

## **Making Intellectual Property a Common Good to Combat Global Pandemics and the COVID-19 Technology Access Pool (C-TAP): Responding to the Challenges Exerted by Big Pharma and Some High-Income Countries**

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### **Abstract**

*The COVID-19 outbreak has created a global race for research into a vaccine, diagnostic and therapeutic among research institutes, governments, and big-tech pharmaceutical companies (Big Pharma). In this context, intellectual property rights (IPRs) play a prominent role in incentivizing COVID-19 vaccines. Simultaneously, IPRs, particularly the patent rights of Big Pharma, create restrictions on fair access to affordable COVID-19 vaccines. Besides, economically powerful high-income countries have purchased and reserved a large amount of COVID-19 vaccines while low and middle-income countries (LMICs) have been struggling to obtain sufficient vaccine doses. These factors have contributed to increasing the gap of access to affordable COVID-19 vaccines between high-income countries and LMICs. Having foreseen the likely effect of LMICs being discriminated against in the global COVID-19 vaccine production and distribution, the global community has already made some efforts to revisit the normative aspects of IPRs by making intellectual property a common good to achieve global health during the pandemic. For example, the World Health Organization (WHO) has launched the COVID-19 Technology Access Pool (C-TAP), considering the proposal made by Costa Rica. The C-*

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*TAP intended to ensure technology transfer, disclosure of research, flexible licensing and open innovations. However, Big Pharma and some high-income countries have criticised and directly interfered in the effective functioning of C-TAP. Therefore, there remains a question as to whether the C-TAP approach would only be idealistic or realistic in the global governance of IPRs and public health. Accordingly, this paper critically analyses the prospects that C-TAP would offer LMICs to overcome IPRs-related barriers and resource constraints in accessing the COVID-19 vaccine and reflect on how to tackle Big Pharma and some high-income countries' influences on the effective functioning of C-TAP.*

**Keywords:**

*Access to medicine, Big Pharma, COVID-19 vaccine, C-TAP, IP as a common good*

**Introduction**

The main objective of this paper is to analyse how the global community and international law and policy can contribute to the effective functioning of the COVID-19 Technology Access Pool (C-TAP) to ensure access to affordable COVID-19 vaccines worldwide. In doing so, this paper pays particular attention to how big tech pharmaceutical companies (Big Pharma)<sup>1</sup> and their supporting high-income countries have responded to C-TAP and the extent to which they have influenced the functioning of C-TAP. This paper further evaluates the common critique on intellectual property (IP) incompatibility of C-TAP through the lens of considering IP as a common good to facilitate health during global pandemic situations. Having analysed the possible barriers that hinder the effective functioning of C-TAP, this paper makes suggestions on how to overcome such barriers. In general, this paper emphasises the importance of a multi-sectoral approach—participation of diverse policy actors in supporting and enabling global health proposals—to respond to global health concerns.

The global race among research institutes, governments and Big Pharma to find a cure for Corona Virus diseases has almost been accomplished with the finding

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<sup>1</sup>Big Pharma is a commonly used term to indicate multinational pharmaceutical companies. The Merriam-Webster Dictionary defines Big Pharma as ‘large pharmaceutical companies considered especially as a politically influential group’.

of COVID-19 vaccines by some pharmaceutical companies.<sup>2</sup> Particularly, intellectual property rights (IPRs) have played a prominent role in incentivising and accelerating the global race for finding the COVID-19 vaccine. At the same time, IPRs have created significant challenges on the issuance of compulsory licenses, open access for research and innovation, and ultimately the assurance of equal access to affordable COVID-19 vaccine (Chiriboga et al., 2020). In this context, the global health community has faced two challenges: first, to accelerate the global search for safe and effective COVID-19 vaccines and second, to ensure fair access to affordable COVID-19 vaccines.<sup>3</sup> Considering these challenges, the World Health Organization (WHO) has launched the C-TAP to create a voluntary patent pool relating to all medicines, technology sharing and furthering research and development in advancing a COVID-19 vaccine, particularly to mitigate potential IPR-based challenges in finding a COVID-19 vaccine and its fair distribution (Anon 2020a).

Even though the C-TAP seemed to be a pragmatic global solution to ensure access to affordable COVID-19 vaccines worldwide, the global policy actors seem to have diverse opinions on C-TAP. A considerable number of WHO members, health advocates, civil society organizations and philanthropical organizations have embraced this proposal. However, Big Pharma publicly criticized C-TAP, and some high-income countries that are home to large pharmaceutical companies raised their objections at WHO and World Trade Organization (WTO) discussions claiming that C-TAP could erode IPRs and thereby slow the progress of the global search for COVID-19 treatment (Anon, 2020c; Newey, 2020). The criticisms of Big Pharma, and more importantly, the objections raised by some high-income countries that represent the interests of Big Pharma have hindered the effective functioning of C-TAP at the global level. The delays in the proper functioning of C-TAP have created barriers in fair access to technology, know-how and IPRs associated with the COVID-19 vaccine, particularly for low and middle-income countries (LMICs). This situation has affected predominantly on LMICs' capacity of producing or importing adequate COVID-19 vaccine doses.

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<sup>2</sup>According to existing data Oxford-AstraZeneca, Pfizer-BioNtech, Moderna, Sinopharm-Beijing, Gamaleya (Sputnik V), and Sinovac are the most commonly administrated vaccines throughout the world. ("Coronavirus (COVID-19) Vaccinations - Statistics and Research," 2021).

<sup>3</sup>Since vaccine plays a prominent role in the global race for COVID-19 treatment, this paper particularly focuses on analysing the matters relating to the COVID-19 vaccine.

