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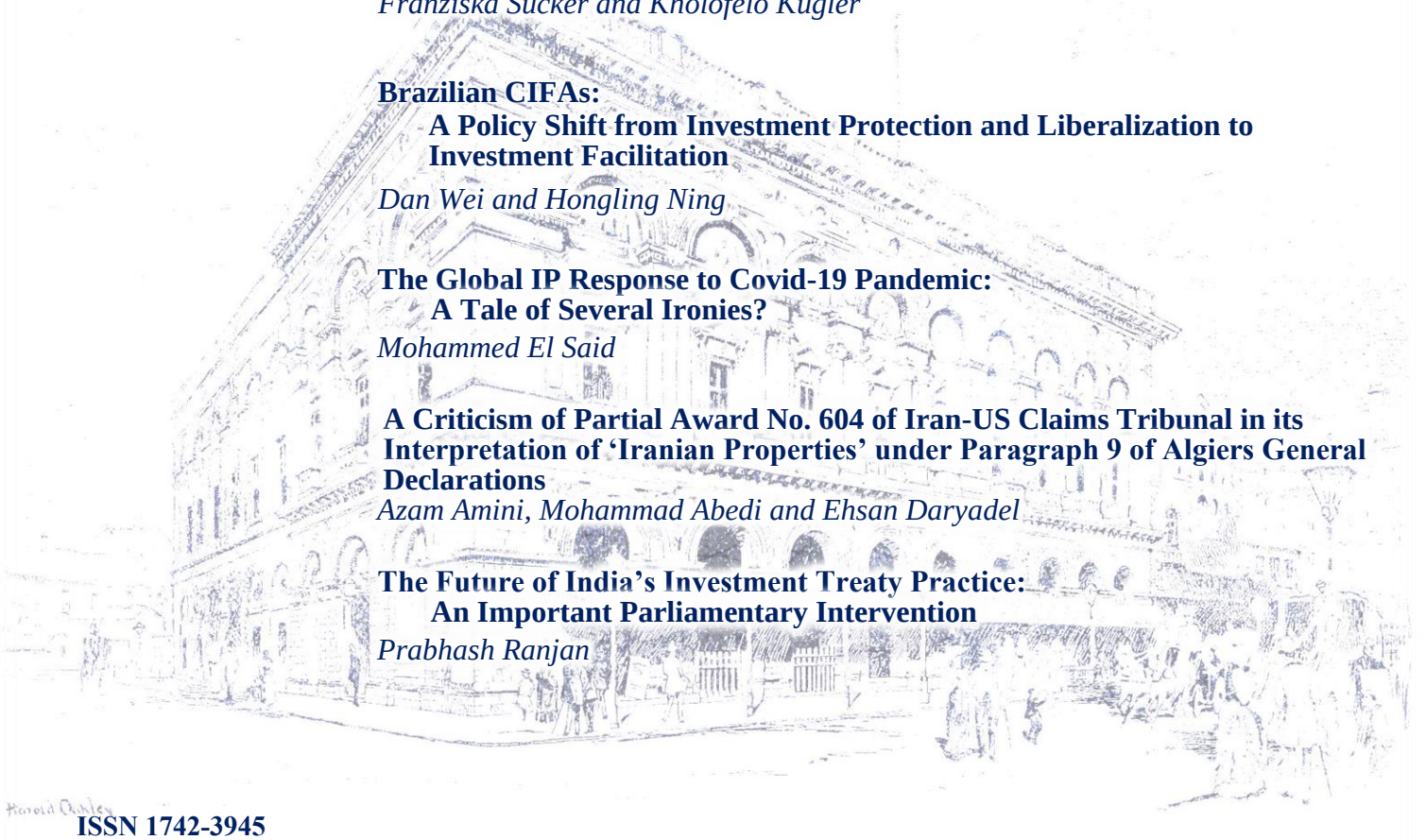

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– – Asif H Qureshi, Editorial, MJIEL, 2004, Volume 1, Issue 1

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The Global IP Response to Covid-19 Pandemic: A Tale of Several Ironies?

Mohammed El Said*

ABSTRACT: *The current pandemic crisis has brought the world to a standstill. The human cost as reflected by the death toll is mounting every day and the current actions taken to prevent the spread of the virus have fallen short of achieving their desired goals. Intellectual property (IP) protection is one component which have impacted the current debate surrounding the affordability and accessibility to vaccines and affiliated medical technologies and products. This article will look at various arguments currently shaping this debate from that perspective and argues about the need to take a more unified global approach in dealing with the pandemic and its repercussions.*

1. INTRODUCTION

The current SARS-CoV-2 pandemic (known as COVID-19) has had a devastating effect on many countries across the globe. In less than a year and a half, COVID-19 has infected at least 150 million individuals and killed more than three million.[1] At the beginning of August 2021, the 200 millionth case of COVID-19 was reported to the World Health Organisation (WHO), only six months after the world passed 100 million reported cases.[2] Current official death estimates (a figure which may be even higher in reality)[3] are hovering around the 5 million figure and remains on the daily rise as we speak. Public health providers are under extreme pressure reaching breaking point, having exhausted largely their financial, institutional and human resources during the past 20 months fighting the pandemic. Patients' queues for medical treatment are getting longer and longer even in those 'developed' countries, whose public health

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[1] 'COVID-19: Make it the Last Pandemic, Report of the Independent Panel for Pandemic Preparedness and Response' (May 2021), https:// theindependentpanel.org/ (accessed 28 October 2021).

