114 Research Paper
June 2020

Equitable Access to COVID-19 Related Health Technologies: A Global Priority

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SOUTH CENTRE

RESEARCH PAPER

114

EQUITABLE ACCESS TO COVID-19 RELATED HEALTH TECHNOLOGIES: A GLOBAL PRIORITY

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JUNE 2020

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The author thanks Dr. Germán Velásquez for his valuable comments and suggestions. The views presented in this paper are however the sole responsibility of the author.

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ABSTRACT

Since COVID-19 was first identified, infections from the virus and the death toll have spiked abysmally. The pandemic has also paralyzed the economies (particularly, global trade, tourism and transport) of many countries. The dire social and psychological ramifications associated with the pandemic are also immense. The threat posed by COVID-19 on global health and the economic downturn resulting thereof necessitates the development of health technologies (such as medicines and vaccines). A global effort to invent new health technologies or the likely application of existing technologies is also underway since the outbreak of the pandemic. Even though the race to develop these technologies can be hailed as a pivotal undertaking, the development of health technologies alone may not expedite equitable access to the outcome of such development. Particularly, the lack of access to health technologies may befall if the conventional model of health technology pricing, which is derived from monopoly rights created by IP protection, is set. However, legal as well as policy tools can be used to overcome such hurdles and ensure global access to health technologies. In this sense, this paper discusses plausible legal and policy options that can help to accelerate access to health technologies targeting COVID-19.

Desde que se identificó por primera vez el COVID-19, las infecciones por el virus y el número de muertes se han disparado. La pandemia también ha paralizado las economías (en particular, el comercio, el turismo y el transporte mundiales) de muchos países. Las graves ramificaciones sociales y psicológicas asociadas a la pandemia son también inmensas. La amenaza que representa COVID-19 para la salud mundial y la recesión económica resultante de ella exige el desarrollo de tecnologías sanitarias (como medicamentos y vacunas). Desde el estallido de la pandemia también se está realizando un esfuerzo mundial para inventar nuevas tecnologías de la salud o la probable aplicación de las tecnologías existentes. Aunque la carrera por desarrollar estas tecnologías puede considerarse una empresa fundamental, el desarrollo de tecnologías sanitarias por sí solo puede no acelerar el acceso equitativo a los resultados de ese desarrollo. En particular, la falta de acceso a las tecnologías sanitarias puede ocurrir si se establece el modelo convencional de fijación de precios de las tecnologías sanitarias, que se deriva de los derechos de monopolio creados por la protección de la propiedad intelectual. Sin embargo, se pueden utilizar instrumentos jurídicos y normativos para superar esos obstáculos y asegurar el acceso mundial a las tecnologías de la salud. En este sentido, en el presente documento se examinan las opciones jurídicas y normativas plausibles que pueden contribuir a acelerar el acceso a las tecnologías de la salud orientadas a COVID-19.

Depuis que le COVID-19 a été identifié pour la première fois, les infections dues au virus et le nombre de décès ont atteint des sommets. La pandémie a également paralysé les économies (en particulier le commerce mondial, le tourisme et les transports) de nombreux pays. Les conséquences sociales et psychologiques de la pandémie sont également immenses. La menace que représente COVID-19 pour la santé mondiale et le ralentissement économique qui en résulte nécessite le développement de technologies de santé (telles que des médicaments et des vaccins). Un effort mondial pour inventer de nouvelles technologies pour la santé ou l'application probable de technologies existantes est également en cours depuis le déclenchement de la pandémie. Même si la course au développement de ces technologies peut être saluée comme une entreprise cruciale, le développement des technologies de la santé ne peut à lui seul accélérer l'accès équitable aux résultats de ce développement. En particulier, le manque d'accès aux technologies de la santé peut se produire si le modèle conventionnel de fixation des prix des technologies de la

santé, qui découle des droits de monopole créés par la protection de la propriété intellectuelle, est établi. Toutefois, des outils juridiques et politiques peuvent être utilisés pour surmonter ces obstacles et garantir un accès mondial aux technologies de la santé. En ce sens, ce document examine les options juridiques et politiques plausibles qui pourraient contribuer à accélérer l'accès aux technologies de santé ciblant COVID-19.

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I. THE GLOBAL HEALTH MENACE: COVID-19

COVID-19 is an infectious disease caused by a new strain of coronavirus.[2] Following SARS, which was first recognized in 2003 in Hanoi, Vietnam and MERS, which was identified in Saudi Arabia in 2012, this is the third coronavirus disease.[3] COVID-19 was first recognized in Wuhan City, Hubei Province of China. In late December, the Health Commission of the Hubei Province revealed the outbreak of a cluster of severe "pneumonia of unknown causes."[4] The origin of the pneumonia illness was initially believed to have a link to a seafood wholesale and live animal market in Wuhan.[5] As studies show "bats, snakes and pangolins have been cited as potential carriers" of the new virus.[6] A study published in the New England Journal of Medicine and some other journals subsequently showed that most of the first cases did not "have known exposure to a seafood wholesale and live animal market in Wuhan."[7] In late December 2019, the World Health Organization (WHO), the United Nations Agency with the responsibility to direct and coordinate international health, was also informed of cases of pneumonia of unknown cause.[8] After having investigated the underlying cause of pneumonia, the Chinese Centre for Disease Control and Prevention (Chinese CDC) however stated on 7 January 2020 that the cause of the disease is a novel strain of coronavirus.[9] Following this, WHO assigned a tentative name to the virus and referred it as 2019-nCoV.[10] On 30 January 2020, WHO declared the disease a Public Health Emergency of International Concern (PHEIC).[11]

On February 11, 2020, by changing the tentative name (2019-nCoV), WHO and the International Committee on Taxonomy of Viruses (ICTV) assigned new names to the disease as well as the virus causing it, respectively.[12] While WHO called the disease "COVID-19",

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[2] See, the World Health Organization, "Coronavirus", (2020). Available from https://www.who.int/health-topics/coronavirus#tab=tab_1 (accessed on 19 May 2010). See also, Domenico Cucinotta, Maurizio Vanelli, "WHO Declares COVID-19 a Pandemic", Acta Bio Med 91, No. 1 (2020):157.

[3] Yongshi Yang et al., "The deadly coronaviruses: The 2003 SARS pandemic and the 2020 novel coronavirus epidemic in China", *Journal of Autoimmunity*, (February 2020):1. See, Klaus Stöhr, "A multicentre collaboration to investigate the cause of severe acute respiratory syndrome", *The Lancet 361*, (17 May 2003): 1730.

[4] See, Cuiqing Ma et al., "From SARS-CoV to SARS-CoV-2: safety and broad-spectrum are important for coronavirus vaccine development", Microbes and Infection, (2020):2. See also, Annoor Awadasseid et al., "Initial success in the identification and management of the coronavirus disease 2019 (COVID-19) indicates human-to-human transmission in Wuhan, China", *International Journal of Biological Sciences* 16, No. 11 (2020): 1846.

[5] Na Zhu et al., "A Novel Coronavirus from Patients with Pneumonia in China, 2019", The *New England Journal of Medicine* 38, No. 8 (2020):727.

[6] Yongshi Yang et al., "The deadly coronaviruses: The 2003 SARS pandemic and the 2020 novel coronavirus epidemic in China," *Journal of Autoimmunity*, (February 2020):1. See also, Awadasseid et al., "Initial success in the identification and management of the coronavirus disease 2019 (COVID-19)", p. 1846.