## **Research Problem**

This paper will consider the research problem: how the global community and international law and policy can contribute to the effective functioning of C-TAP to ensure access to affordable COVID-19 vaccine worldwide. The terms ‘global community’ and ‘international law and policy’ used in this research question have specific meanings and applications in the context of global governance of the COVID-19 pandemic. The term global community used in this question refers to global policy actors such as the WHO, international non-governmental organizations (INGOs), civil society organizations, and philanthropic organizations, and in specific cases the WTO which play a vital role in the international governance of trade and IP. The term international law and policy used in this question refers to the specific branches of international law, including international health law and IP law, that affect the implementation of C-TAP and access to the COVID-19 vaccine worldwide.

## **Methodology**

In answering the above research problem, this paper adopted a legal doctrinal analysis consisting of an extensive literature review and a policy-oriented legal approach. The legal doctrinal methodology has been used in this research to systematically analyse the laws and rules governing C-TAP and access to COVID-19 vaccines, to examine the overlaps of these laws and rules, and to make suggestions for future developments (Hutchinson and Duncan, 2012). An extensive review of primary and secondary legal sources on C-TAP, IPRs and access to medicine were used to identify, evaluate, and suggest how the global community and international law and policy can ensure effective functioning C-TAP. Simultaneously, this paper employed a policy-oriented approach to analyse how the emerging COVID-19 pandemic-related political and socio-economic factors influence formulating global health policies and revitalising normative aspects of IPRs (Chen, 2015; McDougal, 1956).

## **Conceptual Background and Discussion**

This section consists of five subparts, and they provide the contextual background of the discussion of this paper and the suggestions to ensure the effective functioning of C-TAP. Part One discusses the need for global action to combat the COVID-19 pandemic. Part Two analyses the importance of making intellectual property (IP) a common good during a pandemic and Big Pharma’s

arguments against considering IP as a common good. Part Three examines the scope of C-TAP with particular reference to Big Pharma and its supporting governments' critiques. Part Four provides an analysis of the contribution of C-TAP from its inception through to today. Part Five makes suggestions to ensure the proper functioning of C-TAP to achieve its objectives in combating the COVID-19 pandemic and establishing C-TAP as a global mechanism to overcome potential IPR-based challenges of access to fair and affordable vaccine and treatment in future global health disasters.

*No one is safe until everyone is safe*

The rapid transmission of the COVID-19 virus has caused nearly 163 million cases of infection and 3.3 million deaths as of 14 May 2021 worldwide (Roser et al., 2020). COVID-19 has created an unprecedented and novel threat to the world (Abrams and Szeffler, 2020). Chakraborty and Maity have recognised the COVID-19 pandemic as 'the most crucial global health calamity of the century and the greatest challenge that humankind faced since the Second World War' (Chakraborty and Maity, 2020). Considering the gravity and impact of the crisis on every aspect of human existence, the WHO declared the COVID-19 outbreak as a public health emergency of international concern on 30 January 2020 (Harapan et al., 2020). It has also created a considerable challenge before humankind finds a cure to contain the spread of the virus and to ensure everyone's access to affordable COVID-19 vaccine (Bassi and Hwenda, 2020).

The societal and economic impact of the COVID-19 pandemic varies from one country to another based on their economic capacity and resources. Undoubtedly, the low- and middle-income countries (LMICs) face severe public health concerns with this crisis compared to their high-income counterparts (Abrams and Szeffler, 2020). In the pre-COVID-19 era, it was estimated that 2 billion people lacked regular access to essential medicine worldwide, particularly in LMICs (Kohler and Mackey, 2020). For example, the cost of the Hepatitis B vaccine—30 US dollars per dose—was too expensive for many LMICs, and thus, they were not able to afford the vaccine (Vanderslott, Dadonaite, and Roser, 2013; Zakir et al., 2019). Arguably, the COVID-19 pandemic would exacerbate the lack of access to essential medicine and could create considerable health disparities between high-income countries and LMICs.<sup>4</sup> Further, LMICs would likely lag in the global race for the COVID-19

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<sup>4</sup> COVID-19 vaccines range from 3 US Dollars (AstraZeneca-Oxford) to 37 US Dollars (Moderna).

vaccine as they lack the necessary resources and financial capacity to engage in high-tech research and innovation (Chiriboga et al., 2020).

As of 14 May 2021, 7.79 billion of the global population has received at least one dose of the COVID-19 vaccine (“Coronavirus (COVID-19) Vaccinations - Statistics and Research,” 2021). Even though the global COVID-19 vaccine administration has been progressing rapidly since December 2020, it has also been predicted that “it could be September 2023 before [the entire world] have enough doses [of vaccine]” (McDonnell et al., 2020). Besides, there is a considerable gap between high-income countries and LMICs in global COVID-19 vaccine administration (Rouw et al., 2021). As the statistical analysis of COVAX<sup>5</sup> and Duke Global Health Innovation Centre demonstrated there is a gap of COVID-19 vaccine purchase between high-income countries and LMICs (McAdams et al., 2020 : (“Vaccine Procurement: Tracking COVID-19 Vaccine Purchase across the Globe,” 2021)). According to this analysis, 57% of the global COVID-19 vaccine doses were purchased by high-income countries that only account for 19% of global adult population. Conversely, LMICs only purchased 38% of global COVID-19 vaccine doses while accounting for 81% of the global adult population (“Coronavirus (COVID-19) Vaccinations - Statistics and Research,” 2021). The huge disparity in terms of vaccine purchase could exacerbate health inequalities between high-income countries and LMICs. Hence, the global community is no longer presented with a task to develop a vaccine to cure COVID-19; however, the global community has the challenge to ensure fair access to affordable COVID-19 vaccines worldwide.

