1990).

⁴ Lukas Ruthes Gonçalves, *A Tutela Jurídica de Trabalhos Criativos Feitos por Aplicações de Inteligência Artificial no Brasil*, (MAR. 27, 2019) (unpublished M. Sc. dissertation, Universidade Federal do Paraná 2019), <https://bit.ly/2YLBgnN>.

⁵ ELEMENTS OF AI, <https://www.elementsofai.com> (last visited Aug. 18, 2018).

⁶ A.M. Turing, *Computing Machinery and Intelligence*, 59 MIND 433 (1950) (According to the Turing test, an interviewer would interrogate two players, a person and a computer, without knowing their identity, in order to determine if the computer could successfully make the interviewer think that it is human. If successful, this would be proof that a machine could indeed be endowed with intelligence).

⁷ ELEMENTS OF AI, *supra* note 5.

It is important to notice that “even if humanity is not close to developing an AGI that has its own consciousness, its application in a narrow way is already quite widespread in society, even if in a not so evident way”.⁸ Thus, this type of *narrow* application does not prevent existing programs from already having the ability to make decisions based on the information they receive, as will be discussed throughout this paper.

Examples of current uses of AI applications that are already having an effect on society and the contemporary business environment include selection and recruitment of candidates by analysing resumes of current employees, training employees from the use of AI applications in conjunction with augmented reality devices, managing repetitive activities to increase worker productivity, and monitoring the quantity and quality of work performed by employees through AI applications and IoT (Internet of Things) devices.⁹

Thus, the definition of AI was approached as being the area of study dedicated to creating devices that successfully emulate human reasoning, such as those that influence the process of hiring employees or helping a company to make decisions. Now we will talk about the main elements that enable the proper functioning of an application of this type, which are three: software, hardware, and data.

A. Software

To talk about software, let's first glance at another definition of AI. According to McCarthy, AI is the “theory and development of computer systems capable of performing tasks which would normally require human intelligence, such as visual perception, speech recognition, decision making, and translation between languages”.¹⁰ The key term in this definition is “computer systems”, which are nothing more than programs, or software composed of algorithms. The algorithm “is a set of mathematical instructions, a sequence of tasks to achieve an expected result in a limited amount of time”.¹¹ In other words:

Its existence is not necessarily linked to a computer or other electronic device, so that a cake recipe, for example, can be considered an algorithm for the physical world, because it is a series of instructions to achieve a certain end.¹²

According to Solomon Gandz, the term is also the Latinization of the name of a Persian

⁸ Gonçalves, *supra* note 4, at 35.

⁹ Bernard Marr, *Artificial Intelligence in the Workplace: How AI is Transforming your Employee Experience*, FORBES (MAY 29, 2019), <https://www.forbes.com/sites/bernardmarr/2019/05/29/artificial-intelligence-in-the-workplace-how-ai-is-transforming-your-employee-experience/#6f75fcb153ce>.

¹⁰ JOHN MCCARTHY ET. AL., PROPOSAL FOR THE DARTMOUTH SUMMER RESEARCH PROJECT ON ARTIFICIAL INTELLIGENCE (1955).

¹¹ Dora Kaufman, *Os meandros da Inteligência Artificial: conceitos-chave para leigos*, ASSOCIAÇÃO BRASILEIRA DE LAWTECHS & LEGALTECHS (FEB. 22, 2018), <https://ab2l.org.br/os-meandros-da-inteligencia-artificial-conceitos-chave-para-leigos/>.

¹² Gonçalves, *supra* note 4, at 44.

mathematician from the 9th century named Al-Khwārizmi, who taught in his works mathematical techniques to be solved manually, and was responsible for presenting the first solution of linear and quadratic equations.¹³

Turning to the field of computing, according to Cormen et al., an algorithm would be defined as “any well-defined computational procedure that takes some value or set of values as input and produces some value or set of values as output”.¹⁴

On this topic, it was previously stated:

Such a set of instructions that transforms a given input value into an output result can be realized through lines of code that when applied to a given machine perform specific actions. Such lines of code constitute, fundamentally, a computer program.¹⁵

When used in AI applications that draw on Machine Learning, one is looking for “algorithms that can learn and make predictions about data – these algorithms follow strictly static instructions when making predictions or decisions based on data by building a model from sample inputs”.¹⁶

In other words, AI applications that make use of the Machine Learning techniques are computer programs that produce a certain output value that emulates human reasoning based on the information provided to it as input value. This means that the way in which such an application receives and manages this data that serves as *input* is extremely important, as will be seen below.

From the application of the Machine Learning technique has developed a new, more complex programming modality called *Deep Learning*. It uses artificial neural networks (simplified simulations of how biological neurons behave) to extract rules and patterns from given data sets.¹⁷

This technology consists of a series of neuron-like units that combine a series of input values to produce an output value. This output, in turn, is also passed to other neural units, following a chain.¹⁸ Thus, “an application using *Deep Learning* will, in the first step, analyse a sequence of data to arrive at a certain pattern; it will then pass that pattern through a second layer of analysis to arrive at a more refined pattern, and so on”.¹⁹

Temu Roos states that it is precisely this depth of layers that allows the network to learn more

¹³ Solomon Gandz, *The Origin of the Term “Algebra”*, 33 AM. MATHEMATICAL MONTHLY 437 (1926).

¹⁴ THOMAS H. CORMEN ET. AL, ALGORITMOS TEORIA E PRÁTICA 3 (Vandenberg D. de Souza trans., Campus 2nd ed. 2002).

¹⁵ Gonçalves, *supra* note 4, at 45.

¹⁶ Kaufman, *supra* note 11.

¹⁷ *How Machine Learning Works*, THE ECONOMIST (MAY 14, 2015), <https://www.economist.com/the-economist-explains/2015/05/13/how-machine-learning-works?fsrc=scn/fb/te/bl/ed/>.

¹⁸ NAT’L SCI. AND TECH. COUNCIL, PREPARING FOR THE FUTURE OF ARTIFICIAL INTELLIGENCE, at 9 (2016). National Science and Technology Council. Washington, D.C. 20502, p. 9.

¹⁹ Gonçalves, *supra* note 4, at 46.

complex structures without requiring unreasonably excessive amounts of data. Furthermore, the author points out that another big reason for building artificial neural networks would be to use the biological systems present in humans as inspiration to program better AI programs. According to him:

The case of neural networks in general, as an AI approach, is based on an argument similar to that of logic-based approaches. In the latter case, it was thought that in order to achieve human-level intelligence, we need to simulate higher-level thought processes and, in particular, the manipulation of symbols representing certain concrete or abstract concepts using logical rules.²⁰

In summary, we showed that an Artificial Intelligence application consists of software, whose algorithm is made by means of techniques that best emulate human thinking (*Machine Learning* and *Deep Learning*). It is now necessary to verify where this type of program is executed to have an effect in the physical world.

B. Hardware

Hans Moravec makes an analogy that an AI application would need computing power in the same way that airplanes need horsepower. Below a certain threshold the technology would not work, but as the power increases the task becomes easier. In this sense the area of hardware is one that is, fortunately, constantly improving.²¹

Companies like Microsoft have been developing so-called Quantum Computers, which promise to considerably improve the analysis capacity that current machines allow.²² For comparison “in 1997, IBM’s Deep Blue analysed 200 million moves per second to outperform chess champion Garry Kasparov. A quantum machine, on the other hand, would be able to analyse 1 trillion moves every second.”²³

This is because the difference would be in the way a quantum computer works.²⁴ An analysis made by the quantum computing team at Microsoft states that the processing in a traditional computer occurs in a binary way, with information being transmitted from *bits* that can only have a binary value of 0 or 1, which limits the processing capacity. In quantum computing, a *quantum bit* can hold both values at the same time, which is called a superposition state, and this allows the

²⁰ ELEMENTS OF AI, *supra* note 5.

²¹ Hans Moravec, The Role of Raw Power in Intelligence (May 12, 1976) (unpublished manuscript), <https://frc.ri.cmu.edu/~hpm/project.archive/general.articles/1975/Raw.Power.html>.

²² Gonçalves, *supra* note 5, at 49.

²³ Filipe Garrett, *Computador e processador quântico: sete coisas que você precisa saber*, TECHTUDO (MAR. 26, 2018), <https://www.techtudo.com.br/noticias/2018/03/computador-e-processador-quantico-sete-coisas-que-voce-precisa-saber.ghml>.

²⁴ Gonçalves, *supra* note 4, at 49-50.

processing speed to be vastly superior compared to traditional computers.²⁵

Faster Hardware would also make it possible to solve another technological barrier explained by what is called the Moravec Paradox. This is the observation “that complex mental problems require low computational capacity to be replicated and that motor activities of low degree of complexity (such as holding a glass) would, conversely, require enormous resources.”²⁶ According to Moravec:

It is comparatively easy to make computers exhibit adult-level performance in intelligence tests or playing checkers, and difficult or impossible to give them the skills of a one-year-old child when it comes to perception and mobility.²⁷

This difficulty is justified “by the fact that these apparently simpler activities require a large amount of data to be performed, but that are not perceived by the human consciousness”.²⁸ However, for activities that are considered complex, such as information analysis and classification, fortunately the amount and type of data required becomes easier to assess, which makes personal data management operations, for example, easier for AI applications to perform.

C. Data and Information

In addition to advances in computer technology, in the form of software and hardware as stated above, it is necessary for the AI application to have the information needed to produce a certain result. The greater the quantity and quality of data, the better the result in information obtained by a *Machine Learning* program. Pamela McCorduck reported that AI researchers began to suspect that intelligence could very well be based on the ability to use large amounts of different knowledge in different ways.²⁹

Russell and Norvig report that during the 60-year history of computer science, from 1950 until approximately 2010, efforts had been much more focused on the algorithm as an object of study. However, according to them, recent studies in the field of AI reveal that for many problems it would be better to worry more about the data collected than about the criteria about which algorithm to apply. This would be due to the large availability of databases on the Internet.³⁰

These same authors cite a paper by David Yarowsky from the year 1995 on the importance of

²⁵ Microsoft Quantum Team, *The Microsoft approach to quantum computing*, MICROSOFT QUANTUM BLOG (JUNE 6, 2018), <https://cloudblogs.microsoft.com/quantum/2018/06/06/the-microsoft-approach-to-quantum-computing>.

²⁶ Gonçalves, *supra* note 4, at 48.

²⁷ HANS MORAVEC, MIND CHILDREN: THE FUTURE OF ROBOT AND HUMAN INTELLIGENCE 15 (Harvard Univ. Press 1988).

²⁸ Gonçalves, *supra* note 4, at 49.

²⁹ PAMELA MCCORDUCK, MACHINES WHO THINK: A PERSONAL INQUIRY INTO THE HISTORY AND PROSPECTS OF ARTIFICIAL 299 (A K Peters Ltd. 2nd ed. 2004).

³⁰ RUSSELL & NORVIG, *supra* note 2, at 27.

greater data availability for Artificial Intelligence applications. The problem addressed by Yarowski, the authors report, was: given the use of the word ‘plant’ in a sentence, would it refer to flora or a factory? Previous approaches to this question made use of human-labelled examples combined with *machine learning* algorithms. Yarowsky demonstrated that the task could be performed, with over 96% accuracy, without any data selected and classified by humans. Russell and Norvig say that by giving an AI application a large amount of unedited text and only the dictionary definitions of both senses of the word ‘plant’ (‘works, industrial complex’ and ‘flora, plant life’), it was already possible to label the given examples and from that point on only modify the algorithm to learn new patterns that would help identify new examples.³¹

Banko and Brill have a 2001 text of their own also cited by Russell and Norvig in stating that techniques, like the one demonstrated above, perform even better as the available amount of text goes from one million to one billion words. Further, they emphasize that this increase in performance, from using more data, would exceed any difference in the choice of algorithm.

Further, Banko and Brill attest that a low complexity algorithm that has access to an unlabelled training database of 100 million words performs better than a more advanced algorithm with only 1 million words as *input*.³²

How an AI application makes use of databases is a very important issue, because with laws like LGPD and GDPR the controllers and operators of the data are the ones legally responsible for its use. Perna Sindwani mentions a study by Infosys and Gaertner that predicts in the future several offices eliminating the management function of several companies. Perna’s report mentions that fewer managers will be needed as many of their tasks include data collection, supervision, and compliance actions, which could be completed by AI applications.³³

From this, we demonstrate how fundamental it is to understand exactly what the roles of the controller and the operator are according to LGPD and GDPR. This allows a better investigation of the civil liability of operators of the type dealing with AI applications.

III. DATA PROCESSING AGENTS IN ACCORDANCE WITH LGPD/GDPR

There is no single definition for what is meant by data processing, since both legislations, LGPD³⁴ and GDPR³⁵, provide, in a list of examples, several actions³⁶ for its definition, which can be

³¹ *Id.*

³² *Id.* at 28.

³³ Perna Sindwani, *The Boss Machine is Here – AI is set to Eliminate Middle Management in 8 Years*, BUSINESS INSIDER INDIA (JAN. 21, 2020), <https://www.businessinsider.in/careers/news/the-boss-machine-is-here-ai-is-all-set-to-eliminate-middle-managers-in-8-years/articleshow/73474729.cms>.

³⁴ Lei No. 13.709, de 14 de Agosto de 2018.

³⁵ 2016 O.J. (L 119) 1.

³⁶ Lei No. 13.709, de 14 de Agosto de 2018, art. 5 (For the purposes of this Law, it is considered: X - treatment: any operation

summarized as any operation performed with personal data.

Thus, it is also defined to whom such processing functions are foreseen. In the case of Brazil and the European Union, it is the role of controller and operator, whose Brazilian legislation, strongly inspired by the European legislation, defines respectively as: natural or legal person, of public or private law, who is in charge of the decisions regarding the treatment of personal data; and natural or legal person, of public or private law, who carries out the treatment of personal data on behalf of the controller. To clarify, one can very briefly say that the data controller determines if and how the data processing will be carried out. The operator, on the other hand, performs the action relating to the processing.

Thus, there is a close link between the two data processing agents, especially with respect to the actions of the operator on behalf of the controller. Furthermore, it is pointed out the possibility of confusion of roles between agents, as the same person may be responsible for making the decision and executing it. As a result, we will analyse both agents at the same time in the European and Brazilian legislation.

A. Controller and Operator in GDPR

With more than 25 years of experience in the legal protection of personal data, the European Union has developed its protective system, as well as some concepts previously provided for. However, the definitions of *controller* and *processor*— figures imported by the Brazilian legal system as controller and operator — were brought by Directive 95/46/EC and substantially maintained by the GDPR. To better understand the content of this text, we will opt to treat such figures according to Brazilian law i.e., controller and operator.

Thus, European law defines a controller as a natural or legal person, public authority, agency, or other body which alone or jointly with others determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria applicable to its appointment may be provided for by Union or Member State law. In the same vein, it defines a processor as a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller. Then, it is understood that both the controller and the operator may be natural persons or legal entities.

Even before defining who they may be and the duties of the controller and operator, the GDPR lists several recitals that not only observe the peculiarities that underlie the relationship of the

performed with personal data, such as those related to collection, production, reception, classification, use, access, reproduction, transmission, distribution, processing, filing, storage, elimination, evaluation or control of information, modification, communication, transfer, dissemination, or extraction).

European Union with its Member States, but already impose responsibilities to the controller. Three examples are Recital 39, which provides for the duty of the controller to set time limits for erasure or periodic review of data retention, so that it occurs only as long as necessary; Recital 42, which provides that for the data subject's consent to be knowingly given, the data subject should at least know the identity of the controller and the purposes of the processing; and Recital 59, by which the controller should be obliged to respond to requests from the data subject without undue delay and at the latest within one month, and give reasons when he intends to refuse the request.

Also, throughout the regulation, the rights and duties of the controller are sparsely attributed, such as conditions applicable to consent, information to be provided when personal data are or are not collected from the data subject, provisions concerning the legitimate interest of the controller, the duty to rectify inaccurate data, among others. However, by devoting Chapter 4 to the roles of controller and operator, the regulation provides separately for the responsibilities of each.

As stated in Article 24, considering the scope, context and purposes of the data processing, as well as the risks to the rights and freedoms of natural persons, the likelihood and severity of which may vary, the controller shall implement appropriate technical and organizational measures to ensure and to be able to demonstrate that the processing is performed in accordance with the GDPR. Such measures shall be reviewed and updated as necessary and if proportionate in relation to the processing activities, these include the implementation of appropriate data protection policies by the controller. In addition, the controller may demonstrate compliance with its obligations through compliance with approved codes of conduct under Article 40 or approved certification procedures under Article 42.

There is also provision for so-called data protection *by design* and *by default*. In broad terms, this refers to the moment when the appropriate technical and organizational measures, such as pseudonymization, are applied to the processing of the data by the controller, which may be at the moment of definition (*by design*) or during the processing itself (*by default*).

The controller may choose to determine the grounds and means for processing the personal data unilaterally or jointly with other controllers. When jointly, controllers may agree on their respective responsibilities to carry out data processing under the GDPR, which does not prevent the data subject from exercising his or her right against any of the controllers.

Also, the controller acts with the figure of the operator. The operator must provide sufficient guarantees to implement appropriate technical and organizational measures so that the processing of data meets the requirements of the GDPR and ensures the protection of the rights of the data subject. In broad terms, the operator is the one who, as a natural or legal person, acts on

behalf of and subordinated to the controller. For instance, one can imagine a gym that hires a local print shop to produce invitations for an event to be held by the gym, which provides the print shop with the names and addresses for the invitations and envelopes to then send them out. In this case, the gym is the controller of the personal data processed with the invitations, it determines the purposes for which the personal data is processed, which is to send the invitations individually to each address, and it also determines the means by which the processing occurs, by linking the personal data to the detailed address for each individual member of the academy. Thus, the printer is the operator handling the personal data only on instruction of the gym as controller.³⁷

According to the European regulation, the operator may, with the express authorization of the controller, contract another operator. Thus, both the operator-operator relationship and the controller-operator relationship are conditioned to the formalization of a contract or other binding legal instrument in writing. Regarding the content of the controller-operator contract, the instrument must provide that, unless legally obliged to do otherwise, the operator processes personal data only upon documented instructions from the controller, including with regard to data transfers to third countries or international organizations. It must also contribute to audits and provide assistance to the controller to ensure that its obligations are met, and it must delete or return all personal data to the controller after completion of the service provided. Finally, with the GDPR, the European legal system reinforces the importance and responsibilities of the controller and the operator, key figures for the identification and notification of cases of personal data breaches.