[7] See, Na Zhu et al, "China Novel Coronavirus Investigating and Research Team: A novel coronavirus from patients with pneumonia in China," The *New England Journal of Medicine* 338, no. 8 (2019):727-733. See also, Michelle L. Holshue et al., "First Case of 2019 Novel Coronavirus in the United States", The *New England Journal of Medicine* 382, No. 10 (2020):929.

[8] The World Health Organization, "Coronavirus disease (COVID-19) pandemic", (2020). Available from https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/novel-coronavirus-2019-ncov (accessed on 22 May 2020). See also, Victor M Corman et al., "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR", *Euro Surveillance* 25, No. 3 (2020):1.

[9] Na Zhu et al., "A Novel Coronavirus from Patients with Pneumonia in China, 2019," The *New England Journal of Medicine* 38, No. 8 (2020):727&728.

[10] Awadasseid et al., "Initial success in the identification and management of the coronavirus disease 2019 (COVID-19)", p. 1846.

[11] See, Qiang Gao et al., "Development of an Activated Vaccine Candidate for SARS-CoV-2", *Science* 10.1126/science.abc1932 (2020):1. See also, World Health Organization Regional Office for Africa, "COVID-19", External Situation Report 2, (11 March 2020):5.

[12] The World Health Organization, "Naming the coronavirus disease (COVID-19) and the virus that causes it", (2020). Available from https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it (accessed on 22 May 2020). See also**,** Andrea De Giorgio, "COVID-19 is not just a flu. Learn from Italy and act now", *Elsevier* (2020):1.

which is a short form for "coronavirus disease 2019", the ICTV also named the virus severe acute respiratory syndrome coronavirus 2 or SARS-CoV-2.[13] A separate name has been given to the novel virus (SARS-CoV-2) to help accelerate the development of diagnostic tests, vaccines, and medicines, while the distinct name (COVID-19) assigned to the disease is aimed to facilitate "discussion on disease prevention, spread, transmissibility, severity, and treatment."[14] On 28 February 2020, WHO elevated the risk assessment for the SARS-CoV-2 from "high" to "very high." It also declared COVID-19 a global pandemic on 11 March 2020.[15] In a press conference he gave, Tedros Adhanom Ghebreyesus, the Director-General of WHO, underlined that the announcement came because of the rapid surge in the "number of cases outside China."[16] On the day WHO declared COVID-19 as a pandemic, the virus had already reached more than 114 countries. Even though the first death was reported, on 9 January 2020, from China, it was soon made apparent that by the time WHO declared COVID-19 a pandemic, more than 4,291 people had already lost their lives in several countries.[17]

The spread of SARS-CoV-2 from China to other countries did not take much time. As cases in point, six days after the virus was first identified, Thailand reported a case of a passenger from Wuhan on 13 January 2020. Then after, Japan and South Korea also confirmed cases of passengers from Wuhan on 15 January 2020, and 19 January 2020, respectively.[18] The spread of the virus to countries outside of Asia also took place within a few days. In Italy, after the first patient (a 38-year old man from the Italian city of Codogno)[19] was identified on 20 February 2020, the virus spread since then at a staggering pace. It first reached the Northern part (Lombardy region, to be specific) and then spread to all other parts of the country.[20] Italy's health system in general and the healthcare services in Lombardy and Veneto regions, in particular, have always been considered superb.[21] Notwithstanding this, Lombardy and Veneto were two of the Italian regions most affected by the pandemic. Other regions (such as Piedmont) also came later on to take the top position. On 10 March 2020, the Italian government adopted a decree aimed at preventing and controlling the spread of the virus. The decree restricted the movement of people and any form of gatherings in public spaces.[22] For approximately two months, almost all "shops" except supermarkets and pharmacies were also ordered to remain closed. As of 28 May 2020, the number of COVID-

[13] See, the World Health Organization, "Coronavirus(2019-nCoV)," WHO Situation Report – 22, (11 February 2020).
[14] The World Health Organization, "Naming the coronavirus disease (COVID-19) and the virus that causes it", (2020). Available from https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it (accessed on 22 May 2020).
[15] World Health Organization Regional Office for Africa, "COVID-19", External Situation Report 2, (11 March 2020):5.
[16] The World Health Organization, "WHO announces COVID-19 outbreak a pandemic", (12 March 2020). Available from https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/3/who-announces-covid-19-outbreak-a-pandemic (accessed on 22 May 2020).
[17] The World Health Organization, "WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020", Available from https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020, (accessed on 22 May 2020).
[18] See, Victor M Corman et al., "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR", *Euro Surveillance* 25, No. 3 (2020):1. See also, Awadasseid et al., "Initial success in the identification and management of the coronavirus disease 2019 (COVID-19)", 1847.
[19] The reference patient zero is used to refer to a person infected and identified first. See also, Rossella Porcheddu et al., "Similarity in Case Fatality Rates (CFR) of COVID-19/SARS-COV-2 in Italy and China," The *Journal of Infection in Developing Countries* 14, No. 2(2020):126.
[20] De Giorgio, "COVID-19 is not just a flu. Learn from Italy and act now", p. 1. See also, Porcheddu et al., "Similarity in Case Fatality Rates (CFR) of COVID-19/SARS-COV-2 in Italy and China", p. 126.
[21] See, Giuseppe Di Lorenzo and Rosella Di Trolio, "Coronavirus Disease (COVID-19) in Italy: Analysis of Risk Factors and Proposed Remedial Measures," *Frontiers in Medicine* 7, Article 140, (2020):1. See, Lisa Rosenbaum, "Facing Covid-19 in Italy — Ethics, Logistics, and Therapeutics on the Epidemic's Front Line", The *New England Journal of Medicine* 382, No. 20 (2020):1873.
[22] Marzia Lazzerini, Giovanni Putoto, "COVID-19 in Italy: momentous decisions and many uncertainties", *Lancet Glob Health* (2020):1.

19 cases in the country had exceeded 231,000.[23] Based on the number of confirmed cases, Lombardy, Piedmont, Emilia-Romagna, Veneto and Tuscany regions ranked from one to five in number of cases. Similar, but not the same, courses have been observed in other parts of Europe, including Spain, France and Germany. According to the WHO, as of 28 April 2020, "63 per cent of global mortality" from the virus was from the European region.[24]

The spread of SARS-CoV-2 to other nations was also very quick. In the US, the first COVID-19 patient was confirmed on 20 January 2020.[25] However, five months after the first confirmed patient – who was a passenger from Wuhan – was identified, the number of infections has exceeded over 1,698,523 people.[26] The death toll has also surpassed one hundred thousand. As of May 28, 2020, New York, New Jersey and Illinois were the top three States affected based on the number of confirmed cases. The trends in Latin America and Africa are not much different. In South America, the first case was confirmed in Brazil on 25 February 2020. A 61 year-old Brazilian man, who in February 2020 had traveled to the Italian region of Lombardy, was the first to have tested positive.[27] As of 27 May 2020, Brazil, Peru and Chile are the top three countries with the highest number of confirmed COVID-19 cases.[28] In a similar vein, Africa confirmed its first COVID-19 case in Egypt on 14 February 2020.[29] Since then, the virus has reached many African nations such as Ethiopia. Ethiopia confirmed its first case on 13 March 2020. The first patient was a 48-year old "Japanese man who traveled from Japan to Burkina Faso" and who later traveled to Ethiopia.[30] The country is one of the 13 African countries, categorized by WHO as a "top priority for COVID-19 preparedness due to direct links or a high volume of travel to China."[31] A study published in *The Lancet* one day after Ethiopia confirmed its first case also indicated that the country has the second-highest COVID-19 importation risk when compared to other African countries.[32] This, among other things, shows that the infection has already reached in countries with strong as well as weak national health care systems. It has also overwhelmed the healthcare systems of various countries.