There are two factors that are likely to prevent LMICs from accessing COVID-19 vaccines. First, these countries lack the resources to purchase vaccines and develop their own vaccine (Forman et al., 2021). Second, IPRs'-related barriers exerted by Big Pharma could restrict these countries from access to affordable COVID-19 vaccines (Ido, 2020; World Health Organization, 2020). The vulnerability of LMICs accessing the COVID-19 vaccine demands global policy actors' attention and encourages them to consider comprehensive policy options for revitalising the scope of IPRs to accommodate public health concerns. In

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<sup>5</sup> COVAX is an international partnership that aims to support the development, manufacturing and distribution of COVID-19 vaccines, particularly in LMICs. COVAX consists of international non-governmental organizations such as the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, and the World Health Organization.

such a situation, the C-TAP proposal would be an effective global level solution to ensure ‘widespread technology transfer’ by lessening the IPRs-related barriers to access COVID-19 vaccines and treatment (Wouters et al., 2021).

Nevertheless, the world would only be safe when all affected people are cured and the spread of the virus is permanently contained, including in LMICs. Hence, the COVID-19 pandemic echoes the notion that ‘no one is safe until everyone is safe’. Simultaneously, it demands a supra-national and multi-sectoral solution rather than a country-specific or a region-specific approach in addressing the IPRs-related challenges to access vaccine and treatment in global pandemics. Hence, reiterating the need for global solution, this paper proposes making IP a common good through C-TAP as one of the best approaches to address this concern. The section below examines the importance of considering IP as a common good to respond to the COVID-19 pandemic.

### ***IP as a common good to respond to the COVID-19 pandemic***

Considering IP as a common good would challenge the exclusivity of IPRs’ in their duration of protection and IP owners’ rights to use and enjoy their rights, excluding all third parties (Carrier, 2004). However, the dire need to combat the COVID-19 pandemic can be considered a justifiable reason to limit IPRs, particularly patents, by treating them as a common good accessible and useable by third parties for the sole purpose of ensuring access to affordable COVID-19 vaccines around the world. In general, intellectual property has grown over time and entered all aspects of human life in modern days (Sunder, 2010). Even though property rights are considered to be served for human values, there remains a question as to whether the property rights associated with IP truly serve human values or create some barriers and inequalities in access to technology, innovation and knowledge, and realisation of human capabilities (Sunder, 2006). IPRs are largely governed by the Agreement of Trade-Related Aspects on Intellectual Property (TRIPS), which sets the minimum standards for IP protection at the international level (Dinwoodie and Dreyfuss, 2012). The TRIPS Agreement recognises diverse IPRs such as copyrights, trademarks, patents, geographical indications, industrial designs, layout designs, protection for undisclosed information, trade secrets, and control of anti-competitive practises in contractual licenses. More importantly, the TRIPS Agreement outlines the scope of each IPR, ensuring that owners get exclusive protection over their rights for a limited period, however, subject to the exceptions such as

fair use and achieving public interest and public health goals (Garrison, 2006; Guan, 2016a).

Patent rights have gained considerable attention among Big Pharma and global health actors in the race for COVID-19 vaccines and treatment. Particularly, patent rights propounded on economic ideology and incentive theory could become a major impediment in ensuring equitable access to patented pharmaceuticals (Meiners and Staaf, 1990; Zlinkoff, 1943). The rationale behind granting a time-barred monopoly for the inventor or the manufacturer of the patented product is to compensate his investment in developing such a product and incentivise the same, among other factors (Dam, 1994; Shiffrin, 2009). However, the general conception of patent monopoly backed by the incentive theory could create barriers in access to affordable vaccine in a global pandemic (Kohler and Mackey, 2020). The patent rights obtained by Big Pharma on the COVID-19 vaccine could create different barriers to LMICs access to the vaccine. In distributing the COVID-19 vaccine, Big Pharma could be favourable to high-income countries that often represent Big Pharma's interest in global economic and health forums such as the WHO, TRIPS and WTO councils (Nhamo et al., 2021). For example, AstraZeneca had announced that they offer priority in providing the vaccine for both the USA and the UK in mid of 2020 (Roope et al., 2020). Further, in February 2020, the USA has entered into an investment agreement with Sanofi<sup>6</sup> to secure preferential and priority access to the future vaccine (Paton, Griffin, and Koons, 2020; Woods et al., 2020). It seems Big Pharma facilitates 'my country first' approach, which is commonly known as vaccine nationalisation (Abbas, 2020a; Phelan et al., 2020). This situation could be unfavourable and perhaps jeopardise LMICs that face severe health consequences with the rapid progression of COVID-19, and at the same time, that lack financial resources to invest in the developing and purchasing COVID-19 vaccines.

The behaviour of Big Pharma and some high-income countries have revealed that patent monopoly and vaccine nationalization could be a deadly combination on the ethical framework of global vaccine allocation and fair distribution of vaccines in the COVID-19 pandemic. To have an ethical framework for global vaccine allocation and distribution, the global community could consider benefiting people by limiting the harm which could be created by patent monopoly and vaccine nationalisation, and prioritizing the needs of

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<sup>6</sup> Sanofi is a French multinational pharmaceutical company headquartered in Paris, France, as of 2013, the world's fifth largest by prescription sales.



marginalized countries, in this case, LMICs. Considering IPRs as a common good rather than exclusive private property to accommodate more significant societal interests such as public health and human values (Sunder, 2012) would be one way to address the adverse impacts of patent monopoly and vaccine nationalisation on LMICs, particularly in the time of the COVID-19 pandemic.