[2] 'WHO Director General Opening Remarks, WHO Press Conference, Geneva' (11 August 2021), www.who.int/director-general/speeches/detail/whodirector-general-s-opening-remarks-at-the-media-briefing-on-covid19---11-august-2021 (accessed 28 October 2021).

[3] According to The Economist, the number of people who have died from covid-19 is likely to be close to 17m. See The Economist, www.economist.com/graphic-detail/2021/11/02/the-number-of-people-who-have-died-from-covid-19-is-likely-to-be-close-to-17m?fsrc=core-app-economist?utm_medium=social-media.content.np&utm_source=twitter&utm_campaign=editorialsocial&utm_content=discovery.content&fbclid=IwAR3KtOJOmOvg_91InfrA9lM1SttD86hq9GuodqNaGk75gL2W_r49GsUMTRY (accessed 5 November 2021).

regimes were historically more agile in providing public health support to their citizens. The effects of the pandemic are grave and becoming clearer by the day to the extent that one recent study has estimated that the Covid-19 pandemic has 'caused the biggest decrease in life expectancy in western Europe since the second world war'.[4] Within all this gloom, the question which often arises is, what went wrong? How is it possible that despite all the technological and medical advances we have today at our disposal we ended up with such a high toll?

Not since 1918 when the Spanish flu pandemic struck, the world was confronted with such a widespread outbreak bringing many parts of it to a standstill. In a way, the COVID-19 pandemic comes at a unique moment in time carrying several characteristic ironies about it. Firstly, it comes as a time where the world has reached unprecedented levels of connectivity, largely made possible as a result of tremendous advances in travel and digital technologies. Although many parts of the world went into lockdown, some businesses were still able to conduct their daily operations remotely through various technological means. The irony in this context is that because of this global connectivity, the virus was able to spread worldwide in a record period of time (in less than 2 months).[5] Secondly, it is due to the remarkable effort of many governments, NGOs and a number of vaccine producers, several vaccines were introduced into the markets in a record time. Yet, despite the fact that we have a number of effective vaccines in place – this is the first time in history that a vaccine/treatment is available during an ongoing pandemic, we have yet to put an end to it, prompting many to say that we simply have to coexist with it, as it is here to stay. That statement may be true now, although I would like to argue otherwise. In essence, if collective efforts were channelled earlier on, could

[4] The study found that the biggest declines in life expectancy were among males in the US, with a decline of 2.2 years relative to 2019 levels, followed by Lithuanian males (1.7 years). See Jose' Manuel Aburto et al., 'Quantifying Impacts of the COVID-19 Pandemic Through Life-expectancy Losses: A Population-level Study of 29 Countries', *International Journal of Epidemiology*, 2021, 1–12. Moreover, in October 2021, the UK Office for National Statistics estimated that life expectancy for men in the UK had fallen for the first time in 40 years because of the impact of Covid-19. A boy born between 2018 and 2020 is expected to live until he is 79, down from 79.2 for the period of 2015-17. See the Guardian, 'Covid has Wiped Out Years of Progress on Life Expectancy' *finds study* (27 Sep 2021), www.theguardian.com/society/2021/sep/27/covid-has-wiped-out-years-of-progress-on-life-expectancy-finds-study (accessed 28 October 2021).

[5] For instance, As Firth explains,

> the focus of the Justinian pandemic was Constantinople, reaching a peak in the spring of 542. Over the next three years plague reached Italy, southern France, the Rhine valley and Spain. Moreover, the Black Death of 1347 was the first major European outbreak of the second great plague pandemic that occurred over the 14th to 18th centuries. In 1346 it was known in the European seaports that a plague epidemic was present in the East. In 1347 the plague was brought to the Crimea from Asia Minor by the Tartar armies of Khan Janibeg, who had laid siege to the town of Kaffa (now Feodosya in Ukraine), a Genoese trading town on the shores of the Black Sea. The siege of the Tartars was unsuccessful and before they left, in revenge they catapulted over the walls of Kaffa corpses of people who had died from the Black Death. In panic the Genoese traders fled in galleys with 'sickness clinging to their bones' to Constantinople and across the Mediterranean to Messina, Sicily, where the great pandemic of Europe started. By 1348 it had reached Marseille, Paris and Germany, then Spain, England and Norway in 1349, and eastern Europe in 1350.

For more see John Frith, 'The History of Plague – Part 1. The Three Great Pandemics', *Journal of Military and Veterans' Health*, 2012, 20(2): 11-16.

this pandemic have been encircled in its early days? Did we ignore the signs?[6] What are the factors which have led to and/or exasperated the current crises?