Overall, COVID-19 is a critical concern for least developed countries (LDCs), developing, as well as developed nations like the US. Unlike HIV/AIDS and other infectious diseases the effects of which have been felt mainly in LDCs and developing nations, COVID-19 has ravaged the lives of people in developed as well as developing nations. This does not, however, mean that developing countries, LDCs and developed nations are equally

[23] Ministry of Health of Italy, "Covid-19, situation report update at 28 May 2020 18.00", (28 May 2020). Available from http://www.salute.gov.it/portale/nuovocoronavirus/dettaglioNotizieNuovoCoronavirus.jsp?lingua=italiano&menu=notizie&p=dalministero&id=4825 (accessed on 28 May 2020).

[24] The World Health Organization, "Coronavirus disease (COVID-19) pandemic", (2020). Available from http://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/novel-coronavirus-2019-ncov (accessed on 22 May 2020).

[25] See also, Michelle L. Holshue et al., "First Case of 2019 Novel Coronavirus in the United States", The *New England Journal of Medicine* 382, No. 10 (2020):929.

[26] Centers for Disease Control and Prevention (CDC), "Coronavirus Disease 2019 (COVID-19): Cases in the US", (28 May 2020). Available from https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html (accessed on 28 May 2020).

[27] Alfonso J. Rodriguez-Morales, "COVID-19 in Latin America: The implications of the first confirmed case in Brazil", *Elsevier*, (28 February 2020):1.

[28] Statista, "Number of confirmed cases of novel coronavirus (COVID-19) in Latin America and the Caribbean", Available from https://www.statista.com/statistics/1101643/latin-america-caribbean-coronavirus-cases/ (accessed on 22 May 2020).

[29] Marius Gilbert et al., "Preparedness and vulnerability of African countries against importations of COVID-19: a modelling study", *Lancet* 395, (2020):871.

[30] World Health Organization, "First Case of COVID-19 Confirmed in Ethiopia", (13 March 2020). Available from https://www.afro.who.int/news/first-case-covid-19-confirmed-ethiopia (accessed on 23 May 2020.

[31] World Health Organization, "COVID-19 Preparedness Bulletin Ethiopia", (14 February 2020). Available from https://extranet.who.int/sph/news/covid-19-preparedness-bulletin-ethiopia (accessed on 23 May 2020).

[32] Marius Gilbert et al., "Preparedness and vulnerability of African countries against importations of COVID-19: a modelling study", *Lancet* 395, (2020):873.

vulnerable to the effects of the public health crisis.[33] At the time of writing this paper (28 May 2020), the global number of confirmed cases had reached 5.5 million people.[34] In terms of geographic distribution, SARS-CoV-2 has reached 6 continents or over 215 countries or territories.[35]

The situation discussed above, among many measures, requires engagement in research to develop new health technologies (medicines and vaccines) or the application of existing health technologies against the pandemic. Developers (particularly, pharmaceutical companies) may request countries to subject such health technologies to intellectual property (IP) protections. In this context, before proceeding to the main subject of this paper, the next section discusses the nature of patent obligations imposed on the WTO members. Then, the paper analyzes whether or not countries should allow monopoly rights in times of a global pandemic.

[33] British Broadcasting Corporation (BBC), "Coronavirus Pandemic: Tracking the Global outbreak", BBC News, (28 May 2020). Available at: https://www.bbc.com/news/world-51235105? (Accessed on 28 May 2020).
Viviana Muñoz Tellez, "The COVID-19 Pandemic: R&D and Intellectual Property Management for Access to Diagnostics, Medicines and Vaccines", South Centre Policy Brief No. 73, (April 2020):1. Available from https://www.southcentre.int/policy-brief-73-april-2020/.
[34] See, Feng-Cai Zhu et al., "Safety, tolerability, and immunogenicity of a recombinant adenovirus type-5 vectored COVID-19 vaccine: a dose-escalation, open-label, non-randomised, first-in-human trial", The *Lancet*, (22 May 2020):1.
[35] Ibid.

II. PATENT: THE PROVISION OF EXCLUSIVE RIGHTS

More than a quarter of a century has passed since the TRIPS Agreement came into the limelight. The Agreement has changed the scope as well as the enforcement of the multilateral intellectual property in general, and patent regime in particular.[36] Under WTO, there is almost a consensus that legitimate patent protections kindle "socially valuable" research & development (R&D) that contribute to access to affordable health technologies (medicines).[37] This is because new medicine development requires a substantial amount of resources[38] and investments made for this purpose can be recovered based on the exclusive rights conferred by patent.[39] This has also been stressed in the jurisprudence of WTO and domestic cases of some countries. In *Apotex Inc. v. Wellcome Foundation Inc.,* the Supreme Court of Canada highlighted that "A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time."[40] Likewise, the WTO Dispute Settlement Panel in the case *Canada-Patent Protection for Pharmaceutical Products* stated that "Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation." It also specified that the policy of those laws can only be achieved if patent holders "are permitted to take effective advantage of that inducement once it has been defined."[41] Against this backdrop, an examination into the TRIPS patent provisions can be useful before analyzing the core subject (equitable access health technologies for COVID-19 treatment) of this paper.

According to article 27 of the TRIPS Agreement, WTO members are required to confer patents on inventions. In this sense, two separate, albeit interconnected, sentences are included in article 27(1). The first paragraph stresses that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[42] The provision does not, however, define the term "invention." WTO members, thus, have the right to determine the scope as well as elements forming part of the term invention.[43] Vietnam, for instance, defines invention as "a technical concept which is distinguished by having worldwide novelty in terms of the present state of technological development, high level of creativeness and be able to apply to various social and economic sectors.''[44] Under article 27(1), WTO members are required to grant a patent whether the invention is a process or

[36] See, Graeme W. Austin & Laurence Helfer, *Human Rights and Intellectual Property Mapping the Global Interface*, (Cambridge University Press, Cambridge: 2011): 24&28. See also, Amy Kapczynski, "Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector", *California Law Review*, (2009):1579. See also, Susan K. Sell, "TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TTP", *Journal of Intellectual Property Law* 18, No. 2 (2011):448.

[37] See, Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, (New York, USA, Oxford University Press, 2007):275. See also, Aaron S. Kesselheim, "Intellectual Property Policy in the Pharmaceutical Sciences: The Effect of Inappropriate Patents and Market Exclusivity Extensions on the Health Care System", The AAPS Journal 9, No. 3 (2007): E306. Also, Roger Kampf and Hannu Wage, "The Role of the TRIPS Agreement in the Global Health Policy", *Stanford Journal of Law, Science and Policy*, (September 2011):18.