### ***Patent Monopoly Vs Access to Medicine***

This section provides a theoretical account of patent versus access to medicine debate exploring the involvement and response of Big Pharma. The complex relationship between IPRs and public health is a significant concern in patents and access to medicine debate. As Sam Halabi commented, ‘the exclusive control given to pharmaceutical patent holders, ... stands at odds with access to affordable medicines’ (Halabi, 2014). Nevertheless, it is argued that patent monopolies facilitate profits, new and improved medicines and drive knowledge-based economies. The monopoly granted to a patentee in the current context is justified through factors such as the high cost of research and innovation (Sellin, 2015). Even though the rationale behind patent monopoly is to incentivise innovation, the practice of patent holders—pharmaceutical industry—revealed that patent monopoly is ‘gaming the system’ by using IPRs to evergreen patents (having rights indefinitely) and profiteer off public health crises (Hassan, 2020). The patent protection granted to a medicine, vaccine or a pharmaceutical product is a dominant factor in bargaining between the patentee and the public (Khachigian, 2020). Even though innovation for treating and preventing acute diseases could assist millions of vulnerable and sick people, access to essential and life-saving diagnostics and therapeutics for many chronic conditions are limited due to a gaming system by patent holders in the pharmaceutical industry.

As a positive response to this issue, the Doha Declaration on TRIPS and Public Health (Doha Declaration) was introduced in 2001 to allow a flexible reading of TRIPS to accommodate ‘access to affordable, essential drugs in the developing countries’ (Ahmadiani and Nikfar, 2016). Further, it intended to reaffirm the TRIPS members’ rights to regulate public health concerns (Abbas and Riaz, 2013; Abbott, 2002). The post-Doha Declaration era provides a contextual basis for realising how Big Pharma and proxy governments interfered and made it difficult for countries, in particular the LMICs, to effectively utilise Doha proposals to promote access to medicine at national level (Novella, 2010; Williams, 2015). They created different obstacles on the TRIPS members’

efforts to use Doha flexibilities to issue compulsory licenses (CLs) on essential medicine. As discussed in the table below, the most popular tactic was to create hostile situations and impose retaliatory measures against the TRIPS' members' efforts to issue compulsory licenses (Beck et al., 2019; Ford et al., 2007; Wibulpolprasert et al., 2011).

**Table 1: Examples for Industry and Lobbying Country Oppositions on the Issuance of Compulsory Licenses**

<b>Country</b>	<b>Initiative</b>	<b>Opposed industry actor/country</b>	<b>Nature of the hostile situation or retaliatory measure</b>
Brazil (2005-2007)	The decision to issue a CL for antiretroviral (AVR) drugs	Abbott Laboratories United States of America	Demanded the Brazilian government to restrict the CL and moratorium on future price negotiations until 2011.
Thailand (2006 - 2008)	The decision to import a generic version of ARV drugs from India under a CL. - similar license to import ARV drugs. - four additional licenses to import cancer drugs.	Abbott Laboratories  United States of America  European Commission	Decided to withdraw its applications for marketing approval on seven new drugs, condemning Thailand's decision to issue CL on its products. The Office of the United States Trade Representative (USTR) subsequently removed the Generalised System of Preference (GSP) on three products exported by Thailand. A letter issued by the European Trade Commissioner criticised Thailand's decision to issue CL, stating that 'such approaches could lead to Thailand isolation from the global biotechnology investment community'.
India (2012-2015)	The decision to issue CL for a cancer drug.	United States of America	USTR named India on the 'Priority Watch List', and US International Trade Commission (USITC) investigated India's trade and

<b>Country</b>	<b>Initiative</b>	<b>Opposed industry actor/country</b>	<b>Nature of the hostile situation or retaliatory measure</b>
Colombia (2016)	The decision to issue a CL on leukaemia drug listed in the WHO's Essential Medicines List.	Novartis Colombia & Novartis International A.G. Swiss Confederation Colombian Embassy in the United States	investment policies. The Colombian Ministry of Health received different communications that contained the: - allegations on factual inaccuracies and distortion of international trade and IP obligations; - threats of dispute settlement claims; - threats to suspend the promised US funding for the Colombian peace process.

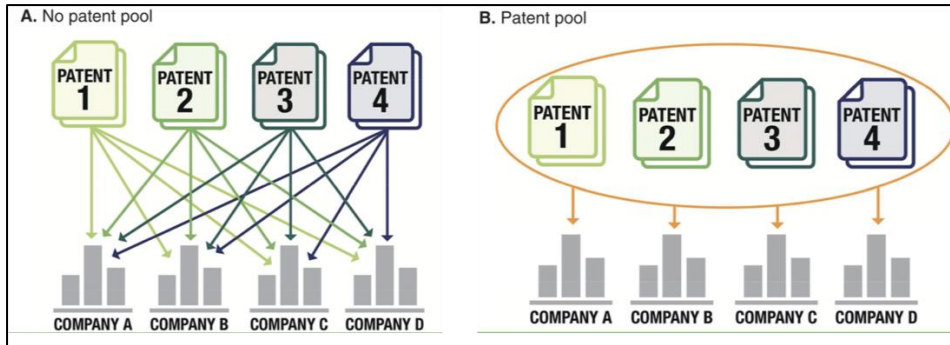
As evidenced, Big Pharma and highly industrialised countries such as the USA, EU and Switzerland created hostile situations and retaliatory actions against other countries' efforts to issue compulsory licenses. Hence, the examples depicted in the above table witness to the power of Big Pharma and some of the high-income countries, in posing obstacles on the use of internationally agreed norms for access to medicine by the LMICs to achieve their public health goals (Dutfield, 2020). This observation leads us to consider the bigger picture of the capacity and the lobbying power of Big Pharma to suppress global efforts to promote public health. Given Big Pharma and proxy governments resisted the Doha Declaration, one can reasonably imagine how they would respond to a WHO level initiative such as C-TAP that is less binding when compared to the Doha Declaration.