There are several ironies which engulf the current situation. At the heart of this, is the failure of the current policies and institutions in dealing swiftly with the devastating situation from the beginning. 'No rush' seems to be the adopted approach at a time where time is of the essence.

This paper will look into some of these challenges with a focus on the important yet controversial role of intellectual property protection within the current debate. It argues that so much time was wasted without achieving any serious results within the current context, and calls for new approaches to be immediately formulated: Part 2 will reflect upon the current challenge facing the issue related to access to medicines while Part 3 will look more into the relationship between IP and access to vaccines. Part 4 will review the current proposals related to the proposed 'IP Waiver' tabled at the World Trade Organization (WTO) and Part 5 will look in more detail at the ongoing discussion around the 'Pandemic Treaty' negotiations. Parts 6 and 7 will review the TRIPS' Agreement flexibilities regime, and the impact of TRIPS-Plus obligations on these flexibilities respectively; and Part 8 will conclude.

2. PRICES OF MEDICINES AND ACCESSIBILITY VS AFFORDABILITY DILEMMA

The prices of medicines have been increasing over the past few years drastically. In many parts of the world, citizens are struggling to access and afford medications and treatment. The world is facing a global challenge, unlike in the past where the debate was largely focused on developing and least developed countries. Recent media reports stated that the pharmaceutical giant Merck is planning to charge Americans forty times its cost for a COVID-19 drug whose development was subsidized by the American government (the plan is to charge Americans $712 for a COVID drug that cost only $17.74 to produce and whose development was largely funded by the American government as some claim).[7] Further, a recent Public Citizen report also found out that US sales of the 20 top-selling drugs totalled $101.1 billion in 2020, while sales of these drugs to the rest of the world totalled only $57 billion, highlighting how Americans massively overpay for drugs.[8] A recent poll by Gallup and West Health found out that about 18 million Americans, or 7% of US adults, say they were recently unable to pay for

[6] Ironically, three months prior to the emergence of COVID-19, the Global Preparedness Monitoring Board (GPMB) issued a warning to the international community warning that a pandemic was only a matter of time, and that the world was not prepared to deal with it as such. It declared in 2019 that 'Were a high-impact respiratory pathogen to emerge, either naturally or as the result of accidental or deliberate release, it would likely have significant public health, economic, social, and political consequences'. See 'Preparedness for a High-Impact Respiratory Pathogen Pandemic' *Johns Hopkins Center for Health Security* (10 September 2019), www.gpmb.org/annual-reports/overview/item/preparedness-for-a-high-impact-respiratory-pathogen-pandemic (accessed 27 October 2021), at 6.

[7] Sharon Lerner, 'Merk Sells Federally Financed COVID Pill to US for 40 Times What it Costs to Make' *The Intercept* (5 October 2021), https://theintercept.com/2021/10/05/covid-pill-drug-pricing-merck-ridgeback/ (accessed 27 October 2021).

[8] Rick Claypool and Zain Rizvi, 'United We Spend: For 20 Top-Selling Drugs Worldwide, Big Pharma Revenue from U.S. Sales Combined Exceeded Revenue from the Rest of the World' *Public Citizen* (30 September 2021), https://mkus3lurbh3lbztg254fzode-wpengine.netdna-ssl.com/wp-content/uploads/united-we-spend-2021-drug-pricing-report.pdf (accessed 29 October 2021).

at least one prescription medication for their household. The poll found out that the situation is even worse for low-income households with annual income of less than $24,000, with almost 20% unable to pay for at least one prescription medication in the prior three months.[9] The irony in all this is clear, it is not enough for a country to host the most advanced pharmaceutical producers capable of finding cure to many medical conditions if it is not possible to access and afford the medicines produced by them.

The above circumstances are replicated in other regions but with a worsened impact upon developing and least developed countries. This is due to the fact that these countries are unable to cater for the basic needs in many instances of their citizens particularly with the heavy toll inflicted by the COVID-19 pandemic as they lack R&D capabilities.[10] WHO estimates that 80% of the world's population lives in countries with zero or very little access to controlled medicines for relieving moderate to severe pain.[11] This situation would worsen with the ongoing COVID-19 pandemic, particularly, in light of the reports suggesting that developing countries had been charged higher prices than developed countries for COVID-19 vaccines.[12] The impact on these countries is being felt beyond the public health sector. A New Global Dashboard on COVID-19 Vaccine Equity finds low-income countries would add $38 billion to their GDP forecast for 2021 if they had the same vaccination rate as high-income countries.[13] More and more austerity measures are being undertaken, hitting hard social services, public health, and educational needs. In conclusion, the global economic recovery and the wealth which nations worked hard to achieve over several decades are at risk if vaccines are not equitably manufactured, scaled up and distributed.