B. Controller and Operator in LGPD

The LGPD provides the hypotheses of data processing exhaustively, with regard to the controller, we emphasize the possibility when necessary for the fulfilment of its legal or regulatory obligation, as well as when necessary to meet its legitimate interests or those of third parties, except in the event that the fundamental rights and freedoms of the data subject prevail and require the protection of personal data. Thus, none of these hypotheses, including and especially the legitimate interest of the controller, can be understood as an authorization without consequences for the processing of the data. The eventual waiver of the consent requirement does not exempt the processing agents from the other obligations provided by law, especially the observance of general principles, such as necessity, and the guarantee of the data subject's rights.

Chapter VI is exclusively dedicated to the provisions concerning the personal data processing

³⁷ *How do you determine whether you are a controller or processor?*, INFORMATION COMMISSIONER'S OFFICE, <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/controllers-and-processors/how-do-you-determine-whether-you-are-a-controller-or-processor> (last visited Sept. 22, 2020).

agents, which, in the style of European regulation, are the figures of controller and operator. However, despite the strong inspiration of the LGPD in the GDPR, it can be said that the former was much more succinct in addressing the topic, having only 4 articles, excluding the section on the data controller and the section on liability and compensation for damages.

In general terms, the law states that agents must keep a record of their personal data processing operations, especially when based on legitimate interest, and it is the controller's responsibility, when determined by the national authority, to prepare the personal data protection impact report when processed (containing, at least, a description of the types of data collected, the methodology used to collect and ensure the security of the information, and the controller's analysis of the measures, safeguards, and risk mitigation mechanisms adopted).

Finally, with respect to the controller-operator relationship, the LGPD provides for the subordination of the operator to the controller, who must perform the processing according to the instructions provided by the controller, who will verify compliance with its instructions and the rules on the matter. Next, the legislation addresses the figure of the data controller and the liability and compensation for damages, ending the chapter on personal data controllers.

In this way, the confusion presented at the beginning of the chapter of this study may end up being accentuated when processing is carried out based on the LGPD, since, unlike the GDPR, the chapter of the law dedicated to personal data processing agents does not clearly present the distinctions, and, in fact, the responsibilities of each agent.

As a possible solution to the lack of legal clarity concerning the attributions and the binding of the operator to the controller, we suggest a contractual formalization, or other legal path, that expressly and objectively regulates this relationship.

IV. CIVIL LIABILITY OF THE AI CONTROLLER AND OPERATOR IN DATA PROCESSING

Technological evolution is the result of the human quest for ways to simplify his life so that he can change the focus of his attention, one of the greatest examples of this being the automation of vehicles. By not worrying about the direction of the vehicle, the driver can become almost a passenger, depending on the level of autonomy of the vehicle, and can, for example, turn his attention to reading or even sleeping. The fact is that the goal of developing artificial intelligence is closely linked to its use as a tool to increase the quality of life of human beings.

Thus, the processing of personal data performed with the aid of artificial intelligence may challenge the identification of the subject to be held liable in cases of violation of personal data protection legislation.

Since there is no legal provision in the Brazilian legal system that attributes civil liability to

artificial intelligence, the comparative study serves as clarification and perhaps guidance. When it comes to protection of personal data, it is natural to compare Brazilian legislation to European

legislation. It so happens that, as far as civil law is concerned, Europe has no unified legislation. Thus, since “the classification of the branches of Civil Law is based on the so-called Germanic classification”, the German Civil Code will be used as a comparative basis.³⁸

A. Objective liability in Europe and Brazil

Regarding strict liability in Europe, Ascensão comments that “we cannot speak of a European Civil Law and even less the intention of creating a European Civil Code. The existence of the European Union does not mean that there is a European Law”.³⁹ For this reason, as emphasized by Ascensão above, “who appears as forming the principles of European Law is German Law”.⁴⁰

In this line, “The German private law that we have today had its outlines more clearly delineated from 1900, when the German Civil Code (Bürgerliches Gesetzbuch – “BGB”) came into force”.⁴¹ Thatiane Pires states that the BGB would comprise not one, but three general clauses of Aquilian civil liability.⁴² That is, the type of objective civil liability arising from non-compliance with legal norms, the focus of this work.

The first of these is a clause about the violation of subjective rights, whose scope is given by §823 I BGB which, according to the translation of Pires provides: “He who maliciously or negligently injures in an unlawful manner the life, body, health, liberty, freedom, property or another right of someone, is obliged before him to compensation for the resulting damage.”⁴³

The second general clause refers to liability for the violation of an objective right, provided in §823 II BGB. According to Pires, this clause imposes an obligation to indemnify anyone who violates a rule designed to protect others. The same author also brings the translation of the quoted § II: “The same obligation is imposed on the one who violates a law that is intended for the protection of others. If, according to the content of the law, violation is possible even without fault, then the obligation to indemnify is only imposed in case of fault”.⁴⁴

Finally, the third general clause is found in § 826 BGB, which, according to Pires “obliges to

³⁸ JOSÉ DE OLIVEIRA ASCENSÃO, DIREITO CIVIL: TEORIA GERAL (INTRODUÇÃO, AS PESSOAS, OS BENS) 16 (Saraiva 3rd ed. 2010).

³⁹ Oliveira Ascensão traça um panorama do Direito Civil europeu, CONSELHO DA JUSTIÇA FEDERAL (NOV. 9, 2011), <https://www.cjf.jus.br/cjf/noticias/2011/novembro/oliveira-ascensao-traca-um-panorama-do-direito-civil-europeu>.

⁴⁰ *Id.*

⁴¹ Thatiane Cristina Fontão Pires, *Desenvolvimento e aplicação da compensatio lucri cum damno no Direito Alemão: o problema da cumulação da indenização civil com as vantagens advindas do evento* 95 (11 Feb. 2019, Universidade Federal de Santa Catarina) (unpublished LL.M. dissertation), <https://bit.ly/3vjfmrM>.

⁴² *Id.* at 101.

⁴³ *Id.*

⁴⁴ *Id.* at 101-102.

indemnify the person responsible for causing damage to another maliciously and contrary to good morals”.⁴⁵ The translation of the legal norm, according to the author, thus states: “He who, contrary to good customs, maliciously causes damage to another, is obliged, before the latter, to repair the damage”.

The German Civil Law provides for both objective and subjective civil liability. Similarly, in Brazil, where, according to articles 186 and 927, the obligation to repair occurs as a result of the commission of an illicit act i.e., violation and damage to others by action or voluntary omission, negligence or imprudence.

Thus, the Brazilian legislator’s preference for subjective civil liability is verified, requiring the characterization of malice or fault. The latter can be of the following types: i) recklessness – a commissive act, in which the subject has no intention of violating the law, but by acting with disregard for the duty of care, must be held liable; ii) inexcusiveness – similar to recklessness, but the duty of care is expected due to the subject’s expertise; iii) negligence – an omissive act, in which the subject fails to act and, consequently, causes damage to others.

By exception, the objective civil liability is timidly observed in the Brazilian Civil Code, although reinforced later by the Consumer Protection Code and taken as correction of the classical and unsatisfactory concept of guilt already outdated.⁴⁶ Reinforcing the concern, still current, and pointing out the challenges of modern society, Sergio Cavalieri Filho states that

“According to this classical conception, however, the victim will only obtain reparation for the damage if he proves the agent’s guilt, which is not always possible in modern society. Industrial development, provided by the advent of machinery and other technological inventions, as well as population growth, generated new situations that could not be supported by the traditional concept of fault”.⁴⁷

In this way, the configuration of liability occurs by the sum of the causal connection to the damage, dispensing with the proof of wilful misconduct or guilt. It is the option of the agent to exercise the activity independently of risk, in this sense, Caio Mário:

In terms of civil responsibility, risk has a special meaning, and civil doctrine has been projecting itself upon it since the last century, with the objective of erecting it as a foundation for the duty to repair, with a view to exclusivity, or with the extremization of the theory itself, opposed to guilt.⁴⁸

This paper does not intend to exhaust the theories of civil liability; however, it argues that,

⁴⁵ *Id.* at 102.

⁴⁶ WILSON MELO DA SILVA, *RESPONSABILIDADE SEM CULPA* 104 (Saraiva 1974), SERGIO CAVALIERI FILHO, *PROGRAMA DE RESPONSABILIDADE CIVIL* (Malheiros 3rd ed. 2002).

⁴⁷ SERGIO CAVALIERI FILHO, *PROGRAMA DE RESPONSABILIDADE CIVIL* 16 (Malheiros 3rd ed. 2002).

⁴⁸ CAIO MÁRIO DA SILVA PEREIRA, *CIVIL RESPONSABILIDADE* (Forense 9th ed. 2001).

although the Brazilian system is mixed and encompasses both objective and subjective civil liability, reparation for damages should not depend on the victim's ability to prove the agent's guilt.

As far as the regulation of civil liability in Brazil and Germany is concerned, both normative systems adopt the subjective and objective possibility, to be analysed on a case-by-case basis.

Thus, considering the provision of the sole paragraph of art. 927 of the Brazilian Civil Code that: "There will be an obligation to repair the damage, regardless of fault, in cases specified in law, or when the activity normally developed by the author of the damage implies, by its nature, risk to the rights of others", it is clear the need for the verification of the legal provision or practical situation that justifies the application of strict liability in cases of violation of rights in the treatment of personal data.

B. Liability under LGPD and GDPR

At the European level, Article 82(1) of the GDPR makes its link to Aquilian civil liability clear by stating that "any person who has suffered material or non-material damage as a result of an infringement of this Regulation shall have the right to receive compensation from the controller or processor for the damage suffered".

The law continues in subsection 2 of the same article that any controller "involved in processing shall be liable for the damage caused by processing which infringes this Regulation". The operator is only liable for the damage caused by the processing if he has not complied with the legal provisions concerning the specific obligations of the operator or if he has not followed the lawful instructions of the controller.

Finally, the law clarifies in section 82(3) that the controller or processor is exempt from liability if it proves that it is not in any way responsible for the event giving rise to the damage. This means that the law takes a more objective liability approach for data controllers, as specifically provided in §§ I and II of Article 823 of the BGB. However, the GDPR leaves room to produce evidence to the contrary that may exonerate these agents in the event of any type of damaging event to the owner of the information used.

The provisions about civil liability according to the LGPD can be found in its Section III of Chapter IV, between articles 42 and 45. Mendes and Doneda discuss this topic:

The consideration of the liability of agents takes into account, first of all, the nature of the data processing activity, which the LGPD seeks to restrict to hypotheses with legal grounds (art. 7) and that do not comprise more data than strictly necessary (principle of purpose, art. 6, III) nor are inappropriate or disproportionate in relation to their

purpose (art. 6, II).⁴⁹

In this sense, article 42 of the LGPD provides that “the controller or operator that, due to the exercise of activities involving the processing of personal data, causes to another individual or collective damage to property or morals, in violation of the legislation for the protection of personal data, is obliged to repair it”. Along the same lines, and like the GDPR, the LGPD in its article 42, § 1, clause I, provides

I – The operator is jointly and severally liable for damages caused by the processing when it fails to comply with the obligations of the data protection legislation or when it has not followed the lawful instructions of the controller, in which case the operator is equivalent to the controller, except in the cases of exclusion provided for in art. 43 of this Law.

Finally, the hypotheses in Article 43 of the LGPD in which processors will not be held liable occur when they prove:

I – that they have not carried out the processing of personal data attributed to them; II - that, although they have carried out the processing of personal data attributed to them, there has been no violation of the data protection legislation; or III - that the damage arises from the exclusive fault of the data subject or a third party.

As a result of the way the LGPD was codified, Mendes and Doneda argue that this justifies “the legislator opting for a regime of objective liability in art. 42, linking the obligation to repair the damage to the exercise of personal data processing activity.”⁵⁰ Such liability regime is the same that can be observed in the GDPR, as shown above.

In this sense, it is worth checking how responsibility would be assigned to a controller or operator that is an Artificial Intelligence application. Being a program of this type i.e., dependent on its algorithm, could the way such an application performs processing tasks be programmed in the machine? Sniesko and Melo when dealing with legitimate use bring an equation regarding legitimate use:

i) If $(Prp)Purpose > (NT)Treatment\ Need + (DT)Holder\ Rights$ ∴ by choosing the legitimate interest, there is a risk assumption by the controller

ii) If $(Prp) \leq (NT) + (DT)$ ∴ there is a chance of more comfortable processing of personal data, drawing on legitimate interest.⁵¹

⁴⁹ Laura Schertel Mendes & Danilo Doneda, *Reflexões Iniciais Sobre A Nova Lei Geral De Proteção De Dados*, 120REVISTA DE DIREITO DO CONSUMIDOR., 469, 476 (2018).

⁵⁰ *Id.* at 477.

⁵¹ Thiago Reyes Sniesko & Leonardo Albuquerque Melo, *Equacionando o legítimo interesse na LGPD*, LEE, BROCK, CAMARGO ADVOGADOS (JULY 22, 2020), <https://bit.ly/3lBbScE>.

According to the authors, this means that verified “in case, that the Purpose is greater than the Need plus the Rights of the data subject (...), availing oneself of legitimate interest would imply a more fragile scenario for the controller”. In this way, the creation of a series of instructions for the treatment of the data is already proposed, and that is an algorithm.

Thus, as shown above, if the operator acts without guidance from the controller, determining whether and how to handle certain data, with respect to that specific data, the operator acts and will respond as if it were the controller. Whereas, due to the technological level of certain AI applications, it is possible for them to operate in ways that are not expected, and the legal challenge is to correctly and fairly find whom to hold accountable, by checking how one would hold accountable a non-human agent that could perform such operations.

C. The Liability of the AI application performing data processing operations

There are already computer programs that monitor cleaners, telling them which hotel room to clean and measuring how fast they do it. Just as there are already AI applications that check how many mouse clicks or calls a telemarketer makes per hour. While automated trucks are on the horizon, robots have already arrived in the role of supervisors and company managers.⁵²

They do this through the techniques discussed above: software programmed with *machine* or *deep learning* techniques that use data to determine the best solution to a given problem, all as governed in their code. With these programs, customer and employee data is collected and interpreted with the aim of optimizing the relationship between the parties.

Even if this is done by an AI application and in some cases, it is the program itself that determines, for example, how many deliveries an Amazon worker should make per hour with the addition of the LGPD and the GDPR, it becomes impossible to stop attributing the responsibility to a human operator or controller.⁵³ This is because these applications rely on the interpretation of collected data and if this data is personal, it will be covered by both laws.

On this subject, Dzieza further comments that a version of these systems that collects data from the workplace in an anonymous matter could be imagined: “Such a system would have some of the efficiencies that make these systems attractive, while avoiding individualized workers being inconvenienced”. The author recognizes that this would mean giving up potentially valuable data but ponders that “there is sometimes value in not collecting data, as a means of preserving space for human autonomy”.⁵⁴

⁵² Josh Dzieza, *How Hard will the Robots Make Us Work?*, THE VERGE (FEB. 27, 2020), <https://www.theverge.com/2020/2/27/21155254/automation-robots-unemployment-jobs-vs-human-google-amazon>.

⁵³ *Id.*

⁵⁴ *Id.*

That is, if there is no such concern with anonymization, the rules of the personal data protection laws apply, because after all, the application of Artificial Intelligence is only a tool. The responsibility, in the objective case as noted above, will fall on the controller and, secondarily, on the data operator. Regarding the importance that the operating system may have for the definition of the agent's role in data processing, therefore, also its liability, the ICO would already say:

If you are acting as both controller and operator, you must ensure that your systems and procedures distinguish between the personal data you process in your capacity as controller and that which you process as an operator on behalf of another controller. If some of the data is the same, your systems should be able to distinguish between these two capacities, and allow you to apply different processes and measures to each. If you cannot do this, you are likely to be considered a joint controller rather than an operator for the data you process on behalf of your customer.⁵⁵

In order to harmonize the use of AI with the processing of personal data in a secure manner, one can draw on the teachings of the Brazilian authors Teffé and Medon, who state that “ethical principles, technical standards, and less closed structure standards will help ensure that the design and development of such technologies are guided by concern for the human person and seek to promote safe, just, and inclusive AI”.⁵⁶

In short, even if use is made of artificial intelligence applications, damages resulting from violations of rights in the treatment of personal data, as well as all other damages, must be remedied. In this sense, Facchini Neto states:

“The fact is that the theory of tort liability includes both fault and risk. Both are to be regarded not as the very foundation of tort liability, but as merely technical procedures which can be used to ensure that victims are entitled to compensation for damage unjustly suffered. Where the subjective theory cannot explain and support the right to compensation, the objective theory should be used. This is because, in a truly just society, all damage must be compensated.”⁵⁷

With regard to civil liability under the application of AI as controller or operator, the conclusion is that AI should be understood as a mere tool to assist data processing agents. Thus, availing itself of the objective theory of civil liability, even though lacking guilt, it is an activity in which both controller and operator assume the risks of their acts and of the execution of the tools they choose to use. Therefore, with regard to civil liability, the agents must observe the effective compliance with the principles legally provided. This must occur both *a priori*, in compliance with the principle of

⁵⁵ INFORMATION COMMISSIONER'S OFFICE, *supra* note 37.

⁵⁶ Chiara Spadaccini de Teffé & Felipe Medon, *Responsabilidade Civil e Regulação de Novas Tecnologias: Questões Acerca da Utilização de Inteligência Artificial na Tomada de Decisões Empresariais*, 6 REVISTA ESTUDOS INSTITUCIONAIS 301, 304 (2020).