Even today, Big Pharma continues to use their devious tactics, threats and retaliation to lock up the knowledge commons by extending control over life-saving drugs using patent rights as a tool (Gotzsche 2019). Further, there are some instances in which the pharmaceutical companies protest against the approval and production of generics (Stiglitz, Jayadev, & Prabhala, 2020). Further, there may be some risks of falsified and substandard medicines, risk of power and influence of pharmaceutical companies and potential system bias, if the process of development of a COVID-19 treatment is left entirely to pharmaceutical companies. Hence, the process should be regulated to some extent and over-sighted by the global health actors, particularly the WHO.

In addition, there are several reasons IPRs should be considered as a common good in responding to the COVID-19 crisis. First, the territorial nature of IPRs could be a significant impediment in furthering IP as a common good in this global pandemic (Rotstein, 2011). Some countries, such as Canada, Chile and Israel, have already adopted pre-emptive measures that facilitate the effective use of compulsory licenses on prospective COVID-19 treatment (Madar et al., 2020). However, country-specific considerations would not create equal opportunities for all countries, in particular the marginalised LMICs, to access affordable COVID-19 treatment. Therefore, it is essential to consider IPRs as a common good at a global level in advancing COVID-19 treatments and the issuance of compulsory licenses for such treatments. Otherwise, the invented vaccine or COVID-19 treatments will only be an asset for Big Pharma or a particular country with strong IPRs protection. Second, the Doha Provisions for compulsory licensing were rarely applied by TRIPS' members due to their highly technical and time-consuming nature (Bhattacharya 2012; Harris, 2011). In respect of COVID-19 treatment, there should be a useful and prompt mechanism to conclude compulsory licenses between patent holders and generic drug companies. In this context, considering IPRs as a common good through the creation of common IPRs and a technology pool would be a pragmatic solution to remove the IP-based regulatory barriers to research and access COVID-19 treatment.

### ***Patent pooling and C-TAP***

The concept of patent pooling can perhaps be considered as an advanced version that has emerged from the compulsory licensing for access to essential medicine. Patent pooling is an agreement that enables two or more patent holders to license one or more of their patents as a package by enabling the third party to pay associated royalties (Verbeure et al., 2006). As demonstrated in the figure below, in the presence of a patent pooling system, the third parties could quickly obtain licenses from the centralised pool without contacting each patent holder, and with less interaction cost (Luca, 2015).



**Figure 1: A comparative illustration of the different licenses needed in the absence and presence of patent pooling.**

Put in other words, patent pooling encompasses a bundle of benefits such as elimination of stacking licenses, reduction of licensing transaction costs, expedition of the exchange of technical knowledge and information, and discouragement of patent litigation. Given that patent pools require voluntary participation of various patent holders, its success would depend on the voluntariness of patent holders. However, patent pooling has been an innovative solution to remove the stacking of multiple patents and multiple patent holders and to enhance the willingness of technology information sharing by patent holders (Verbeure et al., 2006).

The Medicines Patent Pool (MPP) was the first global level public health patent pool established in 2010 with the mandate of improving ‘access to antiretroviral treatment (HIV/AIDS drugs) in the LMICs’ (Burrone et al., 2019; Cox, 2012; Ulrich, 2015). Several pharmaceutical companies signed licensing agreements with the MPP by extending their voluntary support (Abbas, 2020b; FM’t Hoen, 2016). Subsequently, the MPP’s mandate was expanded to include hepatitis C and tuberculosis treatment, the WHO Essential Medicines List, and most recently the COVID-19 medicines and diagnostics (Abbas, 2020b; Moore, 2015). Even though the MPP served as an influential global initiative for patent pooling, its scope was somewhat limited as it is confined to patent rights and limited reach of the LMICs. Accordingly, the C-TAP was launched considering Costa Rica’s proposal as an advance global IPR and technology pool to respond to the COVID-19 pandemic effectively.

***Costa Rica's proposal and WHO's involvement in launching of C-TAP:***

In a letter dated March 23, 2020, the President of Costa Rica, Carlos Alvarado, requested the WHO to undertake an effort 'to pool rights and technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic' (Love, 2020). In general, the proposal was aimed at accelerating access to research outcomes, intellectual property and shared data through a collaborative global effort (Abbas, 2020b). More importantly, the proposal encapsulated the ideologies of a global corporation and voluntary participation to promote global nonexclusive voluntary licensing for COVID-19 treatment (Baker, 2020). According to the President, Costa Rica's proposal was a solidarity call for action to all stakeholders, such as WHO members, academia, companies, research institutions and cooperation agencies, to coordinate joint research and development of a vaccine for COVID-19 (WHO and Costa Rica preview technology pooling initiative to ensure access to COVID-19 health products for all, 2020). Hence, Costa Rica's proposal can be considered as a wake-up call for global solidarity to address the regulatory barriers, in particular the barriers associated with IPRs, in responding to the COVID-19 pandemic.