3. ACCESS TO VACCINES AND IP PROTECTION

There is a growing consensus about the important role vaccines play in controlling and limiting the spread and negative impact of the COVID-19 pandemic in terms of mortality rates at least in the short run.[14] The irony is that throughout history, an effective vaccine was never available to deal with an ongoing pandemic. Yet the dilemma that we face today ensues the old yet ongoing debate about accessibility and affordability of medicines and medical technologies, including access to vaccines. While third booster shots were given already in several countries, the less fortunate ones are yet to vaccinate major part of their citizens with a first shot. For

[9] Dan Witters, 'In U.S., an Estimated 18 Million Can't Pay for Needed Drugs, Gallup' (21 September 2021), https://news.gallup.com/poll/354833/estimated-million-pay-needed-drugs.aspx (accessed 31 October 2021).
[10] For more see the UN Secretary General High-Level Panel on Access to Medicines: Advancing Health-Related SDGs through Policy Coherence, 'Promoting Innovation and Access to Health Technologies' (14 September 2016), http://www.unsgaccessmeds.org/final-report/ (accessed 29 October 2021).
[11] WHO, 'Access to Medicines: Making Market Forces Serve the Poor, Ten Years in Public Health 2007–2017', www.who.int/publications/10-year-review/chapter-medicines.pdf (accessed 29 October 2021).
[12] Oxfam, 'Vaccine Monopolies Make Costs of Vaccinating the World against COVID at Least 5 Times More Expensive Than It Could Be' (29 July 2021), www.oxfam.org/en/press-releases/vaccine-monopolies-make-cost-vaccinating-world-against-covid-least-5-times-more (accessed 29 October 2021).
[13] WHO, 'Vaccine Inequity Undermining Global Economic Recovery' (22 July 2021), www.who.int/news/item/22-07-2021-vaccine-inequity-undermining-global-economic-recovery (accessed 22 October 2021).
[14] Joshua Aizenman et al., 'International Evidence on Vaccines and the Mortality to Infections Ratio', National Bureau of Economic Research, Working Paper 29498, November 2021.

instance, only 2.8% of people in low-income countries have received at least one dose so far,[15] while Africa maintains the slowest vaccination rate of any continent, with just 8.4 percent of the population receiving at least one dose of a vaccine.[16]

Within this environment, we have seen that many countries from the early days of the pandemic resorted to a number of national measures in order to curtail the impact of intellectual property protection upon accessibility and affordability of medicines and various equipment used in the diagnostics and treatment of COVID-19.[17] For instance, in March 2020 the Parliament of Chile adopted Resolution No. 896 declaring that the global coronavirus outbreak justifies the use of compulsory licensing to facilitate access to vaccines, drugs, diagnostics, devices, supplies, and other technologies useful for the surveillance, prevention, detection, diagnosis and treatment of the coronavirus in Chile.[18] Israel also took similar measures by issuing a government use authorization under the Israeli patent law for the importation of generic lopinavir/ritonavir (owned by AbbVie) combination for the treatment of COVID-19 patients from an Indian generic company by a local company acting on behalf of the Israeli ministry of health because AbbVie was unable to provide sufficient supplies of lopinavir/ritonavir.[19] AbbVie has announced that it will not enforce its patent in light of the current pandemic. The list of measures taken by countries continue to grow as in the case of Canada whereby the country has enacted the COVID-19 Emergency Response Act allowing it to issue a compulsory license without first negotiating with the rights holder, or establishing its own ability to supply a product, whilst the patent holder is only entitled to receive an amount as remuneration instead of a compensation thus making it easier to grant a license to the Ministry of Health. Moreover, France further enacted a new law No. 2020-290 which introduced a new addition to the French public health code, granting the French prime minister discretion to order the seizure of all goods and services necessary to fight against sanitary disaster, to temporarily control the prices of products, and to take any measures necessary to make relevant medicines available to patients. IP-related measures, including revocation of patents and grant of compulsory licenses could also fall within the scope of measures that can be adopted by the government under this law.[20] Indeed such measures demonstrate the negative impact IP rules may have on the supply of medications and treatments and the need to take steps to restrict their negative outcome accordingly. Following are some of the relevant debates surrounding the issue of IP and the pandemic which are currently taking place at the global stage.

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[15] Jonah Kanter, Global Citizen, 'Moderna Says Its Done All It Can to Support Global Vaccine Equity. We Look at the Facts' (21 October 2021), www.globalcitizen.org/en/content/moderna-global-vaccine-equity-covid-19/ (accessed 26 October 2021).

[16] Josh Holder, 'Tracking Coronavirus Vaccinations Around the World' *The New York Times* (29 October 2021), www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html (accessed 29 October 2021).

[17] For more on various measures taken see Mohammed El Said, 'Radical Approaches During Unusual Circumstances: Intellectual Property Regulation and the COVID-19 Dilemma', *Development*, 2020, 63: 209–18.

[18] Syam, Nirmalya, 'Intellectual Property, Innovation and Access to Health Products for COVID-19: A Review of Measures Taken by Different Countries' *South Centre Policy Brief 80* (June 2020), www.southcentre.int/policy-brief-80-june-2020/ (accessed 30 October 2021).

[19] *Ibid.*, at 3.