[38] However, part of the R&D cost may be funded by public institutions.

[39] See, Article 2 of the Doha Declaration, which stresses the relevance of a patent for innovating a novel medicine. See, The World Health Organization, "TRIPS, Intellectual Property Rights and Access to Medicines", UHC Technical Brief, (Updated 2017):2.

[40] See, Canada Supreme Court Judgment, *Apotex Inc. v. Wellcome Foundation Ltd*., 4 S.C.R, 153., (2002): Para. 37.

[41] See, The WTO Panel Report, *Canada-Patent Protection for Pharmaceutical Products*, WT/DS114/R (2000): Para. 7.54-7.55.

[42] See, Article 27(1) of the TRIPS Agreement.

[43] See, the UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, (New York, USA, Cambridge University Press, 2005):357.

[44] See, Article 782 of Vietnam's Civil Code of 1995, which was amended by 2005 IP law.

product.[45] While a product patent is a patent given to the product itself (such as an active protein ingredient),[46] a process invention implies a "course of action or procedure through which the said product can be manufactured."[47]

WTO members are required also in article 27(1) to grant patents to all fields of technology, including pharmaceuticals.[48] This is new compared to the Paris Convention for the Protection of Industrial Property.[49] When the Uruguay round of negotiations started in 1986, pharmaceutical products were not subject to patent protection in almost fifty countries,[50] while ten other nations also excluded pharmaceutical processes from the domain of patent protection.[51] The exclusion of pharmaceutical inventions was mainly aimed at preventing potential consequences (inflation in the price of medicine, specifically) of patent protection.[52]

However, even if article 27(1) obliges members to provide for patents, they are bound to do so only if inventions meet patentability criteria (the inventions are new, involve an inventive step and capable of industrial application).[53] WTO members determine the constitutive elements of the criteria. Given these criteria are met, inventions are patentable unless they are excluded under article 27(2&3) of TRIPS. Based on article 27(2&3), members can carve out certain inventions from the scope of patentability.[54] If an invention, however, falls within the domain of a patent, members grant patent protection for twenty years counted from the date an application is filed.[55]

According to article 28(1)(a), patent holders have the right to exclude third parties (such as biosimilar and generic producers) from the "act of making, using, selling or offering for sale and importing" health technologies. Where the subject matter of a patent is a product, the exclusive rights entitle patent holders to prevent third parties from "the acts of making, using, offering for sale, selling, or importing." Likewise, when the subject matter of a patent is a process invention, patent holders are endowed with a transient right to exclude third parties "from the act of using the process and from the act of using, offering for sale, selling or

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[45] See, Peter-Tobia Stoll et al. eds., *WTO-Trade-Related Aspects of Intellectual Property Rights*, (Max Planck Commentaries on WTO Law), (Koninklijke Brill NV: The Netherlands:2009):476. See also, Jennifer Sellin, *Access to Medicines: The Interface between Patents and Human Rights. Does One Size fit All?* (Cambridge, UK, Intersentia, 2014):177.

[46] See, Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, (New York, USA, Oxford University Press, 2007):64.

[47] It can be a method of producing a certain product. However, article 27(1) of the TRIPS does not mandate the provision of process to an already known process.

[48] See, Article 27(1) of TRIPS; See also, Justin Malbon, et al., *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights: A Commentary*, (Cheltenham UK & Northampton, MA, USA, Edward Elgar, 2014):417.

[49] See, The Paris Convention for the Protection of Industrial Property, which was adopted in 1883.

[50] See, The WIPO Document on the Existence, Scope and Form of Generally Accepted and Applied Standards/Norms for the Protecting of Intellectual Property, WO/INF/29, of 15 September 1988, Annex II, 96.

[51] See, Hestermeyer, *Human Rights and the WTO*, p. 55.

[52] See, Nitsan Chorev and Kenneth C. Shadlen, "Intellectual property, access to medicines, and health: new research horizons", LSE *Studies in Comparative International Development* 50, No. 2 (2015):143-156; Rochele C. Dreyfuss, "TRIPS and Essential Medicines: Must One Size Fit All? Making the WTO Responsive to the Global Health Crisis", In *Incentives for Global Public Health: Patent Law and Access to Essential Medicines*, (Thomas Poggie et al. eds.,)(New York USA, Cambridge University Press, 2010):36; Beatrice Lindstrom, "Scaling Back TRIPS-Plus: An Analysis of Intellectual Property Provisions in Trade Agreements and Implications for Asia and the Pacific", *Journal of International Law and Politics* 42, (2010):946.

[53] See, the first sentence of article 27(1) of TRIPS. See also, Matthias Lamping et al., "Declaration on Patent Protection – Regulatory Sovereignty under TRIPS", Max Planck Institute for Innovation & Competition Research Paper No. 14-19, (2014):10; Amy Kapczynski & Mohammed El Said, "Access to Medicines: The Role of Intellectual Property Law and Policy", Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law, (7-9 July 2011):5; Cynthia M. Ho, *Access to Medicine in the Global Economy*, (Oxford, UK, Oxford University Press, 2011): 61.

[54] However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.

[55] See, Article 33 of TRIPS.

importing for these purposes at least the product directly obtained by that process."[56] As such, a process patent holder not only excludes third parties from the use of the process but also protects a product acquired directly by the process.[57] Footnote 6 to article 28(1) states that this right, like all other rights granted under the TRIPS Agreement "in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6."

In this context, the following question arises: should countries allow monopoly rights in times of global pandemic? The next section zooms-in on whether or not States should allow such monopoly rights.

[56] Article 28(1)(b) of TRIPS.
[57] See, World Trade Organization, "Overview: The TRIPS Agreement," (updated 2018). Available from https://www.wto.org/English/tratop_e/trips_e/intel2_e.htm#patents (accessed on 28 June 2018).

III. EXPEDITING ACCESS TO HEALTH TECHNOLOGIES RELATED TO COVID-19

As pointed under section one, starting off as pneumonia of an unknown cause, COVID-19 has engendered a global public health crisis. Governments, depending on their domestic contexts, have enforced various measures, including national lockdowns. Though the measures taken (such as lockdown, self-isolation, mandatory quarantine, social distancing) are estimable, reports indicate that COVID-19 will stay unabated until, at least, health technologies (particularly, vaccines and medicines) are developed.[58] A global effort to develop new vaccines or the likely application of existing medicines are now underway. Though there are no specific medicines at this time, more than one-hundred candidate vaccines are in development worldwide.[59] On 22 May 2020, The Lancet published a study showing that, at least, eight of the candidates have started clinical trials.[60] While "Moderna's mRNA COVID-19 vaccine and CanSino's non-replicating adeno-virus type-5 (Ad5) vectored COVID-19 vaccine entered phase one clinical trials on March 16, 2020, three inactive COVID-19 vaccines manufactured by Sinovac, Wuhan Institute of Biological Products and Beijing Institute of Biological Products has also entered clinical trials in April 2020" consecutively.[61]

However, estimates show that the earliest any of these might be available is in September 2020.[62] AstraZeneca promised to deliver the first dose of vaccine by October 2020 provided that the clinical trials go as planned.[63] The United States for instance launched "Operation Warp Speed" to develop quickly a large amount of vaccines.[64] Though modern technologies (such as "messengerRNA programming") are stimulating the confidence for quicker vaccine development, many scientists, however, cast doubt on the timeframe required to bring vaccines. Ken Frazier, Merck's Chief Executive, for instance, stated that the development of safe and effective COVID-19 vaccines will take more time.[65]