⁵⁷ Eugênio Facchini Neto, *Da responsabilidade civil no novo código*, O NOVO CÓDIGO CIVIL E A CONSTITUIÇÃO 160-161 (Ingo Wolfgang Sarlet ed., Livraria do Advogado 1st ed 2003).

prevention, and *a posteriori*, in light of accountability, in order to demonstrate the adoption of effective measures, in addition to the observance and compliance with the rules of personal data protection.

V. CONCLUSION

Artificial Intelligence applications are true technological marvels that revolutionize the way our civilization performs all kinds of activities, from vehicle automation to business management tasks. That said, they are still tools, which are put into operation under the orders of a human controller.

In this sense, item 1 of this work approached the operation of an application of this type. AI was defined as the area of study focused on developing machines capable of emulating human reasoning, and the three elements that would be necessary for its proper functioning were addressed. The first of these would be the *software*, its programming, which determines what the application will perform and that can be accomplished through techniques such as machine learning or deep learning. The second element is the *hardware*, which is where the computer program is executed. Finally, the last element is data, which works as the *input* needed for the AI application to produce a certain *output*.

In the case of data, with them being personal, it falls under the regency of LGPD and the GDPR, the most recent laws addressing data processing operations and the topic of section 2 of this paper. They attribute responsibility to those who carry out data processing operations and attribute in particular two roles: controller and operator. The controller is the natural or legal person who determines the purposes and means of the processing of personal data, while the operator is the person who processes personal data on behalf of the data controller.

Since both the controller and the operator are natural or legal persons, the law also attributes them a civil liability regime, as seen in item 3. In an analysis of the Brazilian and European legislation it was noted that the applicable law to these agents would be strict liability. That is, it would be enough for the owner of the data to prove a harmful act in order to be able to claim for compensation. In this item, it was also seen that the acts practiced by an AI application that acts as a data operator or controller would still have to have its liability attributed to a natural or legal person.

Although revolutionary tools, AI applications are still instruments of data processing agents. They already have a very large capacity to manage, classify, and change the data they receive, but the current legislation is not open for any other type of civil liability than that of agents and operators who are natural or legal persons.

The very fact that liability is objective already indicates that it is a company or a member thereof that will suffer the consequences for the misuse of the tool. One could only glimpse the possibility of these AI applications having some kind of liability if they effectively reached the singularity and fought for their rights.

This was the conclusion reached in this article, but it is recognized that this is a very recent topic and, especially with these new technologies, it is unfeasible to limit the vision to only one type of protection. We hope this article will make a relevant contribution to a subject that still requires much reflection.

GLOSSARY OF ACRONYMS

BGB - Bürgerliches Gesetzbuch (German Civil Code) AI -

Artificial Intelligence

AGI - Artificial General Intelligence

LGPD - Brazilian General Law of Data Protection GDPR

- European General Data Protection Regulation

THE TRIPS WAIVER: TEXTS, CONTEXT AND POLITICS AT THE WTO

SHANTANU SINGH*

Abstract

On October 4, 2020, India and South Africa circulated the 'TRIPS Waiver' proposal at the World Trade Organization ("WTO"). This proposal, co-sponsored by 64 WTO members, aims to achieve a temporary waiver of certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). However, since WTO practice on waivers requires consensus among members, the proposal has been subject to vigorous debate and opposition from others. This article provides a stock-take of the Waiver debate by mapping the submissions, interventions and proposals made by members in the TRIPS Council during course of the debate. Understanding these discussions is of great significance a time when international intellectual property ("IP") rights are being held up as a barrier for increasing vaccine production and distribution. An overview of these discussions shows that inoperability of the in-built TRIPS flexibilities has been a key motivator for moving the waiver proposal, which presents a 'high-demand ask'. Given this context, this article highlights the negotiating positions and strategies adopted by members before and after tabling of the proposal and how these positions have evolved over time as we approach the WTO's twelfth Ministerial Conference.

I. INTRODUCTION

When Germany's Chancellor Angela Merkel and American President Joe Biden met for a bilateral summit in July 2021, not many expected them to disagree on the task of charting a concerted effort against the COVID-19 pandemic. Rightfully so: were one to read through the transcript of the President's remarks on the summit,¹ it all seemed to be under control. Why then was the summit termed a 'failure'? It would appear that Chancellor Merkel and President Biden had in fact discussed the 'TRIPS Waiver' ('Waiver') – a proposal tabled by India and South Africa at the WTO in October 2021 to temporarily waive away specific obligations related to IP rights standards and enforcement – but the discussion led nowhere due to Germany's opposition to the proposal. Faced with this difficulty, President Biden simply chose not to record this affair in his remarks on the summit.²

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¹ Remarks by President Biden and Chancellor Merkel of the Federal Republic of Germany in Press Conference, THE WHITE HOUSE (Jul. 15, 2021), <https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/07/15/remarks-by-president-biden-and-chancellor-merkel-of-the-federal-republic-of-germany-in-press-conference/>.

² Jake Johnson, "This Summit Was a Failure": Biden-Merkel Meeting Ends With No Deal on Vaccine Patent Waiver, COMMON DREAMS (Jul. 16, 2021), <https://www.commondreams.org/news/2021/07/16/summit-was-failure-biden-merkel-meeting-ends-no-deal-vaccine-patent-waiver>.

If this routine seemed unusual, it also typified in many ways, the approach that the two nations had adopted in addressing the call for a waiver. Currently the European Union (“EU”), the United Kingdom (“UK”) and Switzerland are at loggerheads with a growing group of 64 countries – ‘co-sponsors’ of the Waiver proposal at the WTO – and hundreds of civil society activists and non-governmental organizations. Watching from the side-lines is the influential yet deadpan United States (“US”), which had, until May 2021, strongly opposed the Waiver proposal only to switch sides in a dramatic volte-face episode, agreeing to engage in text-based negotiations on the proposal.

Situated in this politically energized background, this article maps the TRIPS Waiver debate, charting its origin and politics at the WTO. By taking stock of the interventions, submissions and proposals made by WTO members at the TRIPS Council, this article is aligned with the view that the debate not only offers keen insights into the logic and limitations of how the global IP regime is working in the face of a pandemic marking an immediate rise in the global demand for vaccines, it also enables us to understand the role that global intellectual property rules have come to play in members’ efforts to contain the spread of the COVID-19 pandemic locally.

Besides promises, it is pertinent to mention the limitations that the reader may face in trying to understand the TRIPS Waiver debate. First, writing *in medias res* is a testing prospect.³ It is well-known that ahead of the long overdue 12th Ministerial Conference (“MC12”), the WTO is undergoing an ‘existential crisis’.⁴ WTO members are aware that facilitating consensus on a public-health oriented decision such as the TRIPS Waiver would not only ensure the relevance of the WTO as an international institution but also help tackle the long-held belief that the WTO exists for liberalization *tout court*.⁵ With these prospects in sight, members are engaged in formal and informal consultations on an almost weekly basis and updates on these discussions occur faster than they can be written about.

Second, text-based outcome on the Waiver proposal remains far from sight.⁶ While it is true that Waiver proponents have been engaged in text-based discussions and enjoy support from the US, concerted and consistent opposition to the Waiver from the EU, the UK and Switzerland has ensured that negotiating positions on the Waiver remain unchanged since it was first proposed.

³ Adam Tooze, *Chartbook on Shutdown #2: Writing in medias res*, CHARTBOOK (Sept. 4, 2021), <https://adamtooze.substack.com/p/chartbook-on-shutdown-2-writing-in>.

⁴ Banikinkar Pattanayak, *WTO faces deepest existential crisis ahead of its silver jubilee*, THE FINANCIAL EXPRESS (Dec. 9, 2019), <https://www.financialexpress.com/economy/wto-faces-deepest-existential-crisis-ahead-of-its-silver-jubilee/1788127/>.

⁵ This view echoes those presented by Indonesia at the WTO’s TRIPS Council on 13 October 2021 on the TRIPS Waiver. *13 October 2021: Indonesia’s statement on the TRIPS waiver*, KNOWLEDGE ECOLOGY INTERNATIONAL (October 16, 2021), <https://www.keionline.org/36775>.

⁶ Shantanu Singh, *The US support for the TRIPS waiver is only half the battle*, INTERNATIONAL LAW & THE GLOBAL SOUTH (May 6, 2021), <https://internationalawandtheglobalsouth.com/guest-post-covid-19-series-the-us-support-for-the-trips-waiver-is-only-half-the-battle-what-lies-ahead/>.

The apprehension that the calculated enthusiasm of the US will do little to provide a positive direction in text-based negotiations is proving true. In these troubling circumstances, it is difficult to estimate the final outcome of these negotiations at MC12.

The task of mapping the relatively recent history of these negotiations remains of some importance nevertheless. Not only does this exercise provide an overview of how WTO members understand the role that IP is playing in the containment of the COVID-19 pandemic, but it also helps discern those facets and limitations of the global IP regime to which negotiators may revert to in times of future crises – for example, climate change. Accordingly, the next section sets out the discussions in the TRIPS Council prior to the tabling of the TRIPS Waiver. In the section that follows, the Waiver proposal, the draft text and its overall rationale are analysed. This section is followed by another on the TRIPS Council debates and developments which occurred after the tabling of the Waiver proposal. The concluding section summarizes the key takeaways from the TRIPS Waiver debate.

II. THE TRIPS WAIVER DEBATE

A. Setting the stage

At the very outset of the COVID-19 pandemic, as news media reported the rising number of novel coronavirus cases across the world, it was clear that seamless supply of critical medical products and health equipment, such as diagnostic kits and masks, was going to be essential in containing the spread of the virus. Scientists at the UK's Jenner Institute had also started to design vaccines based on genome sequencing released in January 2020.⁷ However, in the face of an unfathomable rise in demand and the lack of a globally coordinated policy response, all preparedness seemed to be falling short.⁸ If the failure of the global supply chains was becoming apparent in the first few months of the pandemic, IP was being pre-empted as a future barrier in accessing COVID-19 cures.⁹

Given this urgent context, it was not long before that IP's potential role in the response to the COVID-19 became a key discussion item – an 'agenda item' – at the behest of South Africa in the TRIPS Council, the WTO body responsible for monitoring the Agreement's operation. The July

⁷ Oliver Franklin-Wallis, *An oral history of Oxford/AstraZeneca: 'Making a vaccine in a year is like landing a human on the moon,'* THE GUARDIAN (Aug. 28, 2021), <https://www.theguardian.com/society/2021/aug/28/oral-history-of-oxfordastrazeneca-making-a-vaccine-in-a-year-is-like-landing-a-human-on-the-moon>.

⁸ *Shortage of personal protective equipment endangering health workers worldwide*, WORLD HEALTH ORGANISATION (Mar. 3, 2020), <https://www.who.int/news/item/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide>; Jinshan Hong & Dong Lyu, *World Ventilator Demand Now 10 Times What's Available, Says Maker*, BLOOMBERG (Mar. 25, 2020), <https://www.bloomberg.com/news/articles/2020-03-25/world-ventilator-demand-now-10-fold-what-s-available-says-maker>.

⁹ Press Release, Médecins Sans Frontières, *African Union says urgent need to address patents and technology barriers for access to future COVID-19 vaccines* (Jul. 1, 2020), <https://reliefweb.int/report/world/african-union-says-urgent-need-address-patents-and-technology-barriers-access-future>.

2020 TRIPS Council meeting was to be its first formal plenary since the pandemic started. Accordingly, South Africa opened the discussion in the Council by taking note of the global shortage of medical supplies and the sheer scale of the crisis at hand.¹⁰

However, the biggest challenge in relation to IP that South Africa was keen to highlight was that of IP itself. South Africa's strategy would show that it had not brought this item onto the meeting's agenda to merely entertain general remarks on the IP-related measures taken during the pandemic. South Africa was apprehending issues related to the in-built flexibilities of the TRIPS Agreement. For one, in a paper circulated prior to the meeting, South Africa noted that understanding of these flexibilities beyond patents were less understood at a national level, noting that national IP laws in some cases may not even provide for access-related flexibilities concerning other IP rights.¹¹ In South Africa's view, it was time to discuss a more 'integrated approach' towards TRIPS flexibilities. The visible strategy then was to nudge the discussion in the Council under another agenda item – on the 'integrated approach' paper circulated by South Africa – as well.

Consistent with this strategy, South Africa utilized the two agenda items to argue that patents were not the only IP-related hurdle in the context of the pandemic. IP-related barriers, the argument went, were also present in other IP rights, such as industrial designs, copyrights and trade secrets. In addition, it noted that while such flexibilities exist under the TRIPS, there are potential legal, institutional and technical challenges which may arise in the operationalization of these flexibilities by developing countries, especially when they had little to no prior experience in utilizing them.¹² Not only did these flexibilities prove far too complex to operate within the domestic markets, but they were likely to be inadequate for operationalizing the export of vaccines to members who had insufficient or no manufacturing capacities under a mechanism established by Article 31*bis* of the TRIPS. Under this Article 31*bis* system, when exports of pharmaceutical products took place under the grant of a compulsory licence for the purpose of exporting products to members who had insufficient or no manufacturing capacities, then the obligation to use compulsory licenses only for domestic markets, as set out in Article 31(f) of TRIPS, would no longer apply.¹³

While this system appeared comprehensive, operationalizing it was a different matter entirely. To highlight this, South Africa recalled that when *Médecins Sans Frontières* tried to use this procedure in 2006

¹⁰ Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting Held in the Centre William Rappard on 30 July 2020*, WTO Doc. IP/C/M/95/Add.1 (Oct. 2, 2020), ¶ 66 [hereinafter *Minutes of July 2020*].

¹¹ Communication from South Africa, *Intellectual Property and Public Interest: Beyond Access to Medicines and Medical Technologies Towards a more holistic approach to TRIPS flexibilities*, WTO Doc. IP/C/W/666 (Jul. 17, 2020).

¹² *Id.* ¶ 69.

¹³ Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 31*bis* 1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter *TRIPS Agreement*].

for the export of crucial HIV medicines from Canada to their operations in Rwanda, it concluded that the Article 31*bis* procedure was “neither expeditious nor workable”.¹⁴ To South Africa, it was becoming apparent that at a time when the inbuilt flexibilities of TRIPS could have played a central role in ensuring equitable distribution of IP-protected products, there was very little in terms of any operating experience which could inspire confidence in the system. In such circumstances, a limited, non-transparent voluntary licencing system and distribution pledges were the only system of vaccine distribution which seemed to be in operation. But such *ad hoc* initiatives, South Africa averred, were inadequate for systematically addressing the IP-related barriers. In other words, ‘business as usual’ i.e., the global IP regime as it exists, was simply not enough.

South Africa’s sentiments were echoed by developing countries, including India, under both the agenda items. As Indonesia stated, the key concern was that in absence of an effective and global mechanism for ensuring cooperation on IP-rights, scaling up of production and distribution of vaccines depended solely on the industry’s policies.¹⁵ Second, Indonesia suggested that even if IP-related flexibilities were available domestically to members, it was unclear how they would be operationalized since many patented products or technologies could also consist of other IP-rights. Zimbabwe averred that South Africa’s proposal was essential as it was aware of pharma companies protecting their products under IP-rights other than patents, such as through trade secrets and industrial designs, flexibilities for which were unclear.¹⁶ Supporting this call to arms declared by South Africa, India took the opportunity to request members to initiate discussions on TRIPS flexibilities applicable to IPs beyond patents.¹⁷

But to even initiate such a dialogue, members had to get past their conceptual differences in how IP was affecting the fight for public health. In the history of the TRIPS, the road from Punta del Este, where the TRIPS negotiations were launched, to the TRIPS ‘flexibilities’ negotiated in Doha had not been an easy ride.¹⁸ It had been the result of careful alliances and negotiating strategies which were going to be revived as the TRIPS Waiver dialogue took shape.¹⁹

The first signs of such a revival could be sensed when the developed countries began to intervene under the two agenda items brought onboard by South Africa. Speaking under the first of the two agenda items, the US made it clear: IP was not a barrier in addressing the pandemic. Instead, IP had motivated the global efforts to find cures; manufacturing capacities and supply chain issues

¹⁴ Minutes of July 2020, *supra* note 10, ¶ 71.

¹⁵ *Id.* ¶ 458.

¹⁶ *Id.* ¶ 489.

¹⁷ *Id.* ¶ 495.

¹⁸ Jayashree Watal, *From Punta Del Este to Doha and Beyond: Lessons from the TRIPS Negotiating Processes* (Dec. 17, 2011), <https://papers.ssrn.com/abstract=1973177>.

¹⁹ Shantanu Singh, *supra* note 6.

were of greater ‘concern’.²⁰ Canada, speaking under the second agenda item, called for an ‘appropriate balance’ between the multilateral framework of the TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health, 2001 (“Doha Declaration on TRIPS”).²¹

The EU and the UK joined the US in arguing that the system of IP, especially patents, provided a platform for innovation; there was evidence to show that the lack of access to medicine stemmed from ‘other sources’; and there were no ‘simple solutions’ to the current crisis.²² The EU, based on a report each from the Europol and the EU Intellectual Property Office, argued that global cooperation was most important in this moment of time since counterfeit, fake or substandard goods, medicines and equipment were quickly taking over the market and threatening public health.²³ While Switzerland agreed with South Africa’s observation that, in the context of the pandemic, IP-related issues were also present beyond patents and medical products, it discouraged members from using coercive measures which limit IP rights. Instead, Switzerland thought voluntary measures, such as licensing, to be preferable as they were faster, provided legal certainty and were more promising than limitations on IP rights.²⁴ While Japan agreed with several points raised by others²⁵, the United States went even further to say that while it recognized the members’ right to use compulsory licensing provisions, such mechanisms could have a negative effect on IP-related investments.²⁶

By asking that WTO members turn their attention towards manufacturing capacity and supply chains, the developed countries were deliberately missing the point. Their interventions stated nothing in particular on South Africa’s concerns about the lack of confidence among developing countries about the Article 31*bis* system. Neither did the developed countries address, for example, South Africa’s concerns about the voluntary licenses being practiced by Gilead in the production and distribution of remdesivir. South Africa noted that while Gilead had agreed to supply the drug to the US on a one-to-one basis, in utter contrast, supply of the drug for 127 other countries was being managed through ‘limited, non-transparent [and] exclusive’ licenses to generic manufacturers in three countries.²⁷ To South Africa, that sounded like an oligopolist

²⁰ Minutes of July 2020, *supra* note 10, ¶ 120.