[20] *Ibid.*

4. BETWEEN GIFTS AND WAIVERS

It has been realised that many countries are reliant on vaccine gifts to cater for their populations during the ongoing pandemic. The US, EU and India have shared millions of vaccine doses through 'vaccine diplomacy' with many needy states during the past few months.[21] In addition, the World Health Organisation is also taking the lead on this through its COVAX initiative which initially aimed towards delivering 2 billion vaccine doses by the end of 2021.[22] However, the process has been too slow, and unfortunately it seems that this target will not be achieved under the current circumstances.[23]

Further, to deal with the lack of access to vaccines, especially in the developing and least developed nations, the idea of a waiver of some parts of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) for a certain period of time was proposed last year. The TRIPS Agreement is one of the important pillars of the World Trade Organization (WTO) concerned with protecting intellectual property rights. A temporary TRIPS waiver was initiated in October 2020 by India and South Africa and supported by more than 100 countries and hundreds of NGOs and academics worldwide. This was triggered by the need for globally distributed, local vaccine manufacturing hubs and centres in low and middle-income countries to ensure sustainable supply of vaccines locally and regionally.[24] As such, the waiver calls for the temporary suspension of Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement and related enforcement under Part III[25] '*in relation to prevention, containment or treatment of COVID-19*.[26] As revised in May 2021, the proposal was updated by making the request that the WTO waive certain provisions of the TRIPS Agreement for the *prevention, treatment or containment of COVID-19, including copyright, designs, patents, and undisclosed information regarding vaccines and other necessary health technologies*; such a waiver is proposed to be in force for at *least three years from the date of the decision*.

The Waiver would trigger the suspension of the said TRIPS provisions thus facilitating a huge increase in vaccine manufacturing capacity and distribution particularly for developing and least developed countries by granting companies more freedom to produce these vaccines while at the same time protect them from legal claims. Accordingly, no country can trigger the

[21] Tyler Pager, Annie Linskey and Emily Rauhala, 'U.S. to Share up to 60 Million Vaccine Doses Amid Pressure to Aid Desperate Countries' *The Washington Post* (26 April 2021), www.washingtonpost.com/politics/us-to-share-up-to-60-million-doses-of-astrazeneca-coronavirus-vaccine-with-other-countries-official-says/2021/04/26/b2dab8a0-a694-11eb-bca5-048b2759a489_story.html (accessed 29 October 2021).

[22] COVAX is co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO. Its aim is to accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world. For more see WHO, www.who.int/initiatives/act-accelerator/covax (accessed 29 October 2021).

[23] Gavi, 'COVAX Has So Far Shipped over 406 Million COVID-19 Vaccines to 144 Participants' (25 October 2021), www.gavi.org/covax-vaccine-roll-out (accessed 29 October 2021).

[24] Recital 6 underscored the need to promote the 'unimpeded and timely access to affordable medical products including diagnostic kits, vaccines, medicines, personal protective equipment and ventilators for a rapid and effective response to the COVID-19 pandemic'. See WTO, https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?CatalogueIdList=268704,268705,267533,267066,266962&CurrentCatalogueIdIndex=4 (accessed 29 October 2021).

[25] Section 1 of the TRIPS Agreement is related to the protection of copyrights while Sections 4, 5 and 7 relates to industrial designs, patents and protection or undisclosed information respectively.

[26] The proposed waiver covers copyright and related rights, industrial designs, patents and the protection of undisclosed information.

WTO dispute settlement procedure in case of TRIPS non-compliance under the national IP waiver.

The waiver is met by opposition from a number of developed countries, including Australia, Brazil, Canada, the European Union, Japan, Norway, Switzerland, the United Kingdom and the United States (although the United States have later on watered down its opposition).[27] As the discussions continue through several rounds in 2021 as mentioned albeit with a slow pace, it is not clear how and when the waiver will see the light.[28] One thing is clear, even if the waiver is finally agreed upon, it is likely that it will take several months if not years until countries are able to start the production and supply of the vaccines. The waiver will not be the silver bullet to the current crises, but rather one element which may contribute to lowering the death toll if properly implemented and aided by other measures. The sad truth is while the discussion about the waiver remains ongoing, people are losing their lives everywhere, every day.

5. 'TO TREATY OR NOT?' – THE MUCH-AWAITED PANDEMIC TREATY

The COVID-19 pandemic exposed the fragility of the global public health regime and its limitations. Yes, it is true that pandemics occur and have occurred throughout history, yet little was initially done to prevent COVID-19 from spreading the way it did globally. As the WHO's Independent Panel for Pandemic Preparedness and Response proclaimed, 'Despite the consistent messages that significant change was needed to ensure global protection against pandemic threats, the majority of recommendations were never implemented'.[29]

Against these challenges, calls for the need to put a global pandemic treaty in place are growing. Earlier in 2021, a Pandemic Treaty debate was tabled at the 148th session of the WHO's Executive Board.[30] An official call was issued on the 30th of March 2021 for countries to join efforts to support the Treaty by WHO. The proposed Treaty's main goal

> would be to foster an all-of-government and all-of-society approach, strengthening national, regional and global capacities and resilience to future pandemics. This includes greatly enhancing international cooperation to improve, for example, alert systems, data-sharing, research, and local, regional and global production and

