



SIX REASONS WHY A TRIPS WAIVER IS NEEDED TO JUSTLY AND EFFECTIVELY END THE COVID-19 PANDEMIC



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INTRODUCTION

**This backgrounder was prepared in support of numerous ongoing initiatives of network members and allies demanding a human rights-based response to the pandemic, including equitable access to COVID-19 vaccines and other health care technologies.*

Trade Related Aspects of Intellectual Property Rights (TRIPS) are international agreements for the protection of intellectual property monopolies (including patents, trademarks, copyrights, trade secrets etc.) monitored by the World Trade Organization (WTO).[1] TRIPS obligates member states to protect intellectual property in their respective domestic legal systems for goods including medical technologies.[2] A variety of medical technologies indispensable for controlling the ongoing COVID-19 pandemic – test kits, masks, vaccines, therapeutics for the treatment of COVID-19 and artificial intelligence – are treated as intellectual property protected technologies under TRIPS.[3]

A waiver mechanism exists for some or all of the TRIPS provisions to be deferred temporarily. In October 2020, India and South Africa formally proposed a temporary waiver of certain TRIPS protections, “in relation to prevention, containment or treatment of COVID-19,” inter alia “[r]ecognising the need for 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.” [4] A TRIPS waiver would allow countries who are WTO members to choose to not enforce intellectual property protections on COVID-19 medical technologies[5] for the duration of the pandemic.

[1] Frequently Asked Questions: The TRIPS Waiver and the WTO, Health Justice Initiative (4 June 2021), see <https://healthjusticeinitiative.org.za/2021/06/04/frequently-asked-questions-the-trips-waiver-and-the-wto/>.

[2] Frequently Asked Questions: The TRIPS Waiver and the WTO, Health Justice Initiative (4 June 2021), see <https://healthjusticeinitiative.org.za/2021/06/04/frequently-asked-questions-the-trips-waiver-and-the-wto/>.

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[4] Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa, World Trade Organization (2 October 2020), see <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf>; Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text, World Trade Organization (25 May 2021), see <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf>.

transfers required to meet urgent need for vaccines in the Global South (e.g. U.S.). Far from leveraging the current situation to make access to critical healthcare technologies in the Global South a priority, Global North countries are using this moment to push for more liberalization, deregulation of Global South markets and interventions that undermine the current flexibilities available to Global South countries at the WTO, for instance in Section 31bis of the TRIPS Agreement, derived from the Doha Declaration which allows measures against frivolous patent claims and for dealing with public health emergency measures.[6] This will impact the WTO response to both the ongoing and future pandemics.

In the absence of rapid development of generic versions of COVID-19 healthcare technologies the total global supply of these technologies as well their prices and manufacture locations remains strictly controlled by a small number of Global North corporations.[7] Intellectual property monopolies controlled by Global North-based pharmaceutical corporations and supported by their home States restrict supply of the most effective vaccinations, therapeutics and other COVID-19 healthcare technologies for much of the world's population living in the Global South.[8] Four major pharmaceutical corporations (Pfizer/BioNTech, Moderna, Astra-Zeneca and Johnson and Johnson (J&J)) have delivered 49 percent of their vaccines to high-income Global North countries which comprise only 16 percent of the world's population, with corporations like Moderna delivering 84 percent of their doses to high-income countries.[9]

Experts believe vaccinating the world with a view to suppressing the evolution of new variants and controlling the COVID-19 pandemic requires a massive increase in the global supply of effective medical technologies pivoted around technology transfers and view intellectual property monopolies as a major barrier.[10]

[6] Frequently Asked Questions: The TRIPS Waiver and the WTO, Health Justice Initiative (4 June 2021), see <https://healthjusticeinitiative.org.za/2021/06/04/frequently-asked-questions-the-trips-waiver-and-the-wto/>; What's Cooking for MC12? Two Processes that Could Reshape the WTO in the Interest of the Most Powerful, Third World Network (14 November 2021), see

https://twm.my/title2/briefing_papers/MC12/briefings/WTO%20reform%20&%20WTO%20pandemic%20response%20TWNBP%20MC12.pdf.

[7] Pg. 2, Waiver of the WTO's Intellectual Property Rules (TRIPS): An Indispensable Tool to Fight the COVID-19 Pandemic, Public Citizen (5 April 2021), see <https://www.citizen.org/article/waiver-of-the-wtos-intellectual-property-rules-existing-trips-flexibilities-unworkable-for-scale-up-of-covid-19-medicines-production/>.