Irrespective of the lack of consensus on the timetable, the health technologies under development can be requested by pharmaceutical companies to be subject to IP (patent, test data, etc.) protections once they are developed. Some countries may also contemplate to do so in response to obligations contained under TRIPS and other agreements.[66] Though the present race to develop health technologies (vaccines and medicines) can be hailed as an extraordinary undertaking, the race also reflects the desire of some pharmaceutical companies to dominate exclusively the global market. This is expected to affect access to

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[58] The Lancet Editorial, "COVID-19: endgames," The *Lancet* 20, (17 April 2020):511.
[59] See, Feng-Cai Zhu et al., "Safety, tolerability, and immunogenicity of a recombinant adenovirus type-5 vectored COVID-19 vaccine: a dose-escalation, open-label, non-randomised, first-in-human trial", The *Lancet*, (22 May 2020):1&2. Cuiqing Ma et al., "From SARS-CoV to SARS-CoV-2: safety and broad-spectrum are important for coronavirus vaccine development," *Microbes and Infection*, (2020).
[60] See, Feng-Cai Zhu et al., "Safety, tolerability, and immunogenicity of a recombinant adenovirus type-5 vectored COVID-19 vaccine", p. 1. See also, The Lancet Editorial, "COVID-19: endgames". See also, The Vaccine Centre of the London School of Hygiene & Tropical Medicine, "COVID-19 vaccine development pipeline", (18 May 2020). Available from https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/ (accessed on 24 May 2020).
[61] See, Feng-Cai Zhu et al., "Safety, tolerability, and immunogenicity of a recombinant adenovirus type-5 vectored COVID-19 vaccine".
[62] The Lancet Editorial, "COVID-19: endgames",
[63] Hannah Kuchler, "Scientists versus Politicians: The Reality Check for Warp Speed Vaccine Research", *Financial Times*, (May 22, 2020). Available from https://www.ft.com/content/1467b1da-28a5-47d4-a5e2-a6f4b68484c3, Accessed on 27 May 2020.
[64] Ibid.
[65] David Crow, "Merck Chief Casts Doubt on Coronavirus Vaccine Timeframe", Financial Times, (26 May 2020). Available from https://www.ft.com/content/7b72a568-9eed-460f-b100-7bf74e3f4cbf?sharetype=blocked, Accessed on 27 May 2020.
[66] See, Article 27(1) of the TRIPS Agreement.

medicines in general and the much-needed access to vaccines. Thus far, studies have confirmed that though several factors affect access to medicines, an inflated price is the principal cause of lack of access.[67] Price spikes are usually fortified by robust IP protection.[68]

Even though IPRs (such as patents) can incentivize the creation of health technologies, one should ask the question, should States allow a monopoly in times of a pandemic? *Prima facie*, pharmaceutical companies may try, as always, to acquire monopoly rights to engage in the conventional model of health technology pricing. However, as COVID-19 stands now, this approach is likely to reinforce the practice of "business as usual" despite the pressing global health crisis. Business as usual, in this context, is used to refer to the provision of monopoly rights to health technology developers so that such developers would exclusively dictate the market. This line of exclusive protection has proved to be ineffective, especially in times of a pandemic, to ensure timely and equitable access to health technologies. It is due to this ineffectiveness that antiretrovirals (ARVs) took years to reach many developing nations. This has been the case, for instance, in South Africa and several other countries. In 2004, about one million South Africans were in a pressing need for ARVs. However, even two years after, only 21% of these population had access to ARVs.[69] According to WHO and the World Bank, at least half the world's population lacks access to essential health technologies even in ordinary times.[70] While the lack of access is higher in developing and least developed nations, developed nations are also not fully exempted from this hiccup.

Thus, giving monopoly rights in times of the current pandemic will certainly reiterate and reinforce such ineffectiveness and, thereby commodify human lives. From the very outset, COVID-19 has also exposed the "inadequacy of the market to serve the public health interest" in low-income, middle-income as well as in developed nations.[71] If countries fail to learn a lesson from HIV/AIDS and follow the same lane, monopoly rights can relegate the global priority, equitable access to health technologies, to an auxiliary position. The United Nations General Assembly (UNGA), in this context, emphasized that equitable access to COVID-19 related health technologies is "a global priority."[72] It also clearly recognized that the availability, accessibility, acceptability, and affordability of health technologies of assured quality are vital to defeating COVID-19. If this premise is accurate, existing and future COVID-19 related health technologies should be treated as global public goods. Global public goods, in this context, is intended to indicate that all health technologies should be available to all (low, middle, and high-income countries) at the same time. Ensuring equitable global access to health technologies, thus, necessitates the need to revisit the present model of health technology pricing (monopoly rights). In a message sent to the 73rd World Health Assembly (WHA), the South Centre also indicated that "All Covid-19 related drugs, diagnostics, vaccines and health products, existing or future, should be considered global public goods." The Centre also specified that considering health technologies as global public goods "will be the only way to make these products available to everyone, everywhere, at the same time."[73]

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[67] Siobhán Elizabeth Stade Murillo, "Fair or Fraud: Has the Protocol amending TRIPS Flourished or Failed?" *Indiana Intl & Comp. Law Review* 27, (2017):191. See also, Ellen F. M. 't Hoen, "TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond", (2003):39.

[68] Ellen F. M. 't Hoen, "TRIPS, Pharmaceutical Patents and Access to Essential Medicines".

[69] Jeremy R. Youde, *AIDS, South Africa and the Politics of Knowledge*, (Hampshire, UK, Ashgate, 2007).

[70] Oxfam, "How to Confront The Coronavirus Catastrophe: The Global Public Health Plan and Emergency Response needed now", Oxfam Media Briefing, (30 March 2020):2. See also, The World Health Organization and the World Bank, "Tracking Universal Health Coverage: 2017 Global Monitoring Report,"(2017):2.

[71] Médecins Sans Frontières, "Urgent Steps are Needed to define how COVID-19 Medical Tools can Really be Global Public Goods", MSF Access Campaign, (1 May 2020). Available from https://msfaccess.org/urgent-steps-are-needed-define-how-covid-19-medical-tools-can-really-be-global-public-goods (accessed on 5 June 2020.

[72] The United Nations General Assembly, "Resolution adopted by the General Assembly on 20 April 2020", Seventy-fourth session, Agenda item 123, A/RES/74/274, (April 21, 2020).

[73] The South Centre, "Message from the South Centre to the 73rd World Health Assembly", (May 2020). Available from https://www.southcentre.int/statement-may-2020/.