[27] See MSF, 'Countries Obstructing COVID-19 Patent Waiver Must Allow Negotiations to Start', www.msf.org/countries-obstructing-covid-19-patent-waiver-must-allow-negotiations (accessed 14 January 2022).
[28] See the WTO, 'Members to Continue Discussion on a Common COVID-19 IP Response up Until MC12' (18 November 2021), www.wto.org/english/news_e/news21_e/trip_18nov21_e.htm (accessed 29 October 2021).
[29] The Independent Panel, 'COVID-19: Make it the Last Pandemic, Report of the Independent Panel for Pandemic Preparedness and Response' (May 2021), https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf (accessed 29 October 2021), at 16.
[30] For a thorough background and history of relevant measures adopted by WHO in the past in this field see Nicoletta Dentico, 'The WHO Pandemic Treaty: Responding to Needs or Playing COVID-19 Geopolitics?' (October 2021), www.globalpolicy.org/sites/default/files/download/Spotlight_Briefing-Nicoletta_Dentico.pdf (accessed 29 October 2021).

> distribution of medical and public health counter measures, such as vaccines, medicines, diagnostics and personal protective equipment.[31]

Further, the recommendation of a new Pandemic Treaty made its way to the 74th World Health Assembly (WHA) in May 2021 — we are yet to see how this will develop. In order to implement the Treaty, WHA is required to establish 'an intergovernmental process' to draft and negotiate this instrument, 'taking into account the report of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies'. However, the pace of progress on this subject remains extremely slow leading some to observe that this could take years to accomplish.[32] In brief, the Treaty aims to promote wider transparency between member states, more collaborative approach with relation to measures taken, and avoid health nationalism practices during times of crisis which we have witnessed with the current pandemic. The situation related to the debates and discussions around the 'Waiver' and the 'Pandemic Treaty' can best be explained by Drahos' words. He explains that '*Negotiations over global intellectual property rules can be seen as linear functions competing against exponential functions of growth (the virus) and decline (the death of people)*'.[33]

6. WHEN A TRIP(S) IS NOT ENOUGH

Intellectual property protection remains central to the current debate. Originator producers insists that the patent regime is important to provide incentives for them to protect their innovations. On the other hand, the opponents argue that the current patent protection regime advanced by developed countries is flawed and is having an anti-competitive effect on developing and least developed countries. Not only this, they further argue that the current regime is also prolonging monopolies and is a major hurdle in accessing medicines are reasonable prices.[34]

Many developing countries believed that the TRIPS Agreement would bring an end to the global regulation of IP rights. As such, they have attempted to introduce several tools to weaken the negative impact IP may have on them. These tools are referred to as the IP regime's 'flexibilities'.[35] They include:

- ***Transition periods.*** Least developed countries (LDCs) were granted an extended transition period exempting them from applying the TRIPS Agreement standards nationally. This is in recognition of their special developmental needs and the balance

[31] WHO, 'COVID-19 Shows Why United Action is Needed for More Robust International Health Architecture' (30 March 2021), www.who.int/news-room/commentaries/detail/op-ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture (accessed 29 October 2021).

[32] See for example Antony Blinken and Xavier Becerra, 'Strengthening Global Health Security and Reforming the International Health Regulations: Making the World Safer From Future Pandemics', *The Journal of the American Medical Association,* 2021, 326(13): 1255-6.

[33] Peter Drahos, 'Public Lies and Public Goods: Ten Lessons From When Patents and Pandemics Meet', EUI Working Paper LAW, 2021/5, at 7.

[34] See Mohammed El Said, 'From TRIPS-minus to TRIPS to TRIPS-plus: Implications of IPRs for the Arab World', *The Journal of World Intellectual Property*, 2005, 8(1): 53-65.

[35] For more see Mohammed El Said, 'Public Health Related TRIPS-Plus Provisions in Bilateral Trade Agreements A Policy Guide for Negotiators and Implementers in the WHO Eastern Mediterranean Region', *World Health Organization. Regional Office for the Eastern Mediterranean* (2010).

that should be put in place prior to the introduction of intellectual property protection under their national law.[36] This means LDCs can elect not to provide legal protection for pharmaceutical patents and clinical trial data before 2033. The decision also keeps open the option for further extensions beyond that date.

- ***Compulsory licensing.*** Allows the state to authorize a third party to exploit patented inventions, generally against a specific remuneration to be paid to the patent holder subject to meeting several conditions (Article 31 and 31 *bis* of the TRIPS Agreement). The aim of compulsory licensing authorisation is to limit anti-competitive behaviour and facilitate the transfer of technology.[37] While compulsory licensing is an effective tool in solving some public health emergencies, this option may not be workable with all developing and least developed countries. The condition that the license should be issued for local supply means that those countries with no technological infrastructure would struggle to manufacture medicines even if such a license was granted. This prompted the amendment of the TRIPS Agreement by introducing the so-called Paragraph 6 Solution allowing countries to issue compulsory licenses for exportation.[38] However the process dictated is so complex that only one country (Rwanda) has resorted to it so far.
- ***Government use exceptions.*** This flexibility gives the state the right to use the patent without the need to acquire the approval of the patent holder for the purpose of public interest, including public health necessities and emergences.[39] Although there are similarities between the conditions needed to issue a government use and compulsory licensing, government use exceptions provide an additional advantage by allowing the license to be issued in a speedy manner, through granting the government the right to use the pharmaceutical patent without the need for prior negotiations with the owner.
- ***Parallel importation.*** This flexibility grants countries the option to obtain patented products when they are lawfully available in a foreign market at a lower price, thus enabling countries to shop for cheaper patented products.[40]
- ***Exceptions to patents rights.*** Article 30 of TRIPS provides that members