Another significant aspect of this proposal was that it emphasised the need for broadening the scope of technology and IP pool from the traditional focus of patent rights to the broadest possible IPRs needed to accelerate the global search for COVID-19 treatments and their fair distribution (Baker, 2020). As cited in the objectives of Costa Rica's proposal:

*This pool, which will involve voluntary assignments, should include existing and future rights in patented inventions and designs, as well as rights in regulatory test data, know-how, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines. It should provide for free access or licensing on reasonable and affordable terms, in every member country (Carlos Alvarado Quesada, Presidente de la República, Costa Rica, and Daniel Salas Peraza, Ministro de Salud, Costa Rica, 2020).*

Therefore, Costa Rica's proposal seems to be more comprehensive than the MPP as the proposal provides 'broader focus of IPRs' and emphasises the need for a 'global approach' (Abbas, 2020b). Based on Costa Rica's open letter, the WHO launched C-TAP on May 29, 2020. Through this initiative, the WHO intended to provide an encompassing strategy for scientific knowledge, technology, data and intellectual property shared equitably among all research

of the globe (Love, 2020). The C-TAP has the following five key objectives (Anon, 2020a).

1. Public disclosure of gene sequences and data.
2. Transparency around the publication of all clinical trial results.
3. The collaboration of governments and other funders encouraged to include clauses in funding agreements with pharmaceutical companies and other innovators about equitable distribution, affordability, and the publication of trial data.
4. Licensing of any potential treatment, diagnostic, vaccine, or other health technology to the MPP.
5. Development of life-saving medicines for LMICs and promotion of open innovation models and technology transfer that increase local manufacturing and supply capacity through joining the Open COVID Pledge and the Technology Access Partnership (TAP).

As seen, all five objectives of the C-TAP associate with multiple forms of IPRs that may be involved in the process of developing and distributing COVID-19 treatment. Accordingly, this global initiative lays a foundation to consider different IPRs such as patents (Guderian, Bican, Riar, & Chattopadhyay, 2021), copyrights (Abeysekara, 2011 and 2012), know-how, and software rights (Kumar, Gupta, & Srivastava, 2020) to be considered as a common good for the sole purpose of accelerating global efforts to combat the COVID-19 pandemic. These objectives do not necessarily mean that the C-TAP would remove entire IPRs from its holders; instead, they require right holders to respect and accommodate the public health exceptions associated with IPRs concerning the global pandemic situation (Baldini and Bonadio, 2020). Hence, it is irrational to argue that C-TAP would eliminate protected IPRs of Big Pharma, and create a permanent negative and unclear precedent in the global research and development landscape (Millar, 2020).

The C-TAP has gained considerable global attention and 37 WHO members, including Sri Lanka, have informed the WHO that they join the ‘solidarity call to action’ to make it a reality and ensure its effective implementation (Anon, 2020c). At the same time, Big Pharma and proxy governments have entered into a war against C-TAP, claiming this initiative deprives their IPRs and vested interests while creating a negative precedent in the global IP landscape. The section below analyses Big Pharma and proxy governments’ responses on C-TAP.

***Big Pharma and its proxy governments' response on C-TAP:***

There has been a considerable resistance from pharmaceutical giants such as AstraZeneca, GlaxoSmithKline, Pfizer, and Johnson & Johnson since the discussion on COVID-19 patent pooling was started (Newey, 2020). Albert Bourla, the Chief Executive of Pfizer pharmaceutical company, has criticised C-TAP, stating that:

*I think it is nonsense, and at this point, it is also dangerous. There is an enormous effort right now happening to find a solution. The risks we are taking [represent] billions of dollars and the chances of developing something are still not very good (Newey, 2020).*

This argument reflects the Big Pharma's position, which always focuses on IP as a motivation for innovations and advanced drug marketing (Grabowski, 2002; Hartmann, 2017). Even though many countries supported C-TAP, the USA has rejected 'any involvement' to the process (Silverman, 2020). It is not surprising that Big Pharma and the USA continue to criticise and disapprove C-TAP, as they have a known history of challenging every pragmatic change introduced to counterbalance IP monopoly, in particular, patent rights over pharmaceutical drugs. Big Pharma's response to early patents pools provides similar examples of resistance. When UNITAID established the MPP in 2009 (New, 2009), some pharmaceutical companies explicitly mentioned that 'they could better accelerate access to medicine themselves rather [than] sign up to the pool' (Jack, 2010). Big Pharma's response to C-TAP seemed to be more aggressive and agitated when compared to their response on MPP. Big Pharma tends to highlight IP as a big issue to challenge and discredit the C-TAP proposal. For instance, as the Chief Executive of AstraZeneca pharmaceutical company stated:

*"I think IP is a fundamental part of our industry and if you do not protect IP, then essentially there is no incentive for anybody to innovate" (Newey 2020).*

Further, the International Federation of Pharmaceutical Manufacturers Association (IFPMA), the executives of top pharmaceutical companies, have questioned the C-TAP, criticising its aim for a voluntary IP pooling (Anon, 2020b). Moreover, the Coalition for Epidemic Preparedness Innovations (CEPI), one of the leading vaccine funding groups, has opposed Costa Rica's proposal, stating that 'it is not effective and not necessary' (Story, 2020). For the success of C-TAP, it is essential to obtain support from major



pharmaceutical companies and highly industrialised countries in which such companies are housed. Such support would dispel the uncertainties of the effectiveness of C-TAP and contribute to rejecting the IP incompatibility argument often leveled against the C-TAP proposal.

### ***Functioning of C-TAP and the journey so far***

It has been nearly ten months since WHO launched C-TAP ‘calling the global community to share knowledge, IPRs and data necessary for [finding and distributing] COVID-19[vaccine and treatment]’(Anon, 2020a). Even though this global initiative has received considerable global attention ever since, little global action has been taken to realize its objectives (Hoen, 2021). Seemingly, Big Pharma and some high-income countries have played a vital role in the process of obstructing the functioning of C-TAP (Anon, 2021). At the same time, WHO and WTO member states and civil society organizations such as Oxfam that represent People’s Vaccine Alliance and Health Action International have directly been involved in encouraging WHO to take concrete actions to realize the objectives of C-TAP (Hoen, 2021). This section assesses the controversial journey of C-TAP so far, referring to its ups and downs, and the future prospects.