It is to realize this similar, but magnanimous, objective that the UNGA adopted a resolution on the "International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19."[74] Having emphasized the importance of considering COVID-19 related health technologies as global public goods, the UNGA resolution directed the UN Secretary-General to collaborate with other institutions (WHO, the international financial institutions, and other UN agencies) and have an active role in the fight against the pandemic. It particularly requested the Secretary-General "to identify and recommend options, including approaches to rapidly scaling manufacturing and strengthening supply chains that promote and ensure fair, transparent, equitable, efficient and timely access to and distribution" of health technologies to make them available to all those in need and more particularly in developing nations.[75] UN Member States and other stakeholders are also urged to quickly take steps to "prevent, within their respective legal frameworks, speculation and undue stockpiling that may hinder access to safe, effective and affordable essential medicines, vaccines, personal protective equipment and medical equipment as may be required to effectively address COVID-19."[76]

Having considered the UNGA resolution, the World Health Assembly, which is the highest decision making body of WHO, also adopted Resolution WHA 73.1 on "COVID-Response" on 19 May 2020.[77] The COVID-19 Response Resolution also recognized the need for "the universal, timely and equitable access to, and fair distribution of, all quality, safe, efficacious and affordable essential health technologies and products, including their components and precursors, that are required in the response to the COVID-19 pandemic as a global priority."[78] The resolution, especially calls for "urgent removal of unjustified obstacles" to the universal, timely, and equitable access to and fair distribution of health technologies.[79] Under the Resolution, the removal of such obstacles should, however, be consistent with the provisions of relevant international treaties, TRIPS, and the flexibilities within the Doha Declaration. As specified in the Resolution, countries can eliminate such obstacles based on many of the TRIPS provisions. For instance, article 73 of TRIPS provides to the WTO members to invoke security exceptions. More particularly, article 73(b) stipulates that nothing in the TRIPS Agreement shall be construed "to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests."[80] The threat to human and the multidimensional social, economic and other challenges posed by COVID-19 can be a reason to count on the security exceptions. If the threat caused by COVID-19 cannot be a reason to invoke essential security interests, there will never be any other viable reason that justifies the use of security exceptions. For instance, in the letter sent to the Directors of the WTO, WIPO, and WHO, the Executive Director of the South Centre, Professor Carlos Correa, stated that the use of article 73 of TRIPS "will be fully justified, as necessary, to procure medical products and devices or to manufacture them so as to satisfy its growing demand."[81] Thus, the urgent removal of –albeit TRIPS consistent– unjustified

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[74] The United Nations General Assembly, "Resolution adopted by the General Assembly on 20 April 2020," Seventy-fourth session, Agenda item 123, A/RES/74/274, 21 (April 2020):2.
[75] Ibid.
[76] Ibid, para. 4.
[77] See also, Priti Patnaik, "A strong call for COVID-19 treatments and vaccines to be global public goods – World Health Assembly", International Health Policy (IHP), (20 May 2020). Available from https://www.internationalhealthpolicies.org/featured-article/a-strong-call-for-covid-19-treatments-and-vaccines-to-be-global-public-goods-world-health-assembly/ (Accessed on 5 May 2020).
[78] The World Health Assembly, COVID-19 response, Seventy-Third World Health Assembly WHA73.1, Agenda item 3, (May 19, 2020):Para. 4.
[79] Ibid.
[80] See, Article 73(b) of TRIPS.
[81] See, Carlos Correa, "COVID-19 pandemic: Access to Prevention and Treatment is a Matter of National and International Security", Open letter from Carlos Correa, Executive Director of the South Centre, (4 April 2020). Available from https://www.southcentre.int/wp-content/uploads/2020/04/COVID-19-Open-Letter-REV.pdf.

obstacles, as contained in the UNGA resolution, is tantamount also to the use of security exceptions to treat health technologies as global public goods.
During the WHA meeting, several Heads of States and Governments of least developed, developing as well as developed countries explicitly stated that existing and future treatments and vaccines related to COVID 19 should be considered as global public goods. Austria, for instance, specified that all countries "should consider future COVID-19 medical treatments and vaccinations as a global public good, accessible to all member states at a reasonable price."[82] It also urged WHO to "play an important role to facilitate solutions regarding intellectual property rights." Similar to Austria, other countries such as Ethiopia uttered "for universal, timely and equitable access to quality, safe, efficacious and affordable essential health technologies and products including vaccines, diagnostics, therapeutics and Protective Equipment."[83] It also requested "the removal of all kinds of legal, policy or technical barriers that impede access."[84] The Chinese President, Xi Jinping, also underlined that his country would make vaccines related to COVID-19 global public goods once they are developed. At the time of launching Access to COVID-19 Tools (ACT) Accelerator, the President of the EU Commission, Ursula Von Der Leyen, also underlined not only the need to develop, produce, and deploy vaccine in every single corner of the world at affordable prices but also the necessity of making such vaccines "universal common good."[85] Similarly, the World Bank in its Project Appraisal Document on COVID-19 Strategic Preparedness and Response Program has specified the fact that the response to COVID-19 should be based on global public goods aspects.[86]

The issues pointed above show that there is increasing support to consider existing and future COVID-19 related health technologies as global public goods. Irrespective of the place where the health technologies will soon be developed, the outcome of such development should be available to all at the same time. However, it is often argued that the implementation of the concept of public goods may not always be easy as it is more of an aspiration. This argument is slightly tolerable as some questions still need to be answered. For instance, though the World Health Assembly Resolution WHA73.1 on "COVID-Response has recognized several objectives that are aimed at ensuring equitable access to health technologies, the Resolution does not specify how these objectives would be implemented."[87] Thus, the above argument can be proved wrong if the promises made thus far by various actors (Heads of States, philanthropies, UN agencies, civil society organizations, and some private firms) are fully, effectively, and equitably put into practice.

In this context, even though the UNGA and WHA resolutions as well as the proposed similar other initiatives are admirable, they cannot be adequate to immediately promote the global priority (equitable access to health technologies) unless concrete steps are taken.[88] Thus, while all stakeholders should participate and play a determinant role, rich countries and countries with the required research & development as well as technological capacities should also take the leading role. Particularly, the UN Secretary-General, as stated under the Resolution on International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19, should intervene to take necessary steps to effectively

[82] See, Patnaik, "A strong call for COVID-19 treatments and vaccines to be global public goods – World Health Assembly".
[83] Ibid. See also, Statement by Dr Lia Tadesse, Minister of Health of Ethiopia on the De Minimis Session of the 73rd World Health Assembly Agenda item 3, (May 2020).
[84] Ibid.
[85] The World Health Organization, "COVID-19 ACT Accelerator launch", (24 April 2020):3.
[86] The World Bank, "COVID-19 strategic preparedness and response program and proposed 25 projects under phase 1 using the multiphase programmatic approach", WB Project Appraisal Document, (2 April 2020):7.
[87] See, Nirmalya Syam et al., "The 73rd World Health Assembly and Resolution on COVID-19: Quest of Global Solidarity for Equitable Access to Health Products", South Centre Policy Brief No 78, (2020):2. Available from https://www.southcentre.int/policy-brief-78-may-2020/.
[88] See, Patnaik, "A strong call for COVID-19 treatments and vaccines to be global public goods – World Health Assembly".

coordinate and follow up on the works of the UN system to stimulate and ensure global access to health technologies.

More importantly and as already reaffirmed by Resolution WHA73.1, the WHO should have an active role to catalyze and coordinate “the comprehensive global response to the COVID-19 pandemic.” Additionally, based on its Constitutional mandate, it should set up and strengthen a system for equitable distribution of health technologies and the full implementation of its resolution. This enables the organization not only to tackle the current pandemic but also to effectively combat future global health challenges. In this sense, countries should also stand in unison and rally behind the organization. As stated by former UN Independent Expert on the Promotion of a Democratic and Equitable International Order, Alfred de Zayas, the organization “deserves maximum cooperation, not “maximum politicization” or “maximum pressure.”