²¹ Minutes of July 2020, *supra* note 10, ¶ 507; World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2 [hereinafter Doha Declaration]. (The origin of the Article 31*bis* system lies in Paragraph 6 of the Doha Declaration.)

²² Minutes of July 2020, *supra* note 10, ¶ 510-534.

²³ Minutes of July 2020, *supra* note 10, ¶ 536.

²⁴ Minutes of July 2020, *supra* note 10, ¶ 563, 564.

²⁵ Minutes of July 2020, *supra* note 10, ¶ 593

²⁶ Minutes of July 2020, *supra* note 10, ¶ 584-585.

²⁷ Minutes of July 2020, *supra* note 10, ¶ 66; South Africa cited a report from The Los Angeles Times. Vidya Krishnan, *How secret deals could keep a COVID-19 drug out of reach for millions*, LOS ANGELES TIMES (July 1, 2020), <https://www.latimes.com/world-nation/story/2020-07-01/gilead-patent-limits-access-to-covid-19-drug-remdesivir>.

managing its competition.

Revisiting the foregoing TRIPS Council discussions is essential to understand the genesis of the Waiver proposal. South Africa and the other developing countries attempted to shape a somewhat consistent narrative about the issues with IP and TRIPS flexibilities beyond patents. This narrative was to form the conceptual foundation for the TRIPS Waiver. But, if these concerns enjoyed only hesitant support from fellow developing countries, the Oratorio-like clarity of the message from a set of developed countries was unmistakable: the exclusivity of IP rights needed to be protected during the pandemic; if flexibilities were to be exercised for the supposed IP-related difficulties, then it must be done in the way implicit in the TRIPS or through voluntary licensing. In this sense, as we shall see, the negotiating positions on the TRIPS Waiver have not changed at all till date.

B. In the Limelight: Contours of the TRIPS Waiver

India and South Africa circulated the Waiver proposal on October 2, 2020.²⁸ In line with the views put forth by the developing countries at the TRIPS Council meeting in July, the Waiver proposal was geared to ensure that IP rights do not become a barrier to access to medicines and scaling up the research, manufacturing and supply of products necessary for combatting COVID-19.²⁹

Taking note of reports about IP causing such hindrances and the extent of the damage caused by the pandemic, the Waiver proposal presented a draft decision text in the communication's annex. It is this draft text which would be recommended to the General Council, the key decision-making body in the intervals between the WTO's biennial Ministerial Conferences, by the TRIPS Council after due deliberation and discussion. Such a decision by the General Council will have to conform to the consensus-based procedures prescribed in Article IX:3 of the WTO Agreement.³⁰

This draft text presents five paragraphs. While paragraph 2 and 3 ensure that the proposed Waiver decision does not affect the protection of rights of performers and producers of sound recordings and broadcasting organizations under Article 14 and is without prejudice to the exemption from the application of TRIPS provided to least-developed countries under Article 66.1, it is paragraph 1 which sets out the key decision. Paragraph 1 of the draft text exempts WTO members from their 'obligation to implement or apply Sections 1, 4, 5 and 7 of Part II of

²⁸ Communication from India and South Africa, *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) [hereinafter TRIPS Waiver].

²⁹ Id. ¶ 3.

³⁰ Arrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154 [hereinafter WTO Agreement]. (Article IX:3 (b), which sets out the procedure for a waiver request for any of the agreements contained in Annex 1A, 1B and 1C of the WTO Agreement and requires that such a waiver request be submitted to the respective Council concerned with that Annex Agreement.)

the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement’.

To understand the effect or operation of this paragraph 1 waiver, it is essential to revisit the purpose of the TRIPS. In stark contrast with the ‘patchwork’ intellectual property regime which had existed prior to the conclusion of TRIPS i.e., the Paris and Berne Conventions, the TRIPS represents a “legally binding set of substantive, minimum IP standards”.³¹ Unlike its predecessors, TRIPS requires WTO members to enact measures within their borders to ensure that they meet the minimum standards set out in the agreement.³² These standards are set out in Part II of the TRIPS agreement, divided into 8 distinct sections, each concerning different intellectual property rights.³³ Part III of the TRIPS provides the minimum standards for the enforcement of intellectual property rights, which include the civil and administrative remedies, criminal remedies, and border or customs measures.³⁴

The function of paragraph 1 of the draft text then is to waive the legal and binding obligations of members with regard to the aforementioned Parts of the TRIPS. Second, the IP rights covered by the draft Waiver text are limited to Copyright and Related Rights’, ‘Industrial Designs’, ‘Patents’ and ‘Protection of Undisclosed Information’. Only these types of IP rights and not others have been included within the scope of the draft text as it is in line with the reasoning that South Africa had first presented in the TRIPS Council meeting in July. The Waiver’s scope is also circumscribed by the paragraph 1 clause stating that such obligations shall be waived “in relation to prevention, containment and treatment of COVID-19”. While somewhat broad, this linkage certifies the purpose of the Waiver.

Paragraph 1 also includes a placeholder of ‘[X] years’. Subject to the decision of the TRIPS Council, this placeholder may represent the duration of the Waiver. Making the decision on the duration of the Waiver is key as we are none the wiser on how long the ongoing pandemic may continue.³⁵ Pending a more coherent understanding of how long virus-induced immunity may last, it was understood that the arrival of vaccine in the near future was going to play a key role in determining the future of the pandemic.³⁶ It is perhaps due to such factors that the Waiver text proposes that it remain in force till such time ‘widespread vaccination is in place’ and ‘majority of the world’s population has developed immunity’.³⁷ Considering these aspects, the ‘[X] years’

³¹ CAROLYN DEERE, *THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES* 1 (2008).

³² *Id.*

³³ Part II, TRIPS Agreement, *supra* note 13.

³⁴ Part III, TRIPS Agreement, *supra* note 13.

³⁵ Megan Scudellari, *How the pandemic might play out in 2021 and beyond*, 584 NATURE 22–25 (2020). (This aspect assumes greater importance with the onset of each new variants, the latest among them being reported as the ‘Omicron’ variant.)

³⁶ *Id.*

³⁷ TRIPS Waiver, *supra* note 28, ¶ 13.

placeholder would permit the TRIPS Council to decide on the Waiver's duration after taking into consideration the latest scientific and technical information related to the pandemic.

In any case, if the Waiver were to be granted, then paragraph 4 of the draft text proposes that the Waiver shall be reviewed by the "General Council not less than one year after it is granted, and thereafter annually until the waiver terminates, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement". The linkage with Article IX:4 is key for this review procedure as Article XI:4 establishes the general procedure regarding any waiver from the various WTO Agreements. To wit, per Article IX:4, each review of the waiver would require the General Council to examine whether the 'exceptional circumstances' which justify the need for the waiver still exist or if the conditions attached to the Waiver have been met. On the basis of this review, the General Council (or the Ministerial Conference) may extend, modify or terminate the waiver.³⁸

Last, and perhaps most importantly, the draft text, in paragraph 5, prohibits any possibility of a member challenging any measure taken in conformity with the Waiver provisions. This provides legal protection to the waiver set out in paragraph 1 by prohibiting members from challenging any conforming measure for nullification or impairment under Article XXIII of the GATT, 1994 or the WTO's Dispute Settlement Understanding generally.

An assessment of the contours of the Waiver proposal shows that it presented a particularly high-standard 'ask' in terms of the demands that it made of WTO members. Wholesale waivers of entire substantive and procedural portions of a WTO Agreement are rare, to say the least.³⁹ But as India and South Africa have argued in the TRIPS Council and through the Waiver proposal, so were the circumstances. The TRIPS Council was well aware that IP was playing a key role in the pandemic, be it in the manufacturing and supply of medical products or in the research and development of novel vaccines. If it is indeed obvious that IP rights are impeding the efforts of countries in tackling the pandemic, the pressure on the TRIPS Council would surely be immense. And this means that regardless of whether the Waiver proposal will help relieve this pressure or whether the proposal's high-demand asks will create more of it, a suffering world is looking to the TRIPS Council – and the WTO – for answers, including an international policy response for addressing current vaccine shortages and those which may arise in the future.

C. No curtain fall after all?

India and South Africa's Waiver proposal was first discussed in the Council's meeting held in

³⁸ WTO Agreement, *supra* note 30.

³⁹ See, e.g., the latest compilation of all waivers granted at the WTO. Note from the Secretariat, *Waivers 1995- 2020*, WTO Doc. WT/GC/W/718/Rev.1 (Jan. 25, 2021).

mid-October and in December.⁴⁰ In the interval, members circulated two submissions related to the Waiver. While South Africa shared a paper titled ‘Examples of IP Issues and Barriers in COVID-19 Pandemic’⁴¹, Australia, Canada, Chile and Mexico shared a set of questions for the Waiver’s proponents on various aspects of the proposed Waiver.⁴² In contrast with the previous TRIPS Council meeting, support from developing countries at the mid-October meeting for the Waiver proposal was clear, with a host of members supporting discussions on the Waiver. For example, by the time the December meeting took place, Kenya, Mozambique, Eswatini, Pakistan and Bolivia had joined the Waiver proposal as co-sponsors. The litmus test for the Waiver proposal, however, was always going to be a measure of how well it sat with the set of developed countries who had intervened in the previous TRIPS Council meeting.

Consistent with its previous submissions, for the EU, there was “no indication that IPR issues have been a genuine barrier in relation to COVID-19 related medicines and technologies”.⁴³ In any case, even if IP became a barrier, the EU, Switzerland and Norway pointed out that the TRIPS contained in-built flexibilities which can be employed. For their part, the US and Japan were deft in rejecting the Waiver proposal⁴⁴, as was Australia.⁴⁵ Besides rejecting the Waiver, the US also posted a flurry of questions on the proposal and expressed concerns regarding the broad scope of the Waiver’s language, in particular objecting to the clause that members’ obligations would be waived “in relation to prevention, containment and treatment of COVID-19”.⁴⁶ Curiously enough, the Waiver proposal was also rejected by Brazil⁴⁷, which had been one of the developing countries battling for access to medicines during the Doha negotiations.⁴⁸

Confronted by this consolidating group of members opposed to the proposal, South Africa took to the floor to reply to their specific queries.⁴⁹ Taking note of the ‘case by case’ nature of the TRIPS flexibilities, South Africa noted that, in contrast, the Waiver proposal represented an ‘expedited, open and automatic’ solution.⁵⁰ Besides recalling the lack of experience with TRIPS flexibilities for IP rights beyond patents and the Article 31 *bis* system, South Africa also took note of the EU’s IP enforcement Report of 2020 and the US Trade Representative’s (“USTR”) Special 301 report of

⁴⁰ Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting Held on 15-16 October and 10 December 2020*, WTO Doc. IP/C/M/96/Add.1 (Feb. 16, 2021) [hereinafter *Minutes of October and December 2020*].

⁴¹ Communication from South Africa, *Examples of IP Issues and Barriers in Covid-19 Pandemic*, WTO Doc. IP/C/W/670 (Nov. 23, 2020).

⁴² Communication From Australia, Canada, Chile and Mexico, *Questions on Intellectual-Property Challenges Experienced by members in relation to COVID-19*, WTO Doc. IP/C/W/671 (Nov. 27, 2020).

⁴³ Minutes of October and December 2020, *supra* note 40, ¶ 1028.

⁴⁴ Minutes of October and December 2020, *supra* note 40, ¶ 1049, 1070.

⁴⁵ Minutes of October and December 2020, *supra* note 40, ¶ 1121.

⁴⁶ Minutes of October and December 2020, *supra* note 40, ¶ 1333.

⁴⁷ Minutes of October and December 2020, *supra* note 40, ¶ 1099.

⁴⁸ Watal, *supra* note 18.

⁴⁹ Minutes of October and December 2020, *supra* note 40, ¶ 1147-1171.

⁵⁰ Minutes of October and December 2020, *supra* note 40, ¶ 1155.

2020, both of which, it argued, acted as deterrents to the issuing of compulsory licenses.⁵¹ Nevertheless, it was key to continue these discussions and South Africa requested that this proposal be kept on the agenda of the TRIPS Council for future meetings.⁵²

Even as subsequent TRIPS Council meetings took place, there was little change in the negotiating positions on the Waiver. In January 2021, Waiver proponents released two comprehensive answer sheets on the queries raised by members.⁵³ In retort perhaps, the Waiver proponents also circulated a paper of their own; this time setting out a list of questions addressed to the Waiver ‘opponents’.⁵⁴

By March 2021, the co-sponsorship of the Waiver had swelled up to 57 members with many others supporting discussions on the proposal. However, progress on the text seemed distant. In fact, even though COVID-19 vaccines had been invented globally, members had made no progress on text-based negotiations on the Waiver. At the TRIPS Council meeting held in February 2021, the Waiver proponents called upon other members to begin these negotiations,⁵⁵ but to no avail. While Switzerland, the EU, Japan, Norway and Australia remained opposed to the waiver, a key change was afoot.

With a change of guard in the US Administration and increased pressure from civil society⁵⁶, the US had become less vociferous in its opposition to the Waiver discussions. Reports noted that the initial signs of this volte-face were present in the Biden administration’s run up to the Oval Office.⁵⁷ Elsewhere, the newly appointed USTR Katherine Tai admitted that the ‘business as usual’ mindset could continue no longer.⁵⁸ Then, instead of its old tactic of drowning the discussions in a barrage of questions and clarifications, the US proposed that it was open to discussions for a multilateral solution.⁵⁹ This meant that while the US was not yet onboard with the Waiver itself, its opponents had lost a significant voice in their cause. Increasingly isolated in the

⁵¹ Minutes of October and December 2020, *supra* note 40, ¶ 1155-1157.

⁵² Minutes of October and December 2020, *supra* note 40, ¶ 1171.

⁵³ Communication from the Plurinational State Of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe, *Waiver from Certain Provisions of The TRIPS Agreement for The Prevention, Containment and Treatment of Covid-19 - Responses to Questions*, WTO Doc. IP/C/W/672 (Jan. 15, 2021); Communication from the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, the Bolivarian Republic of Venezuela and Zimbabwe, *Response to questions on Intellectual-property challenges experienced by members in relation to COVID-19 in document IP/C/W/671*, WTO Doc. IP/C/W/673 (Jan. 15, 2021).

⁵⁴ Communication from India, Mozambique, Pakistan and South Africa, *Waiver from Certain Provisions of The TRIPS Agreement for The Prevention, Containment and Treatment of Covid-19 – Questions by Proponents*, WTO Doc. IP/C/W/674 (Jan. 15, 2021).

⁵⁵ Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting Held in the Centre William Rappard on 23 February 2021*, WTO Doc. IP/C/M/97/Add.1, ¶ 19 (Apr. 7, 2021) [hereinafter Minutes of February 2021].

⁵⁶ *TRIPS waiver: Pressure mounts on WTO as supporting voices grow*, MINT (Feb. 21, 2021), <https://www.livemint.com/news/india/trips-waiver-pressure-mounts-on-wto-as-supporting-voices-grow-11614221180404.html>.

⁵⁷ Kiran Stacey & Aime Williams, *Vaccine diplomacy: inside Biden’s decision on Covid patents*, FINANCIAL TIMES (May 8, 2021), <https://www.ft.com/content/7046b35a-7c6a-4ad4-8b9c-cc9a367da865>.

⁵⁸ *Id.*

⁵⁹ Minutes of February 2021, *supra* note 55, ¶ 242.

TRIPS Council discussions, the Waiver opponents, especially the EU, began to reiterate their support for the in-built TRIPS flexibilities for countering IP-related difficulties.⁶⁰ Meanwhile, the Waiver proponents, emboldened by the wind in their sails, informed the TRIPS Council that they had been working on a revised proposal, focusing on “a pragmatic approach” towards the scope of the Waiver and the introduction of “a specific duration of years based on scientific and epidemiological data”.⁶¹

A strong blow to the opposition came in early May 2021, when, despite having courted strong lobbying from the domestic pharmaceutical industry⁶², the USTR announced its support for text-based negotiations at the WTO.⁶³ A work of mindful drafting, the USTR’s statement only spoke of supporting text-based negotiations for COVID-19 vaccines alone. It was interesting to see how the US, a long-term proponent of IP protections globally, had gone from opposing the Waiver to becoming a key backer of it. Reports on this episode stated that key figures in the Biden administration considered supporting the Waiver to be “a low-risk way to secure a diplomatic win”.⁶⁴ Seen from this viewpoint, the ‘symbolism’ of the USTR’s announcement worked perfectly,⁶⁵ even as it was a sign of how text-based negotiations at the WTO could take months, not more than a year, considering the opposition from the EU and others. Aware of these concerns, the 62-member long set of Waiver co-sponsors circulated a joint statement, calling upon WTO members to “initiate and expedite text-based negotiations”.⁶⁶ While the USTR’s support itself counted for little immediately, it did have an immediate effect in breaking the opposition, as Australia and New Zealand, erstwhile Waiver opponents, along with fence-sitters such as Russia, China and Ukraine, announced their support for the TRIPS Waiver.⁶⁷

⁶⁰ Council of Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting held in the Centre William Rappard on 10-11 March 2020* (WTO Doc. IP/C/M/98/Ag. 10-11 March 2020) (July 30, 2021).