A considerable number of WHO member countries, mainly the countries in LMICs’ cluster, have taken substantial efforts to make C-TAP a reality rather than a proposal. Ethiopia submitted a draft resolution to WHO in December 2020, highlighting the challenges faced by developing nations in establishing robust local production facilities for vaccines, treatments and other health technologies (Balasubramaniam, 2021). Expanding this proposal, China, Eswatini, Ethiopia, Ghana, Kenya, Namibia, Rwanda, South Africa, Sudan, Togo and Zimbabwe have submitted the resolution Strengthen Local Production of Medicines and other Health Technologies to Improve Access to the Executive Board of WHO in January 2021.<sup>7</sup> Even though this resolution recalls the global commitments towards enabling C-TAP, it has not been concluded yet due to the WHO members’ diverse opinions on the language referring to TRIPS health flexibilities and transparency of the C-TAP proposal (Balasubramaniam, 2021). A similar incident happened in the TRIPS Council when considering India and South Africa’s proposal to temporarily waive

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<sup>7</sup>See, PP20 bis of the *Resolution Strengthen Local Production of Medicines and other Health Technologies to Improve Access*, EB148/CONF./9, World Health Organization, 148<sup>th</sup> Session of the Executive Board, (21 January 2021).

TRIPS provisions on copyrights and related rights, industrial designs, patent and undisclosed information to ‘prevention, containment or treatment of COVID-19’ (Usher, 2020).<sup>8</sup> High-income countries such as Switzerland, European Union and the UK opposed this proposal claiming that a ‘well-functioning IPR system would be a solution rather than an obstacle to developing a safe and effective vaccine for COVID-19 (Balasubramaniam, 2020; Reuters Staff, 2021). These oppositions have made India and South Africa’s proposal of temporarily waving TRIPS provisions inconclusive at the TRIPS Council (Mercurio, 2021).

The resolution submitted to the WHO and the proposal presented at the TRIPS Council can be considered substantial efforts taken by countries to recognise the underline premise of C-TAP, which encourages considering IP as a common good to ensure fair access to affordable COVID-19 vaccines worldwide. However, the same considerations of IPRs have been the trigger that creates disagreements between high-income countries where most pharmaceutical industries are housed, and LMICs are keen to obtain fair access to affordable COVID-19 vaccines. Thus, the lack of political support and resistance of some high-income countries prone to represent the interests of Big Pharma have been two key factors that influence the effective functioning of C-TAP at the global level. Further, less faith in C-TAP has evolved due to a lack of clarifications on who provides political leadership for C-TAP and who undertakes the responsibility of ensuring transparency of C-TAP activities.

If C-TAP is supported by many developed nations and functioned efficiently to achieve its major objectives, it could create fair opportunities to distribute the COVID-19 vaccine worldwide. If C-TAP has functioned as intended, it would have expedited manufacturing the COVID-19 vaccine and ensured the transparency of the publishing and disclosing important clinical trials conducted by Big Pharma. Further, if C-TAP has properly functioned through its initiation, it would have contributed to encourage redistribution of resources and finance to ensure that LMICs get the necessary support to overcome resource constraints in manufacturing or buying the COVID-19 vaccine. Moreover, C-TAP would have been detrimental to the proper functioning of COVAX, which provides a significant contribution towards financing and distribution of COVID-19 vaccines among LMICs (Anon, 2021; McAdams et al., 2020). However, the journey so far has not been favourable to the proper functioning of

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<sup>8</sup>*Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, IP/C/W/669, World Trade Organization, Council for TRIPS, (02 October 2020).

C-TAP with its full strength. Hence, it is reasonable to argue that C-TAP has been underutilized or perhaps underperformed at the global level in ensuring that LMICs are not left behind in the battle against COVID-19.

***The uphill battle: responsibility of the global community to advance C-TAP***

Seemingly, the global community has an uphill battle in establishing C-TAP as a global mechanism to facilitate the transfer of technology, IPR and research data necessary to ensure fair and affordable access to the COVID-19 vaccine. The need to make IP a common good through C-TAP can be considered the recent most example of the lingering conflict between IP and public health since adopting the TRIPS Agreement. Even though the TRIPS flexibilities and Doha Declaration provided practical proposals to harness this conflict, it seems Big Pharma and its supporting countries continue to circumvent such proposals using their might. They have already expressed their disappointment with C-TAP (Newey, 2020). Seemingly, there is a strong likelihood that Big Pharma, and proxy governments would continue to use any tactic to dilute the effective functioning of C-TAP. Hence, it is immature to think that anyone could stop Big Pharma and its supporting countries from undermining pragmatic health proposals such as C-TAP. However, the global community could collectively resist and manage such influences (Ekström et al., 2021). Accordingly, this paper suggests increased stakeholder participation and strong corroboration between the WHO and WTO as significant factors in responding to Big Pharma and its supporting governments' interference in enabling C-TAP.

Global solidarity is considered one of the pillars of global governance for health (Gostin, 2014). There have been different calls for stakeholder participation and global corroboration in respect to the C-TAP initiative. The 'General Assembly of the United Nations Resolution on International Cooperation to Ensure Global Access to Medicines, Vaccines and Medical Equipment to Face COVID-19'<sup>9</sup> and the 73<sup>rd</sup> World Health Assembly Resolution on "COVID-19 Response"<sup>10</sup> were adopted to escalate global commitment for a COVID-19 response (Anon, 2020c). These international commitments invited the global actors including, countries and research development funders, knowledge holders of IPRs or data on existing or novel treatments, researchers, patients and communities, inter-

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<sup>9</sup>*Resolution on International Cooperation to Ensure Global Access to Medicines, Vaccines and Medical Equipment to Face COVID-19, A/RES/74/274, General Assembly, UN Doc. A/74/L.56 (08 April 2020).*

<sup>10</sup>*COVID-19 Response, A73/CONF./1 Rev.1, World Health Organization, 73<sup>rd</sup> World Health Assembly, (18 May 2020).*

governmental and non-governmental organizations, and all stakeholders to confirm their participation and accountability for the global action towards combating COVID-19, which includes enabling C-TAP.