  > 'may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.'[41]

  However, the above provision does not define the scope of the permissible exceptions thus awarding member countries some considerable discretion to operate. Examples of

[36] The last 6th of November 2016 Council decision extends until January 2033 the period during which key provisions of the WTO's intellectual property agreement, the TRIPS Agreement, do not apply to pharmaceutical products in LDCs. See the Council for TRIPS, 'Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, Decision of the Council for TRIPS of 6 November 2015'.

[37] The special compulsory licensing system in the amended TRIPS Agreement, and the earlier 2003 waiver decision, (sometimes called the 'Paragraph 6 System' because it refers to paragraph 6 of the Doha Declaration) only deals with compulsory licences to produce medicines expressly for export purposes.

[38] See WTO, 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

[39] See TRIPS Agreement, Article 31.b.

[40] See TRIPS Agreement, Article 6.

[41] See TRIPS Agreement, Article 30.

these exceptions include the Bolar exception,[42] personal use and the research and experimental use exceptions.

- ***Standards of patentability.*** Under TRIPS, patent protection must be granted for products and processes which are *new*, involve an *inventive step* and are *industrially applicable*.[43] These are not defined and can be interpreted and applied by member states in accordance with their national legal regimes. For example, TRIPS does not require countries to protect the patenting of new uses of known products, including pharmaceutical drugs. This flexibility, therefore, allows member countries the possibility of rejecting the patentability of these new uses for lack of novelty, inventive step or industrial applicability.
- ***Other procedural flexibilities*.** Another identified policy tool used by developed and developing counties that may be used to improve the quality of granted patents and limits 'evergreening' are the so-called pre-grant and post-grant patent oppositions. Such proceedings enable interested parties to bring claims before the patent office on the basis that a particular patent does not meet the novelty standards or local requirements.

7. THE SHIFT TOWARDS TRIPS-PLUS

Despite this background and contrary to the belief of developing countries, the TRIPS Agreement did not succeed in bringing an end to global IP standards regulation. As such, Free Trade Agreements (FTAs) and Bilateral Investment Treaties (BITs) included additional obligations which go beyond those of TRIPS Agreement (referred to as TRIPS-Plus) and have subsequently resulted in the weakening of the above referred to flexibilities during the past two decades resulting in the erosion of policy space and diminishing of flexibilities usage in many countries.[44] Examples of these TRIPS-Plus standards include:

- ***Expanding and extending the scope of pharmaceutical patents and creating new drug monopolies:*** this is achieved through lowering the patentability standards and allowing for new and second use patenting in addition to vaccines and gene patenting and prolonging the patent protection term.
- ***Protection and Extension of 'data exclusivity' and patent linkage:*** by requiring protection of at least 5 years exclusivity for information related to new products and 3 more in cases of new uses for old medicines – even when that information is disclosed and available in the public domain.
- ***Prohibition/restriction pre-grant oppositions:*** These restrictions forbid challenges to weak or invalid patents until after they have been granted.

[42] This important exception facilitates the production and introduction of generic medicines into the market on the date of patent expiry. Accordingly, this exception permits the use of an invention for the purpose of obtaining approval of a generic product before the patent expires and without having to obtain the patentee's approval. The WTO ruled that the use of this exception is TRIPS-compliant. For more see the WTO, 'Canada—Patent Protection of Pharmaceutical Products', Geneva, 2000, WTO Dispute Panel Report, WT/DS114/1.

[43] See TRIPS Agreement, Article 27.

[44] Examples of these include the US-Jordan FTA, the US-Oman FTA, the US-Korea FTA and the Trans-Pacific Partnership Agreement (TPPA).

- ***Require new forms of intellectual property enforcement:*** Such as those related to customs detaining shipments, including in-transit shipments, suspected of non-criminal trademark/copyright/patent infringements; require mandatory injunctions for alleged intellectual property infringements; raise damages amounts etc.
- ***Introducing Investor-State Dispute Settlement (ISDS) procedures:*** This controversial aspect of the FTAs and BITs grants private investors considerable power, especially big multinational corporations, to claim huge amounts of money for compensation from investor sympathetic tribunals. Indirectly, this questions the impact of these claims on states' power to regulate in the public interest, in order to safeguard public health priorities and challenges. Other flaws of the ISDS system include the lack of consistency in decision making and huge costs.

There are many studies documenting how these TRIPS-Plus standards have resulted in increasing monopoly durations and curtailing access to medicines.[45] Put simply, TRIPS-Plus obligations prolong the monopoly term of granted patents while at the same time prevent generic medicines from entering the market at an earlier stage. This results in higher prices of medicines and limitation of accessibility.