⁶¹ Council of Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting held in the Centre William Rappard on 30 April 2021* (WTO Doc. IP/C/M/99/Ag. 30 April 2021) (May 30, 2021).

⁶² Hamman Kuchner & J. Michael Smith, *Vaccine makers say IP waiver could hand technology to China and Russia*, FINANCIAL TIMES (Apr. 25, 2021), <https://www.ft.com/content/fa1e0d22-71f2-401f-9971-fa27313570ab>.

⁶³ *Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver*, OFFICE OF UNITED STATES TRADE REPRESENTATIVES (May 5, 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>.

⁶⁴ Stacey & Williams, *supra* note 57.

⁶⁵ Alan Beattie, *Katherine Tai springs a surprise on Covid vaccine patents*, FINANCIAL TIMES (May 6, 2021), <https://www.ft.com/content/0930fe14-5187-45dc-b573-4f4098211bf4>.

⁶⁶ Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe, *Waiver from Certain Provisions of The TRIPS Agreement for The Prevention, Containment and Treatment of Covid-19 – Joint Statement of Co-sponsors*, WTO Doc. IP/C/W/677 (May 18, 2021).

⁶⁷ Kirtika Suneja, *China, Ukraine and New Zealand back India and South Africa’s IPR waiver joint proposal on Covid medical products*, THE ECONOMIC TIMES (June 1, 2021), <https://economictimes.indiatimes.com/news/india/china-ukraine-and-new-zealand-back-india-and-south-africas-ip-waiver-plan-on-covid-medical-products/articleshow/83134286.cms?from=mdr>; Paul Karp & Elias Visontay, *Australia to support vaccine waiver after months of pressure from human rights groups*, THE GUARDIAN (Sept. 8, 2021),

<https://www.theguardian.com/society/2021/sep/08/australia-to-support-vaccine-waiver-after-months-of-pressure-from-human-rights-groups>.

Seeing this renewed impetus in the Waiver debate, the co-sponsors circulated the revised proposal in May 2021.⁶⁸ This revised decision text, considering the members' concerns on the scope of the Waiver, limited it to "health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19". While this improved on the rather broad language of the previous draft text, it did little to actually shift the scope of the Waiver in terms of its coverage. Second, in the revised decision text, instead of the placeholder indicating the duration of the Waiver, a term of "at least 3 years" was proposed through a new paragraph. Furthermore, this duration was made subject to a review process, not unlike the one set out in Article IX:4 of the WTO Agreement. On the whole, the revision exercise had altered precious little in substance. But, if the text had to be amended towards a 'convergence', it required the participation of the WTO membership outside of the Waiver co-sponsors and supporters.

Instead of engaging in that way, in June 2021, the EU drove the divergence further by circulating a paper and a draft decision text of its own.⁶⁹ The crux of the argument presented in these two documents was that the in-built TRIPS flexibilities were enough to tackle the pandemic. All that this system of flexibilities contained in Article 31 and 31*bis* required was clarifications which could simplify its use by members in granting compulsory licenses. Accordingly, the EU's draft decision text proposed that a pandemic was covered within the meaning of 'a national emergency or other circumstances of extreme urgency' in Article 31(b) of the TRIPS, which exempts prospective users of compulsory licences to make efforts towards gaining a voluntary license from the right holder under specific circumstances.⁷⁰ Next, the draft text proposed that the 'adequate remuneration' paid to the right holder within the meaning of Article 31(h) be equal to the "price charged by the manufacturer of the vaccine or medicine produced under the compulsory licence". Last, the EU proposed that in using the Article 31*bis* system, members may issue a single notification for the list of countries to which vaccines and medicines are being supplied by the exporting member.

It is highly doubtful that the EU's draft decision provided any novel clarification or interpretation. For one, the Doha Declaration on TRIPS recognizes the right of each member to

⁶⁸ Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe, *Waiver from Certain Provisions of The TRIPS Agreement for The Prevention, Containment and Treatment of Covid-19 – Revised Decision Text*, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021).

⁶⁹ Communication from the European Union, *Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property*, WTO Doc. IP/C/W/680 (June 4, 2021); Communication from the European Union, *Draft General Council Declaration on the TRIPS Agreement and Public Health in the circumstances of a Pandemic*, WTO Doc. IP/C/W/681 (June 18, 2021).

⁷⁰ TRIPS Agreement art. 31(b), *supra* note 13.

determine what constitutes a ‘national emergency’.⁷¹ Moreover, the Declaration expressly states that “...epidemics, can represent a national emergency’.⁷² At a time when WTO members had adopted unprecedented measures to contain the spread of the pandemic, who would admit that it did not constitute a ‘national emergency’ within the scope of Article 31(b)? In advancing such a redundant proposal, the EU not only further isolated itself and weakened the stance of fellow opponents, it deliberately misrepresented the efforts of the proposed Waiver.

Second, the issue of waiving IP rights was not limited to patents. In the TRIPS Council meetings, Waiver proponents had repeatedly argued that the flexibilities available for use in the case of patents, must also be made workable for other IP rights. The other clarifications presented in EU’s draft text added nothing new to the working mechanism of the Article 31 or Article 31*bis* beyond elaborating upon what was already present in the text of the TRIPS provisions. It was increasingly apparent that the EU’s draft text neither offered any serious clarification nor did it address the outstanding concerns raised by the Waiver proponents.

Split between the divergences of the two proposals, the TRIPS waiver debate entered into another phase at the TRIPS Council meeting held in June 2021. The number of members supporting the Waiver had reached above 100, of which 63 were its co-sponsors. Growing support meant that the Waiver proponents were successful in initiating text-based negotiations at the June meeting.⁷³ While talks on the text would start immediately after the meeting, India proposed that, considering the severity of the rising COVID-19 infections, members must aim to finish the negotiations by the end of July.⁷⁴

The current circumstances reveal that that timeline was not only ambitious, it had resulted in little to no headway. As of September 2021, while the waiver was being co-sponsored by 64 members, opposition from the UK, the EU and Switzerland remained the key roadblock. While the EU wished for convergence at the TRIPS Council meetings held in September and October 2021, leaks from the EU’s Directorate-General for Trade showed that it had explicitly dismissed the Waiver.⁷⁵ Another leak made it apparent that the EU’s understanding of ‘convergence’ was based on expanding its proposal for easing the operation of TRIPS flexibilities contained in Article 31 and 31*bis*.⁷⁶ As before, this would do nothing to address the issues in relation to trade secrets or

⁷¹ Doha Declaration, *supra* note 21, ¶ 5 (c).

⁷² Doha Declaration, *supra* note 21.

⁷³ D. Ravi Kanth, *WTO Members agree to text-based negotiations on revised TRIPS waiver*, THIRD WORLD NETWORK (June 11, 2021), <https://www.twn.my/title2/wto.info/2021/ti210606.htm>.

⁷⁴ Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting held in the Centre William Rappard on 8, 9 and 29 June 2021*, WTO Doc. IP/C/M/100/Add.1, ¶ 409 (Oct. 20, 2021).

⁷⁵ Ashleigh Furlong (@ashleighfurlong), TWITTER (Oct. 14, 2021, 6:53 PM), <https://twitter.com/ashleighfurlong/status/1448640647263571969>.

⁷⁶ Daniel Marans, *New European Vaccine Proposal Offers Limited Help to Developing Countries*, HUFFPOST UK (Oct. 13, 2021), <https://www.huffpost.com/entry/european-union-covid-vaccine-intellectual-property->

undisclosed information, which were brought up by the Waiver proposal. At the opposite end, the Waiver co-sponsors circulated another text in the TRIPS Council, summarizing the context and rationale behind the Waiver.⁷⁷ In sum, as the TRIPS Council Chairperson, Ambassador Dagfinn Sørli, observed, there had been very little change in the overall positions of the members.⁷⁸

Where was the US in all this? In the TRIPS Council meeting held in October, the US reiterated its support for the waiver proposal while stressing the need for consensus in decision-making.⁷⁹ On the same day, when USTR Tai was quizzed about the Waiver at an event in Geneva, she assured the audience that work was being undertaken behind the scenes, alluding to the imagery of a duck which appeared to be sitting still in the waters but vigorously paddling its leg underneath.⁸⁰ Public reports, however, told a different story: that of two flocks of ducks in Lake Léman, each paddling in the opposite direction as the US watched on.⁸¹

Even in the weeks prior to MC12, there were no public reports of a change in stance. At a stocktake exercise conducted in October 2021, Ambassador Sørli reported to the General Council that in the TRIPS Waiver debate, each camp had more or less stuck to their guns.⁸² The writing on the wall was becoming apparent: despite the numerous multilateral, bilateral and small-group meetings being held each week,⁸³ there were little signs of any convergence regarding what the TRIPS Waiver debate will achieve at the upcoming Ministerial Conference.⁸⁴

III. CONCLUSION

In chronicling the rather recent history of the TRIPS waiver debate, this article shares the fate of the Italian chronicler Giovanni Villani. Villani, who chronicled life in Florence, remains famous for never finishing a sentence telling of the end of the Black Death, on account of his own demise

[proposal_n_61664498e4b0f26084edbbff](https://www.wto.org/trade-issues/whatis/press/2021/20210913.htm).

⁷⁷ Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Jordan, Kenya, The LDC Group, Malaysia, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe, *Waiver from Certain Provisions of The TRIPS Agreement for The Prevention, Containment and Treatment of Covid-19*, WTO Doc. IP/C/W/684 (Sept. 30, 2021).

⁷⁸ D. Ravi Kanth, *EU, Switzerland, UK continue opposition, amid support for TRIPS waiver*, THIRD WORLD NETWORK (Sept. 16, 2021), <https://www.twn.my/title2/wto.info/2021/ti210913.htm>.

⁷⁹ Priti Patnaik, *Examining the “subtle shift” in the TRIPS Waiver talks*, GENEVA HEALTH FILES (Oct. 15, 2021), <https://genevahealthfiles.substack.com/p/examining-the-subtle-shift-in-the>.

⁸⁰ Jamey Keaten, *US reaffirms support for easing WTO rules on COVID vaccines*, AP NEWS (Oct. 14, 2021), <https://apnews.com/article/coronavirus-pandemic-technology-business-geneva-global-trade-ad794a94ff05a179dd5ddf329b6ce4f7>.

⁸¹ Alan Beattie, *Talks to waive patents on Covid vaccines are ‘stuck’, WTO head warns*, FINANCIAL TIMES, (Nov. 25, 2021), <https://www.ft.com/content/b9a66140-f031-4ed6-9048-f6029832c511>.

⁸² General Council, *Informal Heads of Delegation – Monday, 25 October 2021 – MC12 October stocktake*, WTO Doc. JOB/GC/279, ¶ 2.2-2.8 (Oct. 26, 2021).

⁸³ D. Ravi Kanth, *EU & allies adopt “diversionary” tactics on TRIPS waiver at WTO*, THIRD WORLD NETWORK (Nov. 8, 2021), <https://twn.my/title2/wto.info/2021/ti211112.htm>.

⁸⁴ Priti Patnaik, *The Emerging Path to the TRIPS Waiver*, GENEVA HEALTH FILES (Nov. 12, 2021), <https://genevahealthfiles.substack.com/p/the-emerging-path-to-the-trips-waiver>.

from the plague.⁸⁵ Much the same, we remain too ill-equipped – and too out of time – to estimate the outcome of the TRIPS Waiver debate as we approach MC12. However, an overview of these discussions does allow us to frame some key takeaways at this stage.

First, the Waiver proposal did not appear out of the blue. While the pandemic presented the precise circumstances for it, the Waiver co-sponsors had crafted a clear strategy by voicing their concerns on the limitations of the TRIPS flexibilities in the face of a pandemic-like crisis. Second, the Waiver proposal presented a ‘high-demand ask’ by calling for the waiver of obligations under entire Parts of the TRIPS, notwithstanding its duration. This was possible only because the proponents drew heart from the swelling support among civil society actors and the volte-face of the US. And because the initial proposal presented a high-standard ask in the firstgo, it enabled the co-sponsors to table a ‘revised’ proposal which offered little in the way of a substantial revision. Third, while the USTR’s change in stance was a key milestone in the TRIPS waiver debate, the US has done precious little to argue anyone’s cause in it – giving increased impetus to the idea that the volte-face was nothing but a symbolic act.⁸⁶

Fourth: at the other end of the debate, the opponents, led by the EU, find themselves increasingly isolated. Under immense pressure to make their opposition understandable, the camp has chosen to present interventions and proposals in this debate which drag it back to the original question: are the in-built flexibilities of TRIPS enough to deal with a crisis of this proportion? The nature of the debate embodies an anxiety that these flexibilities cannot meet the challenge. Any point of ‘convergence’ or resolution in the foregoing waiver debate then must reflect an effort to rework the global IP regime to be an adept facilitator times of crisis like the COVID-19 pandemic.

⁸⁵ OLE JØRGEN BENEDICTOW, *THE BLACK DEATH, 1346-1353: THE COMPLETE HISTORY* 69 (2006).

⁸⁶ Gabriele Steinhauser et. al., *Prospects of Intellectual-Property Waiver on Covid-19 Vaccines Fade*, *THE WALL STREET JOURNAL* (Nov. 18, 2021), [wsj.com/articles/prospects-of-intellectual-property-waiver-on-covid-19-vaccines-fade-11637251190](https://www.wsj.com/articles/prospects-of-intellectual-property-waiver-on-covid-19-vaccines-fade-11637251190).

**PROTECTION OF INDIGENOUS CULTURAL EXPRESSIONS OF MUSIC IN INDIA:
NEED FOR AN ACCESS AND BENEFIT SHARING SYSTEM**

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Abstract

The expansion of the domain of intellectual property gave rise to its many different classifications, one of which constitutes traditional knowledge [“TK”] and cultural expressions. As a separate subset designed to accommodate the skills and findings of indigenous communities of a region, it includes a plethora of artistic works passed on from founding generations to the next. Such indigenous knowledge, however, is severely mismanaged and subject to various kinds of infringement and intellectual trespassing. Various instances of misappropriation of traditional knowledge have been reported with regard to advancements in music, dance, medicine, etc. Thus, a need to enforce a robust and accommodative veil of protection for these indigenous inventions becomes a necessity in order to strengthen the realm of intellectual property in its entirety. Such protection will also need to ensure the sustained innovation of such cultural expressions by ensuring the safety of ownership and accruing benefits thereof to the rightful indigenous creators. The Indian legal framework is in special and swift need of such a system as it is currently in an unappreciated war with biopiracy. Controversies around the unauthorized acquisition of patents over TK such as turmeric, basmati rice, neem, etc. highlight the impact of the absence of such a protective system. The authors have formulated the creation of a separate body established to administer all problems concerning indigenous expressions, which shall be titled the Board for Indigenous Cultural Expressions (BICE). The proposal for the setup of BICE is targeted towards the primary function of monitoring the warranted use of cultural musical expressions and the redressal of any infringement in favour of the aggrieved community. The framework has been devised in a manner that accounts for the social, cultural and economic interests of its benefactors. The principal mode of redressal is potentially designed at the obtaining and allocation of royalties in favour of the indigenous community, thereby ensuring the accomplishment of its primary purpose.

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I. INTRODUCTION

In recent years, two broad categories of indigenous knowledge have evolved: traditional knowledge and traditional cultural expressions. Traditional knowledge (TK) includes knowledge, innovation, and skills of the indigenous and local communities, which are associated with the patent law system. Traditional cultural expressions, on the other hand, include the artistic works, music, and performances that have been produced collectively and handed down from one generation to another. Due to rapid globalization and increasing demand for commercialization of traditional knowledge, the expressions of culture, sustainable management of natural resources, land-use practices, and medicinal properties of local species of the indigenous society is being infringed upon.

¹ There have been serious concerns about the misappropriation of such traditional cultural expressions and calls for their preservation as well as the protection of the rights of such people. The principal argument revolves around recognizing the property rights over such indigenous knowledge by creating a regulatory framework based on the notion of collective property rights. The protection of such TK can be realized in two ways. Firstly, by adopting a defensive protection theory to restrict outsiders from acquiring rights over the TK of a particular community.² Secondly, through positive protection theory which allows the TK holders to exercise their rights to promote and benefit from such commercial exploitation.³

An efficient system of intellectual property for the protection of TK is crucial to promote innovation of such knowledge. Although the Constitution of India, under Articles 48A and 51A(g), imposes a mandatory obligation on the States and a duty on the citizens respectively, to promote and enrich the natural environment and safeguard forests and wildlife, this does not directly address the issue of protection of TK. It also recognizes the fundamental right of the citizens of India to conserve their language, script, and culture.⁴ One of the primary issues of such indigenous knowledge is its vulnerability to biopiracy. India has faced many struggles in trying to protect her traditional knowledge. There are have been serious controversies around the unauthorized acquisition of patents over TK such as turmeric, basmati rice, neem, etc. Such TK has translated itself to prove beneficial to mankind through various commercial uses with an

¹ CHARLES LAWSON, *WIPO, Genetic Resources and TK: The Evolution of a Formal Intellectual Property Agreement Protecting TK Associated with Genetic Resources*, in *GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE*, 31, 48 (Tania Bubela & E. Richard Gold et al. eds., 2012).

² WIPO Media Center, *Background Brief on Traditional Knowledge and Intellectual Property*, https://www.wipo.int/pressroom/en/briefs/tk_ip.html (last visited Feb. 28, 2020).

³ *Id.*

⁴ INDIA CONST. art 29, cl.1.

insignificant amount of investment in time, money, and research. If such knowledge is overprotected, it will hinder future innovation and discoveries as indigenous people do not have the means to conduct such research. But, if it is unprotected, it would lead to overexploitation and deprive the holders of such knowledge from receiving their due share of compensation. Hence, it is indispensable that the intellectual property rights of these native people must be protected, and just compensation should be guaranteed to curb the mining of the riches of such indigenous knowledge.