The tug of war between some high-income countries and LMICs concerning C-TAP at the international level provides an example of the fragmentation of international law (Koskeniemi and Leino, 2002; Trachtman, 2011; Young, 2012). At the same time, it emphasizes the importance of integrating health and IP norms and building partnerships among TRIPS Council, WTO, and WHO to respond to global health crises (Drope and Lencucha, 2014). Therefore, it needs greater co-operation between WHO and WTO to minimise the normative and institutional fragmentation of health and IP norms simultaneously in enabling the effective functioning of C-TAP. Given that WTO focuses on trade liberalization, we cannot reasonably expect WTO to facilitate C-TAP as the WHO does. However, WTO could facilitate and encourage the integration of trade norms with health norms, particularly in the ongoing discussions of temporarily waving TRIPS provisions at the TRIPS council (Zarocostas, 2021). In fact, as the paternity rights holder of C-TAP and as the custodian of global health, WHO has a greater responsibility to enable C-TAP's functioning with the support of its member countries. As clearly stated in a letter sent by OXFAM addressing the WHO Director-General, WHO could provide further clarifications of aspects such as the strategy, mandate, political leadership and the mechanism of ensuring transparency of that activities carryout by C-TAP (Hoen, 2021). Further, it is also important that WHO drafts model agreements that C-TAP could use in concluding matters of sharing of rights in the invention, research data, biological resources, knowhow and knowledge transfer.

In addition to these institutional collaborations and the particular involvements of WHO, the following two aspects should be considered in justifying C-TAP in international law and policy, particularly in the context of IPR regulations. First, the normative integration of IP, human rights and public health can be used as a theoretical base for verifying IP as a common good through the C-TAP amid the COVID-19 pandemic. The normative integration of IP and public health emphasises that individual IPRs should be interpreted and understood in a manner sensitive to public health (Guan, 2016b). Accordingly, international developments of IP and public health could be used to defend IP-based challenges on the C-TAP proposal. Second, the cardinal premise of the Sustainable Development Goals 2030 Agenda (SDGs) – ‘leave no one behind’ – can be used to justify the need for global participation to ensure the LMICs are

not left behind in the global race for COVID-19 vaccines (Buse and Hawkes, 2015; Filho et al., 2019). Further, SDGs Goal 3, which denotes ‘health and well-being for all’, and SDGs Goal 17, which requires ‘global participation’, can be used to substantiate collaborative actions towards enabling C-TAP (“Sustainable development goals – United Nations,” n.d.). These aspects would contribute to verifying IP as a common good in the time of the COVID-19 pandemic, foster stakeholder participation and global corroboration to ensure the smooth functioning of C-TAP, and finally, affirm fair distribution of COVID-19 vaccines among every country without discrimination.

## **Conclusion**

This paper concludes that the participation of global policy actors, including the partnership among the WHO, WTO and TRIPS Council, are important factors in tackling the influence of Big Pharma and some high-income countries on the effective functioning of C-TAP to ensure that every country gets a fair opportunity to access affordable COVID-19 vaccines. As this paper has investigated the cardinal premise of C-TAP— making IP a common good to respond to the COVID-19 pandemic—it provides a theoretical account of the role of IPRs in a global health crisis. In this vein, this paper emphasizes the importance of making IP a common good to uphold health equity which ultimately every country receives fair opportunities to access affordable medicine, particularly in global health emergencies such as the COVID-19 pandemic. Further, this paper witnesses the power that the multinational corporations have accumulated, particularly Big Pharma, and how these companies and some high-income countries react to undermine the global health proposals utilising the IPRs protected under the TRIPS Agreement. Big Pharma’s intervention on C-TAP mirrors how multinational companies interfere with shaping international law and policy, particularly the global health proposals (Freudenberg, 2014). Similarly, there is a tendency that Big Tobacco, Big Alcohol and Big Food use their full might to interfere with the effective implementation of pragmatic global health policies (Damle, 2018; Delobelle, 2019; Reeve and Gostin, 2019). These multinational corporations are economically powerful, politically strong and strategically equipped in subverting any health policy which may affect their trade, profitability and long-term sustainability. Big Pharma's blatant war against C-TAP is a clear demonstration of this long-lasting issue. Hence, the COVID-19 crisis can be considered as a wake-up call for the global health community, and countries to proactively resist and manage pharmaceutical industry tactics and the

involvements of their supporting high-income countries in undermining the global health proposals. The solidarity action would make the public health community and stakeholders more potent than Big Pharma and some of the high-income countries that lobby for Big Pharma. Such a commitment would ultimately pave the way to ensure effective functioning of C-TAP and access to fair and affordable COVID-19 vaccines worldwide in the current pandemic situation; and lay a strong global-level foundation that could be used to mitigate similar effects in future global health disasters.

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The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

### **Authors' Contributions**

A.A.C.J Adikari carried out the preliminary literature review and drafted the manuscript. Sanath Sameera Wijesinghe carried out further literature review and contributed to develop the manuscript. Both authors have read and approved the final version of the manuscript and agree with the order of presentation of the authors.

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