8. CONCLUSION: WAKE-UP CALL

Our current battle is not only with COVID-19 but is also a battle against time. COVID-19 has already developed several variants which seems to spread faster and also evade vaccine immunity.[46] The possibility of new emerging variations remains high and worrying.[47] As Drahos explains,

> This speed of reproduction creates many more opportunities for adaptation, as the rapid emergence of antibiotic resistant bacteria illustrates. The human immunodeficiency virus (HIV), first discovered in 1984, has proved to have a remarkable rate of both reproduction and mutation, evolving approximately a million times faster than humans. More than 35 years and some 38 million deaths from HIV/AIDS later, there is still no effective vaccine. Any system for managing pandemic risk has to be responsive, as best it can, to the fast-mutating and exponentially-scaling nature of microorganisms and viruses.[48]

[45] See Mohammed El Said, 'The Impact of "TRIPS-Plus" Rules on the Use of TRIPS Flexibilities: Dealing with the Implementation Challenges', in Carlos M. Correa and Reto M. Hilty (eds.), *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (Springer, 2022).

[46] Michelle Roberts, 'What are the Delta, Gamma, Beta and Alpha Covid variants?' *BBC* (19 October 2021), www.bbc.com/news/health-55659820 (accessed 1 November 2021).

[47] Around the end of November 2021, a new variant (so-called Omicron) emerged. In a statement, the WHO stated that 'This variant has a large number of mutations, some of which are concerning'. See WTO, 'Classification of Omicron (B.1.1.529): SARS-CoV-2 Variant of Concern' (26 November 2021), www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern (accessed 27 November 2021). During the second week of January 2022 only, more than 15 million new cases of COVID-19 were reported globally, by far the most cases ever reported. For more see Kerry Cullinan, 'Omicron Infection Curve "Staggering" – 36 Countries Have Vaccinated Less than 10% of Citizens' *Health Policy Watch*, https://healthpolicy-watch.news/omicron-infection-curve-staggering-while-36-countries-have-vaccinated-less-than-10-of-citizens/ (accessed 13 January 2022).

[48] Drahos, *supra* note 33, at 1.

There are various scenarios about how COVID-19 may develop, yet the fact remains that we are losing lives because of this virus every minute.

The lack of coordinated global action will only make the situation worse with time. It is because of this, immediate steps without any further delay should be taken to deal with the current crises. The agreement on the Waiver and the Pandemic Treaty would be a welcomed step, but alone they will not solve the crises. More serious holistic reforms which should go beyond the current pandemic should be taken immediately.

To start with, developing countries have to rely more on South-South cooperation on many fronts including production levels, medicine development, sharing of know-how and with relation to coordination at the international arena. They cannot afford to remain bystanders or divided in the debate. Indeed, the cooperation in sharing vaccine know-how between Russia and China in order to increase manufacturing capacity and supply of Russia's Sputnik-V vaccine is an example of this.[49] This collaboration should more solidly extend to other areas including climate change and sharing of green environmental technologies.

More importantly, a revisiting of the global patent regime should be undertaken, with the view to scale back all TRIPS-Plus standards to those of the TRIPS Agreement.[50] Moreover, the current global patent regime should be reformed to include a built-in waiver mechanism to deal with pandemics and extreme health emergencies promptly and without the need for wasting time to obtain specific and time-bound waivers. Finally, for any waiver to be meaningful and effective, it should also extend to explicitly suspend the impact of TRIPS-Plus conditions included under various FTAs as well and not only those related to the TRIPS Agreement.

Finally, it is time for all to consider the COVID-19 vaccines as a global public good to ensure that vaccines are made equitably available to all countries, and not only to those who bid the highest for these vaccines. Indeed, there are growing global calls for this to take place, yet the wealthy and interest groups are showing no signs of doing so. Several counties – including China – in addition to other international organisations such as WHO, UNESCO[51] and even the Pope have made explicit calls in this regard.[52]

The current COVID 19 Pandemic will not be the last one which we must deal with. Now that there is a general acceptance that we need to adapt to its coexistence, we need to have a clear and effective plan to confine it and also prevent other pandemics from taking a similar trajectory in the future. We also need to keep in mind that there are other challenges in place with no less importance than COVID-19 which needs to be addressed promptly including climate change and rising global inequality levels. Indeed no one is safe in today's global

[49] Drahos, *supra* note 33, at 9.
[50] El Said, *supra* note 45.
[51] 'UNESCO Calls for COVID-19 Vaccines to be Considered a Global Public Good' (24 February 2021), https://en.unesco.org/news/unesco-calls-covid-19-vaccines-be-considered-global-public-good (accessed 20 January 2022).
[52] Global Citizen, 'Pope Francis Calls for Universal Access to COVID-19 Vaccines and Lifting of Patent Restrictions' (8 May 2021), www.globalcitizen.org/en/content/pope-francis-covid-19-vaccines-vax-live/ (accessed 20 January 2022).

village until we are all safe. It is clear that the current model is no longer viable in dealing with these types of challenges. It is time for common sense triggered by humanity's common destiny to prevail.