II. THE GENESIS OF A TRADITIONAL EXPRESSION

The terminology 'traditional expression' has been coined to denote the work of any collection of individuals hailing from a particular community differentiable either on grounds of ethnicity, language, etc. However, it is imperative to understand the process through which a traditional cultural expression originates. Can the simple reason that the creator of a work belongs to an indigenous community suffice to classify an artistic work as traditional knowledge? Unfortunately, a conclusion cannot be drawn on such simple grounds. Various factors such as the period of time, the contribution by the community and the unique nature of the work play a key role in deciding as to the qualification of a work as traditional cultural expression. In order to attain a better interpretation of the subject, one can view traditional expressions as a matter of 'commons', similar to that of the tales told by a wandering storyteller.⁵ It must subsist in the form of a work originating from a community for the use of the community itself. The absence of individuality provides a distinction between a normal artistic work and a cultural expression. The existence of such a condition must not lead to the notion that tradition as such is the property of all.⁶ While they contribute to the heritage of a state or a nation, no party can step forward and claim free use of that work if it can be identified that a certain community has invested work and resources into its creation or if such work stems from the efforts of their predecessors. In the seminal discussions of Roman Jakobson and Piotr Bogatyrev,⁷ the aspect of balance of creator and communal rights has been discussed wherein they state that while an individual might create the folkloric work, it exists only insofar as a particular community has accepted it and made it its own.⁸ Unlike a written work, neither an individual nor a community would be capable of creating folklore in isolation.⁹ The next factor to be taken into consideration would be the period of time taken for it to be considered an 'expression of tradition'. An indigenous cultural expression cannot stem within a night. Rather, it must be attributable to the conscious effort of one or more

⁵ Diarmuid Ó Giolláin, *Who Owns Folklore? From Collective Creation to Collective Ownership*, 79 BÉALOIDEAS 44, 45(2011).

⁶ *Id.* at 46.

⁷ Roman Jakobson & Petyr Bogatyrev, *Le Folklore: Forme Spécifique De Création*, in QUESTIONS DE POÉTIQUE, 59-72 (1973).

⁸ *Id.*

⁹ GIOLLÁIN, *supra* note 5, at 44, 47.

generations of a community as a means of establishing its existence as a timeless piece. A traditional expression must obtain a distinct character of identification, prevalent to such a level wherein it is commonly identifiable by a layman as to its origin or style dwelling from a particular community's work. Such a mark of identification can only be obtained through a reasonable passage of time and the existence of that work during said efflux. The final ingredient required to denote a work as a traditional expression would be the unique element or flavour provided by the community to highlight a distinction in their work, thereby separating it from other similar music forms. Instances of many existing works and their highlights can be taken to elucidate upon the matter. Beats originating from indigenous groups of Tamil Nadu make use of a severely bass-oriented beat in their musical works, thereby attributing uniqueness to the sounds apart from the type of instrumentation employed. Similarly, Kerala folk music makes use of a tempered mid-treble sound in its beats to mark its point of distinction. Punjabi music relies on its line-up of instruments to produce a distinct style of music altogether by way of producing elements through the Dhol, Ektara and the Dilruba. Examples of International traditional expressions include the African vocal choir and the unique instruments used by the African tribes such as the Djembe and the Kalimba. The sound production must either be so distinct or unique that one can easily attribute the style to a certain indigenous community through means of audial perception alone.

III. CURRENT INTERNATIONAL FRAMEWORK ON THE PROTECTION OF RIGHTS OF THE INDIGENOUS COMMUNITY

The primary purpose of any law is to direct its efforts to satisfy the existing needs of TK holders, which includes the promotion and preservation of TK, as well as the sustained development and usage of TK systems. Assuming the existence of an entitlement to TK by a given group, that entitlement may be protected through any of the following four mechanisms.¹⁰ Firstly, a property regime that makes it mandatory to obtain consent for the use of TK. Secondly, a liability regime requiring no form of permission or sanction but inclusive of compensation payable to the indigenous right holders. Thirdly, an inalienability regime barring the 'transferable' component of TK. Fourthly, a combination of any of the above systems. The protection of the rights of indigenous communities in some international instruments is as follows:

- a) Article 27 of the Universal Declaration of Human Rights;¹¹
- b) Article 27 of the International Covenant on Civil and Political Rights;¹²
- c) Article 15(1)(c) of the International Covenant on Economic, Social and Civil Rights;¹³

¹⁰ Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules and Inalienability: One view of the Cathedral*, 85 HARV. L. REV. 1089, 1090 (1972).

¹¹ Universal Declaration of Human Rights, art 27(2), Dec.10,1948, G.A Res. 217 (III) A.

¹² International Covenant on Civil and Political Rights, art. 27, Dec. 16, 1966, 999 U.N.T.S 171.

¹³ International Covenant on Economic, Social and Civil Rights, art. 15(1)(c), Dec. 16, 1966, 993 U.N.T.S 3.

- d) Article 8(j) of the Convention on Biological Diversity;¹⁴
- e) Articles 13, 15 and 23 of the International Labour Organization Convention (No 169) concerning Indigenous and Tribal Peoples in Independent Countries;¹⁵
- f) Berne Convention for the Protection of Literary and Artistic Works;¹⁶
- g) Agreement on Trade-Related Aspects of Intellectual Property Rights;¹⁷
- h) Principle 22 of the Rio Declaration on Environment and Development;¹⁸ and
- i) Articles 11 and 31 of the Declaration on the Rights of Indigenous Peoples.¹⁹

Demands for the protection of folklore were first made at WIPO and UNESCO in the 1960s.²⁰ The failure of the Berne Convention in ensuring adequate protection to traditional cultural expressions led to the commencement of several discussions by the WIPO Governing Bodies in 1978, thereby convening the meetings of the Committee of Governmental Experts. In the mid-1990s, there was a renewed interest in the international protection of folklore. This led to the adoption of the Model Provisions for National Laws²¹ to protect and maintain expressions of folklore against unauthorized exploitation. The Plan of Action Committee of the World Forum on Protection of Folklore²² suggested the drafting of an agreement on the *sui generis* protection of folklore as the current copyright regime was not adequate to ensure such protection.

The growing concerns of 'biopiracy' led to the increased international interests in the relationship between intellectual property, traditional knowledge and genetic resources which acquired the form of the Convention on Biological Diversity.²³ Pursuant to these recommendations, the WIPO General Assembly established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in 2000.²⁴ The Fact Finding Mission (FFM)²⁵ cemented the bleak hopes of the indigenous community that their concerns about the

¹⁴ Convention on Biological Diversity, art. 8(j), June 4, 1993 1760 U.N.T.S 69.

¹⁵ International Labour Organization Convention (No 169) concerning Indigenous and Tribal Peoples in Independent Countries, Sept. 5, 1991, 1650 U.N.T.S 383.

¹⁶ Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, 828 U.N.T.S 221.

¹⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S 299.

¹⁸ Rio Declaration on Environment and Development, June 14, 1992, UN Doc. A/CONF.151/26 (vol. I), 31 ILM874.

¹⁹ United Nations Declaration on the Rights of Indigenous Peoples, Sept. 13, 2007, A/RES/61/295, (2007) (hereinafter UNDRIP).

²⁰ AHMED ABDEL-LATIF, *Revisiting the Creation of the IGC: the limits of constructive ambiguity?* in PROTECTING TRADITIONAL KNOWLEDGE: THE WIPO INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE, 10, 11 (Daniel F. Robinson, Ahmed Abdel-Latif and Pedro Roffe et al. eds., 2017).

²¹ WIPO, MODEL PROVISIONS FOR NATIONAL LAWS ON THE PROTECTION OF EXPRESSIONS OF FOLKLORE AGAINST ILLICIT EXPLOITATION AND OTHER PREJUDICIAL ACTIONS (1985), <https://www.wipo.int/export/sites/www/tk/en/folklore/1982-folklore-model-provisions.pdf>.

²² WORLD FORUM ON THE PROTECTION OF FOLKLORE, Apr. 1997, UNESCO-WIPO/FOLK/PKT/97.

²³ LAWSON, *supra* note 1, at 40.

²⁴ WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, April 2000, WIPO/GRTKF/IC/1.

²⁵ WIPO Fact Finding Missions on Traditional Knowledge, Innovations and Practices of Indigenous and Local

rapacious exploitation of their knowledge and natural resources would be controlled through the IGC process and their rights recognized and traditional knowledge protected. However, even after the passage of 19 years, there has not been any substantial fulfillment of the aims of these indigenous communities. In 1982, a Working Group was established to look into the discrimination and oppression being faced by the members of the indigenous community. The Working Group presented to the Sub-Commission on the Prevention of Discrimination and the Protection of Minorities with a preliminary draft of the declaration on indigenous peoples' rights, which was later accepted in 1994. However, several issues raised by the States with respect to the provisions of the 1994 Declaration led to the setting up of an intersessional working group to consider the same. It was much later in 2007, that the UN General Assembly passed the Declaration on the Rights of Indigenous Peoples.²⁶ The States under this Declaration “*shall consult and cooperate in good faith... to obtain their free, prior and informed consent before adopting and implementing legislative or administrative measures that may affect them*”²⁷. Article 31 grants the right to ‘maintain, control, protect and develop their intellectual property’²⁸ over traditional knowledge and traditional cultural expressions to the indigenous people.

The WIPO-UNESCO Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and other Prejudicial Actions, 1982 (Model Provisions) were incorporated to prevent ‘illicit exploitation’ which can be detrimental to the interests linked with the use of expressions of folklore. They recognize mainly, four forms of expressions of folklore, i.e., verbal, musical, tangible expressions and expressions by actions.²⁹ Section 10 provides for the setting up of a competent authority to grant authorizations for certain kinds of utilizations of expressions of folklore, to receive applications for authorization of such utilizations, to decide on such applications and, where authorization is granted, to fix and collect a fee—if required by law.³⁰ It makes it mandatory to comply with the requirement of acknowledgement of the source in printed publications and treats any unwarranted utilization of an expression of folklore where authorization is required, as an offence. These provisions brought in place a *sui generis* type of law in order to protect the indigenous community against illicit exploitation.

IV. CURRENT FRAMEWORK ON ACCESS AND BENEFIT SHARING

The global framework for access and benefit sharing (ABS) is set up by the Convention on Biological Diversity (CBD) and the Nagoya Protocol. The CBD was one of the multilateral treaties signed at the Rio Earth Summit in 1992 which aims at conservation of bio-diversity as

Communities: Progress Report, May 3, 1999, https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=994.

²⁶ UNDRIP, *supra* note 19.

²⁷ UNDRIP, *supra* note 19, art. 19.

²⁸ *Id.* at 9. WIPO.

²⁹ WIPO, *supra* note 21, §2.

³⁰ WIPO, *supra* note 21, §10.

well as the fair and equitable sharing of the benefits resulting from the utilization of genetic resources.³¹ Such a system of ABS rests on the principle of prior informed consent (PIC) which is granted by a provider to the user and deliberations between the parties to develop mutually agreed terms (MAT). Article 8(j) states that “*Each Contracting Party shall...Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities.... and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising therefrom.*”³² Article 15 deals with access to genetic resources, while Article 16 recognizes the impact of intellectual property on access and benefit sharing. It recognizes the sovereign rights that each State shall have over its natural resources and works towards providing access on mutually agreed terms and with prior informed consent. It also provides for laying down administrative, legislative and policy measures to ensure access to genetic resources and transfer of technology to use the same.

The Nagoya Protocol, adopted under the CBD lays down the mechanism for access to genetic resources and associated TK, thereby encouraging the fair and equitable sharing of benefits. It institutes the setting up of the compliance mechanism for the ABS System by allowing access to genetic resources based on the PIC and MAT of the country of origin or the indigenous local communities. It also provides for the setting up of a national competent authority to register ABS agreements, grant permits for access and also to investigate claims where ABS regulations have not been followed. The competent national authorities will also be responsible for converting the national permits to internationally recognized certificates through the ABS Clearing House.³³ India ratified the CBD in the year 1994 and further went on to enact the Biological Diversity Act (BDA) in order to take cognizance of the provisions of the CBD. The ABS mechanism under the BDA is implemented through the National Biodiversity Authority, which shall regulate activities of commercial utilization, research, bio-survey and bio-utilization of biological resources in India.³⁴

In pursuance of the provisions of the Nagoya Protocol, the Ministry of Environment, Forest and Climate Change notified the ‘Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations’ (“ABS Regulations”) in 2014³⁵. They were issued in order to curb the drawbacks of the ABS system under the BDA and to protect Indian genetic resources from exploitation. It lays down the process for access to biological resources and the

³¹ THE CONVENTION ON BIOLOGICAL DIVERSITY AND NAGOYA PROTOCOL: INTELLECTUAL PROPERTY IMPLICATIONS, UNCTAD/DIAE/PCB/2014/3, (2014).

³² *Supra* note 14, art. 8.

³³ UNCTAD, *supra* note 31.

³⁴ NATIONAL BIODIVERSITY ACADEMY, ABS MECHANISM UNDER THE BIOLOGICAL DIVERSITY ACT, 2002: GUIDANCE MANUAL, <http://nbaindia.org/unep-gef/pub1/Guidance.pdf> (last visited Feb. 28, 2020).

³⁵ NATIONAL BIODIVERSITY ACADEMY, GUIDELINES ON ACCESS TO BIOLOGICAL RESOURCES AND ASSOCIATED KNOWLEDGE AND BENEFIT SHARING REGULATIONS, 2014, http://nbaindia.org/uploaded/pdf/Gazette_Notification_of_ABS_Guidlines.pdf.

mode of benefit sharing in cases of commercial utilization, research or bio-survey. It also permits the granting of intellectual property rights for inventions that are based on such biological resources.

V. THE BASIS OF PROTECTION AND INFRINGEMENT OF MUSICAL WORKS

The dominion of music and its commensurate copyright mechanism has posed various challenges to the legal machinery with regard to adjudicating upon cases of potential infringement. The theoretical foundation of music, coupled with its aural perception and rhythmic progression provides for a complex bundle of sounds that make it difficult to ascertain as to whether a certain part of a tune has been inspired or blatantly ripped from another protected source. While the twelve notes of a musical scale can be arranged in potentially infinite ways, only some of them may sound pleasant enough to pass off as a work of art.³⁶ Moreover, the efflux of time has led to the exhaustion of a major segment of creativity and originality in the field of music. A large number of upcoming works can have their roots traced back to certain classical pieces.³⁷ Judge Irving Goldberg also held that the mere placement of two works side-by-side would not suffice to test for infringement if they can be traced back to a work of Bach.³⁸ The tools of originality in musical composition comprise of three elements – rhythm, melody and harmony.³⁹ It is essential for a musical work to be unique or originally expressed in all these forms to constitute an original work. It is, however, not the sole grounds for adding flavours of uniqueness and variance. Musicians can also choose to diversify or increase the range of instrumentation used in their works to bring about originality in their tune.⁴⁰ The protection granted under copyright law for works of music may not be accurate or true at all times, as it would be impossible for any authority to scourge through a vast repository of musical works to ensure originality of expression. Barring classical works, other works are subject to absolute constraints in order to ensure that two musical pieces do not share any form of major similarity with one another. It is vital for both composers and the copyright society to impose upon themselves a duty of care and responsibility to ensure that the work in question is true in its form and has not been substantially ripped off of another source. While certain relaxations can be provided through the means of sampling and the use of royalty-free sounds, the scope for error is still highly minimal due to the limited vocabulary provided by the element of music.⁴¹

In order to constitute an act of ‘copying’, there must be substantial proof of striking similarities between two works coupled with the access by one party to the work of another. The existence of

³⁶ PAUL GOLDSTEIN, *GOLDSTEIN ON COPYRIGHT* (3rd ed. 2008).

³⁷ Jose Bellido, *Popular Music and Copyright Law in the Sixties*, 40 J. OF L. AND SOC'Y 570, 573 (2013).

³⁸ *Ferguson v. National Broad Co.*, 584 F.2d 111, 114 (1978).

³⁹ GOLDSTEIN, *supra* note 36.

⁴⁰ *Id.*

⁴¹ *Id.*

these two criteria is imperative in order to adjudge the situation and frame solutions for it. However, a suit for infringement cannot be brought before the court where the claim lies with one work being a common or unprotected source. While the composer would still be considered to have ‘copied’ the track, it will be warranted by the legal provisions of that open source. The most prominent precedent for the deduction of an act of copying is the case of *Selle v. Gibb*,⁴² where the court held the act to be an infringement on the grounds that the two songs had “such striking similarities that they could not have been written independent of one another”⁴³. The use of an expert testimony was also present in this case, although it attracted criticism as only one expert testimony was produced wherein two or more could be obtained to strengthen the observations of the court. Modern precedents commonly make use of expert testimonies to decide on the matter of copying, but its admissibility has a divided view. While a court can accommodate for it, various instances of appellate courts have held that a lower court would not be in error only because it has refused to adopt such measures to adjudge the situation.⁴⁴

VI. ACCESS AND BENEFIT SHARING SYSTEM IN INDIGENOUS EXPRESSIONS OF MUSIC

India is a citadel of rich and diverse cultures and religions.⁴⁵ Indigenous cultural expressions of music are “expressions of folklore” which consist of characteristic elements of the traditional artistic heritage developed and maintained by a community in the country or by individuals signifying the customary artistic expectations of such a community.⁴⁶ Folklore traditions in India consist of contributions made by the co-existence of tribal, non-tribal and even urban culture, which has evolved into a common culture. However, with modern developments in technology, there has been unauthorized reproduction and commercialization of such traditional cultural expressions without any sharing of benefits and have been exploited to the detriment of those to whom they belong. Traditional songs and music can be recorded, publicly performed and downloaded from any free music archives and stored as digital information that can then be transferred into other sound files and new compositions.⁴⁷

In India, such traditional cultural expressions of music form the subject matter of copyright under the Copyright Act, 1957. It grants a special right to artists who engage in performances for a period of 60 years.⁴⁸ Indigenous artists can be protected under this section as any sound

⁴² *Selle v. Gibb*, 741 F.2d 896, 223 (1984).