IV. A VOLUNTARY COVID-19 IP POOL: A CONTRIBUTION TO ACCESS TO HEALTH TECHNOLOGIES

In addition to the issues raised above, a voluntary initiative has also been proposed by Costa Rica to encourage global access to affordable health technologies.[89] In March 2020, Costa Rica initiated a proposal to set up a voluntary COVID-19 IP pool.[90] It, particularly, requested the WHO to "undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic."[91] In a letter written to the WHO Director-General and signed by the President of Costa Rica (Carlos Alarado Quesada) and the Minister of Health of Costa Rica (Daniel Salas Peraza), Costa Rica asked for the establishment of a pool that should include "existing and future rights in patented inventions and designs, as well rights in regulatory test data, know-how, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines."[92] The proposal also requests either for free access to the pool or licensing on reasonable and affordable terms, in every country.[93] Having considered the proposal, the WHO Director-General also called upon "countries, companies and research institutions to support open data, open science and open collaboration so that all people can enjoy the benefits of science and research."[94]

The establishment of the pool, if effectively implemented by all stakeholders, will have paramount importance to encourage timely access to medicines. For instance, experience from the Medicines Patent Pool shows that a voluntary licensing scheme has the potential to stimulate access to medical technologies. The Medicines Patent Pool has reached, in this context, estimable agreements with IP owners for a voluntary license. Though the agreements mostly have come after protracted negotiations, the license contributed to the promotion of access to medicines for the treatment of diseases such as hepatitis C, HIV/AIDS.[95]

Beyond this, the 2003 SARS experience may provide an additional indication. Following the 2003 SARS outbreak, WHO set up a network of scientists from eleven leading laboratories, among other objectives, to expedite the development of "a robust and reliable diagnostic test."[96] Sharing data was also highly encouraged within the members of the group to advance

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[89] World Health Organization, "WHO and Costa Rica preview technology pooling initiative to ensure access to COVID-19 health products for all", (15 May 2020). Available from https://www.who.int/news-room/detail/15-05-2020-who-and-costa-rica-preview-technology-pooling-initiative-to-ensure-access-to-covid-19-health-products-for-all (accessed on 25 May 2020).

[90] Adam Houldsworth, "World leaders hatch further plans for accessibility of covid-19 IP rights," IAM, (9 April 2020). Available from https://www.iam-media.com/coronavirus/world-leaders-hatch-further-plans-accessibility-of-covid-19-ip-rights (accessed on 24 May 2020). See, Grace Ren, "WHO, Costa Rica & Chile Announce Official Launch Of COVID-19 Intellectual Property Pool", *Health Policy Watch*, (15 May 2020). Available from https://healthpolicy-watch.org/who-costa-rica-announce-official-launch-of-covid-19-intellectual-property-pool/ (Accessed on 24 May 2020).

[91] See, Carlos Alvarado Quesada & Daniel Salas Peraza, Letter to the WHO Director General, Tedros Adhanom," (23 March 2020). Available from https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf (accessed on 25 May 2020).

[92] Ibid.

[93] Ibid.

[94] World Health Organization, "WHO Director-General's opening remarks at the media briefing on COVID-19 - 6 April 2020," (6 April, 2020). Available from https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---6-april-2020 (accessed on 28 May 2020).

[95] Viviana Muñoz Tellez, "The COVID-19 Pandemic: R&D and Intellectual Property Management for Access to Diagnostics, Medicines and Vaccines," p. 4.

[96] See, Klaus Stöhr, "A multicentre collaboration to investigate the cause of severe acute respiratory syndrome," The *Lancet* 361, (17 May 2003):1731.

research and development collaboratively.[97] While, in principle, the data was to be shared only within the members of the network, it was also shared outside the network "with the approval of the laboratory from which the data originated."[98] As Kalus Stöhr specified, in this context, the establishment of the network facilitated "the simultaneous analyses of samples from the same patient in several laboratories with different approaches, and real-time sharing of results."[99] By being part of the network, participating nations (such as the US, China, Germany, etc.) were also able to identify coronavirus rapidly.[100]

In a similar and even a better manner, the establishment and effective implementations of a voluntary COVID-19 IP pool may result in expedited access to affordable health technologies for all, including the poor. Brook Baker, in this context, has argued that the pool will accelerate access by "in-licensing the broadest possible range of medically relevant intellectual property rights and data and by out-licensing those rights to all qualified producers" that can then conduct follow-on research and development to manufacture in large-scale the most pressing health technologies.[101] The initiative can be relevant especially for developing countries and LDCs as they are highly vulnerable to the effects of the global health crisis.[102] The UNGA Resolution on the International cooperation to ensure global access to medicines, vaccines, and medical equipment to face COVID-19, for instance, recognized the fact that the COVID-19 pandemic "has a disproportionately heavy impact on the poor and the most vulnerable, in particular in low-income, middle-income and developing countries." In a similar vein, the World Bank stated that "even if the COVID-19 transmission could be halted today in the most heavily affected countries, the spread of new infections in poor, densely populated countries, where weak health systems need massively scalable investments in human capital, supplies and infrastructure, will continue to threaten the entire global community."[103]

However, the initiative may not only be beneficial to LDCs and developing countries with no or low medical technologies manufacturing capacity but also countries with technical and technological capabilities to develop the vaccines. Recently released data could support the latter claim. SARS-Cov-2 related research projects around the world have been accelerated or started only after viral genome sequences were released publicly.[104] On 10 January 2020, China released on the internet "a viral genome sequence for immediate public health support."[105] Two days later, the country also deposited four other "genomes in the viral sequence database curated by the Global Initiative on Sharing All Influenza Data (GISAID)."[106] The deposited genome sequences have indicated the presence of a virus that has a resemblance to SARS-related coronavirus.[107] Releasing the data allowed many

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[97] Ibid.
[98] Ibid.
[99] Ibid.
[100] Matthew Rimmer, "The Race to Patent the SARS Virus: the TRIPS Agreement And Access To Essential Medicines", *Melbourne Journal of International Law* 5, (2003):2-3. See, Stöhr,"A multicentre collaboration to investigate the cause of severe acute respiratory syndrome", 1731.
[101] Brook Baker, "Rationale For Supporting Costa Rica's Proposal for Emergency COVID-19 Technology IP Pool for All Countries", American University Washington College of Law Program on information Justice and Intellectual Property, (25 March 2020). Available from http://infojustice.org/archives/42137 (accessed on 25 May 2020.
[102] Viviana Muñoz Tellez, "The COVID-19 Pandemic: R&D and Intellectual Property Management for Access to Diagnostics, Medicines and Vaccines," p. 1.
[103] The World Bank, "COVID-19 strategic preparedness and response program and proposed 25 projects under phase 1 using the multiphase programmatic approach", WB Project Appraisal Document, (2 April 2020):7.
[104] Institut Pasteur, "Whole genome of novel coronavirus, 2019-nCoV, sequenced", *ScienceDaily*, (31 January 2020). Available from https://www.sciencedaily.com/releases/2020/01/200131114748.htm (accessed on 25 May 2020).
[105] Victor M Corman et al., "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR", *Euro Surveillance* 25, No. 3 (2020):1.
[106] Ibid.
[107] Ibid.