⁴³ *Id.*

⁴⁴ *Overman v. Loesser*, 205 F.2d 521, 524 (1953).

⁴⁵ NATALIE P STOIANOFF AND EVANA WRIGHT, *Fair Use and Traditional Cultural Expressions*, in *MAKING COPYRIGHT WORK FOR THE ASIAN PACIFIC: Juxtaposing Harmonisation with Flexibility* (Susan Corbett & Jessica A Lai et al. eds., 2018).

⁴⁶ WIPO, *supra* note 21, § 2.

⁴⁷ Anurag Dwivedi & Monika Saroha, *Copyright Laws as a Means of Extending Protection to Expressions of Folklore*, 10J.INTELL. PROP. RIGHTS, 308,310 (2005).

⁴⁸ Copyright Act, 1957, § 22, No. 14, Acts of Parliament, 1957(India).

recording or visual recording of their works requires their consent. Section 31-A makes provisions for compulsory licensing in the case of unpublished works or in cases where the author cannot be traced, by allowing the finder of any knowledge to apply for copyright.⁴⁹ However, the system of protection would change majorly with regard to traditional cultural expression as it does not co-exist with any existing conventional Intellectual Property right. On the outset, one may argue that some of the characteristics of indigenous knowledge are incompatible with the basic requirements of copyright protection.⁵⁰ To counter this line of argument, it is first necessary to break down the veil of traditional knowledge itself and look into the true nature of the work in question. While the work may be a rendition of the efforts of various members of a community based on the knowledge and experience of their collectiveness, the ultimate nature of the work formed would still be an artistic work of sound or vision. Every cultural musical expression consists of a bunch of sounds that are unique in nature in either form: instrumentation or arrangement. Therefore, it would not be an outlandish theory to try and include the element of traditional cultural expression within the realm of copyright protection. However, it is also vital to cautiously ensure that the entirety of copyright regulation is not made applicable to cultural musical expressions. Certain elements of copyright protection would be detrimental to the preservation of traditional musical expressions if made applicable to them. One such element would be the limitation of duration of a copyright that is granted to a person. It is common knowledge that a copyright holder has an absolute interest over his work for only a limited period of time, passing which such resource would be made available to the public as free access.⁵¹ However, the implementation of a similar system would prove to be harmful to the interests of the local community that has actively worked over a period of time to create such an instance of art. The transfer of intellectual ownership of that work from the hands of their community would effectively hinder the interests of future generations that would be rendered unable to reap the benefits of the works of their ancestors. The very aspect of copyright is concerned with the creative output of people who enrich the cultural and intellectual dimensions of life.⁵² The primary and unspoken purpose of a copyright system is to ensure that copyrighted works are created and disseminated as widely as possible, keeping in mind the benefits and interests of all parties concerned.⁵³

The indigenous musical expressions are undeniably the creations of human intellect and hence require adequate protection under the intellectual property system in order to meet the needs of

⁴⁹ Copyright Act, 1957, § 31A, No. 14, Acts of Parliament, 1957 (India).

⁵⁰ Jacob L. Simet, *Copyrighting Traditional Tolai Knowledge?*, ANU Press 62, 63 (2013).

⁵¹ Copyright Act, 1957, § 22, 23, No. 14, Acts of Parliament, 1957 (India).

⁵² Denis De Freitas, *Copyright and Music*, 114 J. OF THE ROYAL MUSICAL ASS'N 69, 69 (1989).

⁵³ *Id.*

indigenous people and traditional communities. The best approach is to set up a copyright society under Section 33 of the Copyright Act, 1957 in order to collectively administer the work of protecting the copyrights of these indigenous communities.⁵⁴ The composition of such a copyright society shall be open to individuals who are well-informed about the traditional and cultural heritage of India, individuals having adequate knowledge about music and representatives from various indigenous local communities across India. This society will undertake the task of issuing and granting licenses pertaining to the musical works of the indigenous communities in which copyright subsists or in respect of any other right given by the Copyright Act. It is essential that the term of copyright over the musical works of such communities shall not be restricted to a fixed period of time as this would defeat the purpose of providing such protection. Such works reflect the characteristic elements of the traditional artistic heritage developed and maintained by the community as a whole and hence, it is unfair to grant such protections to a particular individual and impose limitations regarding the term of protection.

Broadly, the mechanism for granting protection to such indigenous and local communities can be classified into two:

Firstly, when such communities have already obtained a registration of their works from the Copyright society;

Secondly, when such communities have not obtained any copyright protection over their works. The first category also recognizes those communities who have published their musical work in any form, i.e., those who have obtained copyright protection over their works through de-facto publication. Any composer or singer who wishes to use the works of such a community will have to obtain a license from the copyright society. It is of utmost importance that such communities receive a fair and equitable share in the benefits arising therefrom. This demands the setting up of the 'Board of Indigenous Cultural Expressions (BICE)' in order to facilitate the system of access and benefit sharing. Any producer or composer who obtains a license from the copyright society for the purpose of commercial utilization shall be required to comply with the requirements of the BICE in order to operationalize fair and equitable sharing of benefits. Any producer who intends to acquire an intellectual property right for any musical composition involving the musical expression of the indigenous local communities will be required to pay such monetary benefit as agreed between the applicant and BICE. However, when there is no evidence which points to the origin of any musical work to a certain indigenous community, any producer who uses any such traditional music will be required to deposit such amount to a common fund created under the BICE. The purpose of such a fund would be to develop the Traditional Knowledge

⁵⁴ Copyright Act, 1957, § 33, No. 14, Acts of Parliament, 1957 (India).

Digital Library (TKDL) in order to create a database for traditional and cultural expressions of music of the indigenous and local communities of various parts of India.

The composition of BICE shall be similar to that of the copyright society and it shall be vested with the powers to look into the infringement of the copyrights of the indigenous local communities and effective implementation of the ABS mechanism. It is therefore expedient to introduce such a mechanism under the aegis of the current copyright framework to ensure protection against biopiracy of their musical works.

The proposed system of Access-Benefit Sharing would ensure that the needs and interests of the traditional communities are secured at all points of time. In many cases, artists often take advantage of the resources provided by them due to their inability to legally challenge the infringement or their complete lack of knowledge of such infringement. The most popular case of the 21st Century with regard to the infringement of traditional knowledge is the controversy that arose due to pop artist Shakira's *Waka Waka*. The song's hook was blatantly taken from a Cameroonian song recorded around 30 years before the creation of the female pop artist's song. The song was considered to be inspired from the 1986 global hit "*Zangalewa*" by the group Golden Sounds of Cameroon. The song features Zolani Mahola of the South African group 'Freshlyground' singing in Xhosa, one of the official languages of South Africa.⁵⁵ In this case, the artists were not able to approach a forum of relief on their own account in the initial part of the legal battle. Such would be the case of many other local communities that would be left helpless in the case of any infringement by a third party. Therefore, there is an underlying need to place a *suo moto* duty on the part of a dedicated institution to combat this lacuna. The law must accommodate for the setup of a body specialized in dealing with such issues of infringement in order to give effect to the propositions of the authors. The creators of traditional knowledge require a more complex and variegated system of norms for the protection of their interests as opposed to harmonized global IP regime.⁵⁶

VII. CONCLUSION

The realm of copyright and its intertwining with the aspect of traditional knowledge poses numerous challenges, the traversing of which are essential in order to ensure a proper mechanism for the preservation of the interests of local indigenous communities. The collection of traditional knowledge provided by various communities of India is extensive and numerous, thus subjecting the aspect of protection to various hardships. Moreover, various socio-cultural

⁵⁵ *Shakira Used Cameroonian Pop Song for World Cup Anthem Without Asking*, THE OBSERVERS (May 13, 2010) <https://observers.france24.com/en/20100513-shakira-used-cameroon-pop-song-world-cup-anthem-without-asking>.

⁵⁶ William Fisher, *Two Thoughts about Traditional Knowledge*, 70 L. AND CONTEMPORARY PROBS 131, 132 (2007).

perceptions also serve as additional obstacles to the upholding of the rights and interests of indigenous communities. The consideration of indigenous knowledge as a sub-category of heritage as under the WIPO glossary⁵⁷ also opens the door of thought to consider it as a public resource as opposed to its existence as a community product. It is imperative that the legal provision for the countering of these problems is sound and equipped with the powers and functions required to effectively settle disputes and monitor the use of traditional knowledge resources. The proposal for the setup of a Board for Indigenous Cultural Expressions (BICE) is targeted towards the primary function of monitoring the warranted use of cultural musical expressions and the redressal of any infringement in favour of the aggrieved community. The framework has been devised in a manner accommodating of the social, cultural and economic interests of its benefactors. The primary mode of redressal must be set towards the obtaining and allocation of royalties in favour of the indigenous community as it is the penultimate interest of the creators, owing to the numerous advantages that can be derived from such compensation. The setup of such a Board is also instrumental in redressing the inadequacies of the copyright societies as their purview does not extend to the protection and consideration of traditional knowledge sources. While the facet of the proposition may be a constraint on the existing legal machinery with respect to financial and redrafting grounds, its success or failure must not be based on short-term performance. The plethora of records of indigenous cultural expressions would make it exceedingly difficult for the Board to accurately identify a potential infringement in its early stage. Adequate temporal development must be allowed for the development of the TKDL repository to serve as a means of referencing for the Board to carry out its activities. In the long run, the interests of indigenous communities must be preserved with the synergies of copyright law and traditional knowledge dominion.

⁵⁷ Christoph Antons, *Asian Borderlands and the Legal Protection of Traditional Knowledge and Traditional Cultural Expressions*, 47 MOD. ASIAN STUD. 1403, 1407 (2013).

**DRONE JOURNALISM AND COPYRIGHT: AN ANALYSIS OF THE DUO UNDER
INDIAN COPYRIGHT LAW**

ANJANA GOPINATH*

Abstract

With countries connecting as a global economy, and international treaties and bodies forming laws to maintain global unity and security, journalism has become a vital component connecting nations across the world. A single event that occurs in a small part of the world may cause a ripple effect introducing new circumstances in different parts of the world. From the print revolution to the emergence of computers and digital cameras, to the intense use of the internet, and now the developing use of drones, journalism has gone through a wide range of development. Earlier, the idea of copyright being vested in a computer or machine was not a concern, as they were merely used as tools for producing the desired creation. However, in the present era, Artificial Intelligence, and works generated through AI with little human intervention have not only created wide commercial implications but have also become a concern in the field of Intellectual Property. The introduction of drones into journalism has raised several Intellectual Property considerations and concerns including the ownership of copyright. This paper seeks to analyze the concept of drone journalism in light of the Copyright law and regulations in India. The reforms needed and precautions to be taken for the protection of Intellectual Property, particularly, copyright in the field of drone journalism is yet another aspect that the author has placed significance upon. The paper concludes with suggestions for reform regarding the laws connecting and concerning drone journalism and Copyright protection in India.

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I. INTRODUCTION

The emergence and evolution of technology have benefited a vast number of fields including mass communication. The development of technology has brought about new ways to approach digital journalism. One of the latest developments in the world of journalism is the use of Unmanned Aerial Vehicles (“UAVs”) or Drones. Drones or Unmanned Aerial Vehicles/Systems are aircrafts that have the capacity to fly without being controlled by a pilot on board.

¹ The International Civil Aviation Organisation, which oversees the regulations concerning airways has also defined them as Remote Piloted Aircraft Systems.² They are controlled by radio waves or work autonomously using a programmed route.³ The number of countries using or planning to obtain drones has been increasing over the years. Similarly, the uses of drones are also increasing, and they also vary from basic civilian use to military uses. One of the recent developments regarding the use of drones involves its presence in journalism. Named *drone journalism*, it refers to the use of Unmanned Aerial Vehicles/Systems for journalistic commitments.⁴ Drone journalism has the capability of becoming a primary source of journalism. However, the law governing drone journalism and its relation to the concept of intellectual property, particularly, copyrights, is still under development. With the advent of an era that promotes drone journalism, there arises a need to discuss the concept to curb any potential legal threats and loopholes surrounding the same.

II. DRONE JOURNALISM AND INTELLECTUAL PROPERTY

In 1858, Gaspard-Félix Tournachon, a French Photographer, Balloonist, and Journalist used aerial photographs in journalism for the first time.⁵ With the help of cameras attached to hot air balloons or even kites, photographers in the late 19th and early 20th century captured photos of landscapes, the damage caused by earthquakes and the aftermath of battles.⁶ Subsequently, the world also saw fixed-wing aircrafts and helicopters being used during the emergence of Electronic News Gathering.⁷ Drones or UAVs in the present-day work in a similar manner – by capturing numerous photos, videos, and even other data without demanding the direct presence of

¹ Ram Gopal Lakshmi Narayanan & Oliver C. Ibe, *Joint Network for Disaster Relief and Search and Rescue Network Operations*, Wireless Public Safety Networks 1, (2015).

² *Unravelling the Future Game of Drones*, NISHITH DESAI ASSOCIATES (Apr. 2018), http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research%20Papers/Unravelling_The_Future_Game_of_Drones.pdf.

³ Piotr Kardasz et al., *Drones and Possibilities of Their Using*, 6 J. CIVIL ENVTL ENGINEERING, no. 3, 2016, at 1, 1.

⁴ *Drone Journalism and the Law*, UNC CENTRE FOR MEDIA LAW AND POLICY, <https://medialaw.unc.edu/resources/drone-journalism/> (last visited Nov. 28, 2021).

⁵ Elna Martinique, *How the History of Aerial Photography Ultimately Inspired the Creation of Drones*, WIDEWALLS (Mar. 26, 2017), <https://www.widewalls.ch/magazine/aerial-photography-drone>.

⁶ Avery E. Holton et al, *Unmanned Aerial Vehicles: Opportunities, Barriers, and the Future of “Drone Journalism”*, 8 JOURNALISM PRAC. 634, 636 (2014).

⁷ Kriti Singh, *Drone Journalism: Potential and Challenges*, CENTRE FOR AIR POWER STUDIES (Mar. 25, 2014), https://capsindia.org/wp-content/uploads/2021/10/CAPS_Infocus_KS4.pdf.

the operator in the location concerned.⁸ Thus, with the help of UAVs, the persons operating them do not have to deal with challenging or dangerous circumstances themselves. Additionally, with other benefits like the flexibility to reach inaccessible areas quickly, easy manoeuvrability, and cost-benefit, the concept of drone journalism will see significant growth in the coming years.

Intellectual Property advances with inventions that increase day by day. Drones, being classified as one of the recent advancements in technology, have become one of the most debatable issues in the field of Intellectual Property. With the application of robotic technology on these systems, the development of robotics in IPR has also seen the limelight.

The responsibility of any infringement by the drone shall lie upon the inventor who carries the right in the invention, and thus, it will be the owner, controller, or holder of the drone who shall be liable to respond in case of any civil or penal action.⁹ Moreover, there are several rights that are associated with the author of a work as well as a copyright holder¹⁰. Hence, it is important to discuss who shall have the major IP right of the copyright associated with drone journalism.

III. COPYRIGHT AND DRONE JOURNALISM: AN ANALYSIS OF THE CONCEPTS UNDER THE COPYRIGHT REGIME IN INDIA.

Copyright legislation concerns itself broadly with the creation of the human mind and seeks to protect the interests of innovators and creators through protection over their works.¹¹ The same protection extends to a variety of creations, which includes photographic works. With the usage of drones in journalism, it is vital to discuss the ownership in copyright in circumstances that involve drones, employees, and employers in the field of journalism.

It is pertinent to note that the use of drones in journalism to assist the latter implies the use of Artificial Intelligence (AI). AI algorithms enable robots to thrive in the field of journalism in all kinds of activities, including data gathering, data analysis, and the writing of narratives¹². Drones, being a significant creation of robotic technology,¹³ have been utilizing similar algorithms while being employed in the field of journalism. And for the same reasons, it is significant to analyse the concept of copyright in drone journalism particularly in the light of authorship, while giving due regard to the legal status of AI in India.

⁸ Avery E. Holton et al., *Drone Journalism*, in 2 THE SAGE INTERNATIONAL ENCYCLOPAEDIA OF MASS MEDIA AND SOCIETY 509 (Debra L. Merskin ed., 2020).

⁹ *Drones and the Challenges of Intellectual Property*, BRLATINA, (Feb. 10, 2016), <https://brlatina.com/blog/2016/drones-and-the-challenges-of-intellectual-property-for-new-tech/>.

¹⁰ Copyright Act, 1957, No. 14, Acts of Parliament, 1957 (India) [hereinafter Copyright Act, 1957]

¹¹ WORLD INTELLECTUAL PROP. ORG., UNDERSTANDING COPYRIGHTS AND RELATED RIGHTS (2d ed. 2016).

¹² Noam Lemelshtrich Latar, *Can Robot Journalists Replace Human Journalists in the Coverage of Wars?* (2016), https://www.researchgate.net/publication/315685166_Can_Robot_journalists_Replace_Human_Journalists_in_The_Coverage_of_Wars.

¹³ Geetali Tilak, *Drones and Media Industry*, 25 RUDN J. ST. LIT. & JOURNALISM 360-366 (2020).

A. The Products of Drone Journalism and the Copyright Law in India

Drones have brought about impressive results as a tool to capture footage for news agencies. The technique has been used to cover news in areas damaged by earthquakes and floods like those in Nepal and India, for investigative journalism like the infamous case of the Columbia meatpacking firm, and the recent cases of police brutality in the USA.¹⁴ Drones have the potential to deliver a massive amount of work for journalism, with less human touch or work involved. However, the legal lacuna, especially in the area of copyright, is intricate.