countries to develop test kits to detect infections of COVID-19.[108] Thus, the establishment of a voluntary COVID-19 IP pool will highly expedite access to affordable health technologies for all countries. For instance, scientists of Johnson & Johnson, which is a New Jersey-based pharmaceutical company, began the process of potential vaccine development after genetic sequencing of SARS-Cov-2 was publicly released.[109]

Similar to China, attempts have been made and are being made by scientists and others, at the early stage of the COVID-19 outbreak, to quickly share data (such as research publications).[110] WHO and its partners also launched a "Solidarity" clinical trial for COVID-19 treatments.[111] The Solidarity Trial is a global clinical trial to support the finding of an effective treatment for the pandemic. Since running "randomized" clinical trials require a long time, the Solidarity Trial, among other things, is intended to cut the time taken by 80 per cent. Medicines such as "remdesivir, lopinavir and ritonavir in combination, lopinavir/ritonavir plus interferon-beta and chloroquine and hydroxychloroquine" are being tested.[112] Thus, while the attempts made, thus far, to share COVID-19-related data are estimable, the effective implementation of a voluntary COVID-19 IP pool may have the effect of encouraging the production on a large-scale of medicines for all.

As much as some pharmaceutical companies are willing to license their existing patented medicines, other investors are already requesting "pharma companies to ensure huge profits."[113] This move is not only avaricious but also indefensible during this global pandemic. It evident that the exclusive rights given in article 28 of TRIPS enable developers (their investors) to charge an inflated price. Pharmaceutical companies also try to justify a high price by claiming that it helps to recuperate the costs of R&D. Though this argument is slightly acceptable, the high price or monopoly rights cannot be justified especially during this pandemic as governments, donor organizations and numerous others have transferred a huge amount of money into COVID-19 vaccine development.[114] The contributions made by public and donor institutions should not only enable developers but should also allow the public to benefit from it. It is due to the same reasoning that Costa Rica asked the WHO Global Observatory on Health R&D (the observatory) to "create a database of R&D activity related to COVID-19, including estimates of the costs of clinical trials, and the subsidies provided by governments and charities."

Any contrary tactic to be adopted to manage the IP rights will certainly curtail the timely availability of and access to medical technologies, especially in developing countries. It may also have the effect of commodifying the life of human beings. If the pandemic has shown us

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[108] Muñoz Tellez, "The COVID-19 Pandemic: R&D and Intellectual Property Management for Access to Diagnostics, Medicines and Vaccines," p. 2. See also, Brook Baker, "Rationale For Supporting Costa Rica's Proposal for Emergency COVID-19 Technology IP Pool for All Countries", American University Washington College of Law Program on information Justice and Intellectual Property, (25 March 2020). Available from http://infojustice.org/archives/42137 (Accessed on 25 May 2020).

[109] EHS Today, "Johnson & Johnson Partners with U.S. Government on COVID-19 Vaccine Development", (2 April 2020). Available from https://www.ehstoday.com/health/article/21127572/johnson-johnson-partners-with-government-on-covid19-vaccine (accessed on 5 June 2020).

[110] Vasee Moorthy et al., "Data sharing for novel coronavirus (COVID-19)", *Bulletin of World Health Organ* 98, (2020):150.

[111] World Health Organization, "solidarity" clinical trial for COVID-19 treatments", (18 March 18, 2020). Available from https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments (accessed on 25 May 2020).

[112] Ellen 't Hoen, "Covid-19 and the comeback of compulsory licensing", *Medicines Law and Policy*, (23 March 2020). Available from https://medicineslawandpolicy.org/2020/03/covid-19-and-the-come-back-of-compulsory-licensing/ (Accessed on 27 May 2020).

[113] Henning Grosse Ruse-Khan, "Access to Covid-19 Treatment and International Intellectual Property Protection – Part I: Patent protection, voluntary access and compulsory licensing", *European Journal of International Law* EJIL at 30, (15 April 2020): 2.

[114] Hannah Kuchler, "Scientists versus Politicians: The Reality Check for 'Warp Speed' Vaccine Research", *Financial Times*, (22 May 22, 2020). Available from https://www.ft.com/content/1467b1da-28a5-47d4-a5e2-a6f4b68484c3 (accessed on 27 May 2020).

one thing, it is our interdependence. If this premise is true, the “traditional market model”, the creation of monopoly rights and the associated excessive medicine pricing, cannot enable the production, marketing and supply of large scale health technologies to all countries around the World. Thus, since especial and pressing times need especial and urgent measures, solidarity and cooperation that prioritize equitable global access to medicines should be a new global norm. It is worth noting that a voluntary initiative may not be effective and beneficial unless there is a strong commitment (particularly, political) across many sectors. Given the fact that companies may not voluntarily contribute to the Pool, donors, public institutions, and sectors that provide resources to COVID-19 vaccines development, should give such resources by attaching conditionalities that require and ensure equitable global access to health technologies.

V. CONCLUSION

The outbreak of COVID-19 has not only threatened the health and economy of nations but also ravaged the social fabric in many countries. In cognizance of the threat posed, commitments to develop health technologies (medicines, vaccines, and others) are already underway by several pharmaceutical companies. The development of health technologies alone, however, may not effectively ensure equitable access to the outcome of such development. Particularly, this can be the case if the traditional market model, which allows monopoly rights that enable the exclusion of others from the act of making, selling, using and importing health technologies, is reinforced. Although the debate concerning patent and access to health technologies, especially medicines is not fresh, the recent debate is unique as we all live in the time of a global pandemic. Given the fact that the pandemic has caused unprecedented damaging effects on lives, economies, global trade and several other sectors, the response to the pandemic should also be based on a cooperation and solidarity among all actors. As such, allowing monopoly rights in a pandemic will certainly exacerbate the global public health problem. This is the case since, among other reasons, IP holders cannot produce or engage in large-scale production, distribution and supply of an adequate amount of affordable health technologies within a short span of time.

Thus, recognizing this and the threat of the global pandemic, the health technologies under the process of development should be considered as global public goods. This will make health technologies to be available to everyone, everywhere, at the same time. Even though there are questions that still need to be answered, especially regarding the modality of effective implementation of the global public goods, the health technologies, as stated by the UNGA resolution and later reiterated by WHA 73.1, should be considered as global public goods. As also stated by UNGA, equitable access to COVID-19 related health technologies should be a global priority. The global health crisis has clearly shown the fact that no country is immune to the negative ramifications ensuing from the pandemic. Thus, the response to be made to tackle the pandemic should take into account the needs of all, especially least developed and developing nations. Even though priority should be given to treat the health technologies as global public goods, the effective implementation of a voluntary COVID-19 IP Pool may also have the potential to ensure access to health technologies for all, including the poor. It is essential, however, to note that as much as the proposed Pool is pertinent for access to medicines, its success highly depends on strong political commitments and support from the public and private sectors as well as civil society organizations. Should stakeholders, especially pharmaceutical companies fail to engage in the Pool, the WTO Member States should effectively use compulsory licenses and other TRIPS flexibilities to produce, sell, use, and import patent-protected health technologies. Any contrary action to be taken by the public or private sectors will have the effect of unlocking the “Pandora box” that sustains the pandemic at the expense of human life.

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ISSN 1819-6926