As far as work created by AI is concerned, the US case of *Feist Publications v. Rural Telephone Service Company, Inc.*,¹⁵ the Australian case of *Acohs Pty Ltd v. Ucorp Pty Ltd*¹⁶ and *Infopaq International A/S v. Danske Dagbaldes Forening*¹⁷ from the Court of Justice of the European Union are examples where it has been held that copyright only subsists on works that are created by human beings or are results of a human's intellectual creativity. Moreover, countries like Germany, Spain, and France require works to bear the "imprint of the author's personality." The lack of a "personality" in AI, thus denies authorship to AI in the AI-generated works.¹⁸ In the case of India, it can be interpreted from Section 2(d)(vi)¹⁹ which accords authorship in a computer-generated work in the person who causes the work to be created, that an AI, or a drone for the purposes of drone journalism, does not in itself hold the authorship in the work it creates.

However, the concept of copyright needs to be further studied based on two main factors, namely, the scope of protection and the ownership in the right.

1. The Scope of Copyright Protection

The 1957 Copyright Act of India, under Section 13,²⁰ confers protection to all original literary, dramatic, musical, and artistic works, along with cinematographic films and sound recordings, and this copyright refers to a bundle of exclusive rights vested in the owner under section 14 of the Act.²¹ This bundle of rights includes the right to reproduction, publication, adaptation, translation, communication of the work to the public, and the like. These rights can be exercised only by the owner of the copyright or by any person licensed by the owner in this regard.²²

¹⁴ Usha Rani Das, *How drones changed the face of Journalism*, BUSINESS INSIDER (Jun 19, 2015), <https://www.businessinsider.in/how-drones-changed-the-face-of-journalism/articleshow/47735970.cms>.

¹⁵ *Feist Publications v. Rural Telephone Service Co.*, 499 U.S. 340 (1991) (India).

¹⁶ *Acohs Pty Ltd v Ucorp Pty Ltd*. (2009) 201 FCR 173 (Austl.).

¹⁷ Case C-5/08, *Infopaq Int'l A/S v. Danske Dagbaldes Forening*, E.C.R 2009 I-06569.

¹⁸ Brigitte Vézina & Brent Moran, *Artificial Intelligence and Creativity: Why We're against Copyright Protection for AI-Generated Output*, CREATIVE COMMONS (Aug. 10, 2020), <https://creativecommons.org/2020/08/10/no-copyright-protection-for-ai-generated-output>.

¹⁹ Copyright Act, 1957, § 2(d)(vi).

²⁰ Copyright Act, 1957, § 13.

²¹ Copyright Act, 1957, § 14.

²² Copyright Act, 1957, § 30.

For any work to be protected under the Copyright laws in India, it has to be:

- i. Original;²³ and
- ii. Fixed in a tangible medium of expression.²⁴

Copyright subsists in literary works as well as photographs among other works, as long as they are original. Here, 'original' in regards to literary work does not imply the originality of an idea, but the originality concerning the expression of the thought.²⁵ Similarly, an original photograph on which some degree of skill and effort has been expended, will be protected as an original artistic work, irrespective of their artistic quality.²⁶

Additionally, as stated above, copyrightability also depends on whether the work has been fixed in a tangible medium of expression. Copyright subsists in expressions and not ideas. The Supreme Court of India has held that there could be no copyright in an idea, subject matter, themes, or plots and that copyright is confined to the form, manner and arrangement, and expression of the idea by the author of the work.²⁷ The Bombay High Court has also observed that an idea is not protected by the Copyright law and that it becomes a copyrighted work only when it is given embodiment in a tangible form,²⁸ and minor forms of expression including concept notes also fall under the same.²⁹

With India's minimum requirements for originality, and with the fixation of a work captured by a drone in an electronic medium, the work can effortlessly pass the two criteria, and thus no legal issues would ideally arise in regard to the qualification of the work to be protected under the copyright law in the country.

The major question, thus, is as to who shall be considered as the copyright owner of a picture taken by a drone, while being utilized for drone journalism.

2. *Ownership of Copyright*

Section 17 of the Copyright Act³⁰ states that the author of the work shall be the first owner of the copyright therein. However, there are certain exceptions to the same, like in case of work made for hire. This shall be discussed in detail later in this section.

²³ *Camlin Private Limited v. National Pencil Industries*, 2002 (24) PTC 349 (Del) DB (India); *Eastern Book Company v. D.B. Modak*, (2008) 1 SCC 1 (India).

²⁴ *Zee Telefilms Ltd. v. Sundial Communications Pvt. Ltd.*, 2003 (27) PTC 457 (Bom)(DB) (India).

²⁵ *Rediff.com India Ltd. v. E-Eighteen.com Ltd.*, 2013(55) PTC 294 (Del) (India).

²⁶ VK Ahuja, *Law Relating to Intellectual Property Rights*, 42 (3rd ed., 2017).

²⁷ *R.G Anand v. Delux Films*, AIR 1978 SC 1613 (India).

²⁸ *Supra* note 22.

²⁹ *Zee Telefilm Limited v. Aalia Productions*, 2000 PTC 382 (India).

³⁰ Copyright Act, 1957, § 17.

Section 2(d) of the Copyright Act of India,³¹ provides that the author of a literary work is the author of the same; and similarly, in relation to a photograph, it is the person who takes the photograph who is the author of it. Similarly, as stated before, Section 2(d)(vi) of the Act defines the author of any literary, dramatic, musical, and artistic work which is computer-generated to be the person who causes the work to be created. Thus, the Indian Copyright law does not give rights to AI for creating work as the Indian law has always laid importance to human interference as a prerequisite for giving copyright protection.³² Furthermore, the Practice and Procedure Manual issued by Copyright Office in 2018 also states that only the details of natural person(s) must be provided as the Author of the work for the purpose of Copyright.³³ AI, not being a natural person, shall not be able to meet such a condition. Therefore, it can be seen from the language of the legislation that the legislators intend to give copyright to the person involved in the making of the work, and not to any “inanimate machine” involved in the process of the creation of the work.

When drones are being used in journalism, the owner of the copyright would be decided according to Section 17 of the Copyright Act. Section 17 provides that the author of the work shall be the first owner of the copyright. However, clause (a) to the section provides an exception to the same. In case the author of artistic work made the same under the employment of a proprietor of a newspaper, magazine, or similar periodical under a contract of service or apprenticeship for the publication of the same, it will be the proprietor who will be considered as the first owner of the copyright unless a contract to the contrary has been entered into.³⁴ Similarly, clause (b) to the section states that in case of a photograph taken at the instance of any person, such person shall be considered as the first owner of the copyright, again, if no contract to the contrary has been made between the parties.³⁵ This implies that if a journalist under the employment of a news channel or newspaper, uses a drone for capturing images, the owner of the copyright would automatically be the newspaper proprietor that has hired the journalist, and not the drone or the journalist. Even if the drone belongs to the journalist, it merely acts as a tool for newsgathering.³⁶ Thus, even then, according to the act, the copyright owner would be the newspaper or the channel. The only exception to the proprietor not holding the ownership is when an agreement has been formed between the parties specifically stating that the author of the work shall be

³¹ Copyright Act, 1957, § 2(d).

³² Lucy Rana & Meril Mathew Joy, *India: Artificial Intelligence and Copyright- The Authorship*, MONDAQ (Dec. 18, 2019), <https://www.mondaq.com/india/copyright/876800/artificial-intelligence-and-copyright-the-authorship>.

³³ Lukas Schroth, *Drones and Artificial Intelligence*, DRONE INDUSTRY INSIGHTS, (Aug. 28, 2018), <https://www.droneii.com/drones-and-artificial-intelligence>.

³⁴ Copyright Act, 1957, § 17 (a).

³⁵ Copyright Act, 1957, § 17 (b).

³⁶ Epp Lauk et al., *Drone Journalism: The newest global test of press freedom*, in FREEDOM OF EXPRESSION AND MEDIA IN TRANSITION: STUDIES AND REFLECTIONS IN THE DIGITAL AGE 117 (Ulla Carlsson ed., 2016).

considered as the owner of the copyright and not the proprietor. However, this is possible between human beings, being legal persons. This is because under Indian law, only a “legal person” can be competent to enter a valid contract. The general rule thus far has been that an AI may not qualify as a legal person, and therefore, a contract entered into by an AI of its own volition may not be regarded as a valid contract in India.³⁷ Furthermore, section 11 of the Indian Contract Act, 1872 states that “*every person is competent to contract who is of the age of majority according to the law to which he is subject, and who is of sound mind and is not disqualified from contracting by any law to which he is subject.*”³⁸ The criteria of the age of majority and soundness of mind cannot be calculated for a drone or any AI stimulated robot for that purpose. In such a case, a drone or the AI connected to the same, cannot be made a party to a contract. Consequentially, a drone or its AI technology cannot enter into an agreement with the proprietor of the newspaper or media channel to assign the copyright to the former.

A drone or the AI technology associated with the same, cannot be granted copyright ownership also due to the following reasons:

i. Term of Copyright Protection

Section 22 of the Copyright Act³⁹, provides that “*copyright shall subsist in any literary, dramatic, musical or artistic work published within the lifetime of the author until sixty years from the beginning of the calendar year next following the year in which the author dies.*” A drone or AI does not die like a human being and can exist for an infinite period. The calculation of the copyright period shall be an issue in such a scenario.

Furthermore, Section 23⁴⁰ (term of copyright in anonymous and pseudonymous works) or Section 24⁴¹ (term of copyright in posthumous work) would also not apply in the case of a drone or an AI, as work created by it would not fall under the said categories.

Therefore, there exists a lacuna in regards to the term of copyright protection in relation to works created by an AI.

ii. Rights Associated with Copyright Ownership

There are a few rights that a copyright owner enjoys, including moral rights, right of paternity and right of integrity, right to sue and be sued, right to assignment, and the right to license. These are rights that can only be enjoyed by human beings.

(a) MORAL RIGHTS

³⁷ Huzefa Tavawalla, *Can Artificial Intelligence Be Given Legal Rights And Duties?*, MONDAQ (Jun. 25, 2018), <https://www.mondaq.com/india/new-technology/712308/can-artificial-intelligence-be-given-legal-rights-and-duties>.

³⁸ Indian Contract Act, 1872, § 11.

³⁹ Copyright Act, 1957, § 22.

⁴⁰ Copyright Act, 1957, § 23.

⁴¹ Copyright Act, 1957, § 24.

The High Court of Delhi, in the celebrated case of *Amar Nath Sehgal v Union of India*,⁴² had recognized the moral rights of the author as the “soul of his works.” Moral rights emanate from the recognition of human emotions. Emotions cannot be associated with an AI. The Copyright Act under Section 57 also recognizes the right to paternity (*droit de paternite*) and the right to integrity (*droit de respect de l'œuvre*). While the former states that the author of a work shall have the right to claim its authorship,⁴³ the latter provides that an author shall have the right to claim damages for any mutilation or distortion of the work if it is prejudicial to his/her honour or reputation.⁴⁴ A drone or an AI, being an inanimate object cannot have honour or reputation attached to it.⁴⁵ Thus, any instance of determining honour or reputation would automatically rest with the individual having ownership in the said drone or AI. Therefore, it can be concluded that a drone cannot have moral rights. This brings us to the next issue faced in providing copyright ownership to AI.

(b) RIGHT TO SUE AND BE SUED

In the absence of AI being recognized as a legal entity, it will be impossible for it to sue for an infringement of copyright, or to assert its rights as a copyright holder. The purpose of copyright protection itself would fail if a right exists, but cannot be claimed. In such an instance, a representative, who would be a human being, would be necessary to assert the rights held by an AI.

Additionally, the law as it currently stands does not attach liability for infringement on an AI system; and the liability for such copyright infringement will thus fall on a natural person. Where a work infringes on a copyrighted work, it is the author of the infringing work who is generally held liable. Accordingly, if the creator of an AI is considered to be the author of any works created by the AI, then the creator of the AI will be held responsible for infringements of copyright by the AI.⁴⁶

A drone/AI can also not be held liable to pay damages to the person whose copyright has been infringed. This again has to be paid by the person or company having ownership of the drone or AI.

Therefore, an AI holding copyright ownership would unnecessarily complicate a situation that would not occur, had the copyright subsisted on the person who designed the AI or has the ownership to it.

(c) THE OWNER'S RIGHT TO ASSIGN OR LICENSE COPYRIGHT

⁴² *Amar Nath Sehgal v Union of India*, 2005 (30) PTC 253 (Del) (India).

⁴³ Copyright Act, 1957, § 57 1(a).

⁴⁴ Copyright Act, 1957, § 57 1(b).

⁴⁵ *Legal Remembrancer v Manmatha Bhusan Chatterjee*, (1924) ILR 51 Cal 250 (India).

⁴⁶ Bharucha and Partners, *Copyright in works created by artificial intelligence: issues and Perspectives*, LEXOLOGY (Feb. 18, 2021), <https://www.lexology.com/library/detail.aspx?g=4513277a-6571-40f1-923d-c09ec5366fdd>.

The copyright owner has the right to assign or license the interest in the copyright to any person at his or her will, as per sections 18⁴⁷ and 30⁴⁸ of the Copyright Act, respectively. However, the incapacity to contract would make it impossible for an AI to assign or license its rights to a third party. Thus, two of the very important rights in relation to copyright cannot be enforced by a drone or AI, even if it holds ownership in the same.

It is pertinent to note that in November 2020, for the first time in India, the copyright office recognized an artificial intelligence tool named RAGHAV Artificial Intelligence Painting App (RAGHAV), as the co-author of a copyright-protected artistic work⁴⁹. RAGHAV is the co-author of a painting titled “Suryast” along with Ankit Sahni, an IP lawyer who owns the AI-based app, and commissioned the said painting. Here, it is important to note that Mr. Sahni’s initial copyright application which listed RAGHAV as the sole author of an artistic work, was rejected by the Copyright Office. It was the second application, on which both Sahni and RAGHAV were named as co-authors, that was granted registration on the 2nd of November 2020. This has opened a new pathway to India recognizing AI as a co-author. The possibility of AI technology being regarded as the sole author is still a pending question.

Nevertheless, even if an AI is considered a co-author, it still would not be able to assert the above-mentioned rights on its own. Only the human co-author or the inventor/owner of the AI can represent it before the court as a legal person. In the light of the same, it is safe to conclude that the current legal system in India is unsuitable for according copyright ownerships in drones or any type of AI tool, for that purpose.

IV. SUGGESTIONS AND CONCLUSION

A significant amount of reformation is necessary for the copyright regime of the country to efficiently analyse the copyright implications surrounding drone journalism. After the aforesaid analysis, the author has come forward with the following suggestions taking into regard the current legislations in the country:

1. A major reform required in the light of increased use of drones and robotic technology is the need for domestic drone regulations which provide express provisions over the ownership of IP rights associated with the drone or any data captured by it. This may be made possible by inserting a separate chapter in the Copyright Act, which governs all types of works created by an AI tool of any kind; including, but not limited to drones. The provisions should be wide enough to cover any possible future inventions in technology in addition to existing

⁴⁷ Copyright Act, 1957, § 18.

⁴⁸ Copyright Act, 1957, § 30.

⁴⁹ ROC No. A-135120/2020, Diary No. 13646/2020-CO/A. <https://copyright.gov.in/SearchRoc.aspx>.

technologies like robots and drones.

The reform should also aim to clarify the position of authorship in an AI-created work. This could be done by adding an explanation to Section 2(d)(vi) of the Copyright Act. The said section states that “author” in “relation to any literary, dramatic, musical or artistic work which is computer-generated” is “the person who causes the work to be created”. The explanation thus inserted, could be as follows:

“Explanation. - For the purposes of this sub-clause, a “computer-generated work” includes work created through tools of Artificial Intelligence.”

A similar explanation could be added to Section 17 of the Act. It could state that *“For the purposes of this section, the first owner of copyright in an AI-created work would be the person who causes the work to be created, or in other words, the owner of the AI tool. Provided that, if the work is made under a contract of service or apprenticeship, the person at whose instance the work was created shall, in the absence of any agreement to the contrary, be the first owner of the copyright therein.”*

Insertions and explanations like those mentioned above could remove the ambiguity as well as lacunas in relation to the copyright ownership in works created by an AI-run machine like drones.

2. The complete rejection of AI-created works would discourage inventors from developing new versions of AI, thus conflicting with the essential purpose of Intellectual Property legislation, i.e., to foster an environment in which creativity and innovation can flourish⁵⁰. Therefore, instead of outrightly denying copyright protection to AI-created works, the Copyright Act should provide copyright protection to the same, by recognizing the individual who created the AI, or the owner who uses the same in order to create original works. Thus, in the case of a drone utilized for drone journalism, copyright protection can be given to the proprietor of the newspaper or the journalist who owns the drone.
3. Similarly, provisions regarding cases of copyright infringement by an AI tool should also be addressed under the Copyright Act of India. With AI not being regarded as a legal entity, the next possible and practical way is to hold the inventor or owner of the AI accountable for an infringement. A natural person, can sue and be sued and will be able to pay damages for any infringement that has occurred. This clears the concern on what shall happen if a suit arises around or is related to AI-caused infringements.

The Indian Copyright law provides sufficient clarity regarding the demarcation of rights of authors and news proprietors. The scope of legal provisions to deal with concerns in considering an AI, in this instance, a drone, as the copyright holder, is fairly grey. There is no difficulty in concluding that it is the drone that captures images and footage for journalistic purposes. However, it must be realized that it is the journalist or the owner of the drone who puts in the

⁵⁰ *What is Intellectual Property*, WIPO, <https://www.wipo.int/about-ip/en/>.

intellect to decide what to capture and how to associate it with the news matter. Section 17 of the Copyright Act provides for two separate instances in case of works made for hire. The first instance deems the person who commissions the work to be made as to the first owner of the copyright. The second instance recognizes a contract in contradiction to the first instance, where the author of the work would be considered as the first owner. The second instance is where the whole legal concern surrounding a drone or an AI, having authorship in the work created, and thus, the copyright in the same, would arise.

The Indian Copyright Office has started recognizing the authorship of AI tools like RAGHAV, the AI painting app. In the light of such developments, and also giving due regard to the ever-developing field of technology and Artificial Intelligence, it is important that the government of the country bring about certain reforms in the copyright regime, to deal with the legal concerns, and above all, to eliminate any ambiguity that exists.