[8] Sociologists and development economists use Global North to refer countries with high income and levels of technological advancement concentrated in the northern hemisphere whereas Global South is used to refer to countries in the Southern hemisphere with generally low-income and levels of technological advancement. Pg. 3, 16, 35, 37-38, 41-46, GDP's Report on Access to COVID-19 Vaccines, GRUPO DIREITO E POBREZA (GDP) (2021), see https://00b9f5d9-efc5-42db-80ec-1bbdbf542ad1.filesusr.com/ugd/81c13c_4a64de6a52bf4008a956b785e2b671ba.pdf.

[9] Pg. 2, A Dose of Reality, Dose of Reality: How Rich Countries and Pharmaceutical Corporations are Breaking their Vaccine Promises, The People's Vaccine (21 October 2021), see <https://peoplesvaccine.org/g20/>.

[10] Pg. 1, Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies, MSF Briefing Document, Médecins Sans Frontières (May 2021), see https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf.

Most recently, South African scientists detected the Omicron variant, saying it has mutations which potentially allow it to evade immune responses and make it more transmissible.[11] The variant was then designated a variant of concern by the World Health Organization (WHO) on the advice of its Technical Advisory Group on Virus Evolution.[12] In response, Global North countries including the U.S., the United Kingdom, Belgium, France, Germany, Israel, Italy, Japan, Singapore and Netherlands resorted to punitive and discriminatory travel bans against several countries' populations in southern Africa.[13] The WHO issued a plea against the travel bans, noting, "putting in place travel bans that target Africa attacks global solidarity. COVID-19 constantly exploits our divisions. We will only get the better of the virus if we work together for solutions." [14] The current situation underscores the role of vaccine equity as a precondition for ending the pandemic justly and effectively. Instead of imposing travel bans which are less effective[15] at containing the spread of virus variants than other measures and disincentivize open communication/cooperation over emerging virus variants, Global North countries must use the current moment to change course in favor of a TRIPS waiver as a first step in making vaccine equity and consequently global epidemic control a reality.

It is estimated achieving control over virus variants will require 16 billion doses a year – enough for the global population to be vaccinated once per year.[16] At the same time, earlier projections of an estimated 12 billion vaccine doses to be manufactured in 2021 have included estimates of vaccines still in development and unapproved for use in any jurisdiction as of October 30, 2021, such as the Novavax, CureVac and Inovio vaccines.[17] Data suggests actual production of vaccines from the above-mentioned four major pharmaceutical corporations is expected to fall 17 percent below their stated projections for 2021.[18] Even so, as

[12] Update on Omicron, World Health Organization (28 November 2021), see <https://www.who.int/news/item/28-11-2021-update-on-omicron>.

[13] As Omicron Spreads, Studies Suggest That Travel Bans Don't do Much Good, NPR (November 29, 2021), see <https://www.npr.org/sections/coronavirus-live-updates/2021/11/28/1059619823/omicron-travel-bans-covid>.

[14] WHO Stands with African Nations and Calls for Borders to Remain Open, World Health Organization (29 November 2021), see <https://www.afro.who.int/news/who-stands-african-nations-and-calls-borders-remain-open>.

[15] Chinazzi et. al., The Effect of Travel Restrictions on the Spread of the 2019 Novel Coronavirus (COVID -19) Outbreak, *Science* (24 April 2020), see <https://www.science.org/doi/10.1126/science.aba9757>.

[16] Data and health experts say the long-term prospects for COVID-19 include it becoming an endemic disease like influenza which requires regular vaccination. Five Reasons Why Herd Immunity is Probably Impossible, *Nature* (18 March 2021), see: <https://www.nature.com/articles/d41586-021-00728-2>; Pg. 19, Hit Hard, Hit Fast Globally, A Model for Global Vaccine Access, PrEP4All (19 March 2021), see <https://www.prep4all.org/news/hit-hard-hit-fast-hit-globally>.

[17] In March 2021, experts at the Duke Global Health Innovation projected that COVID-19 vaccine makers would produce more than 12 billion doses in 2021. These projections included estimates of vaccines still in development and unapproved for use in any jurisdiction at the time of publication, such as the Novavax, CureVac and Inovio vaccines. Pg. 3, Issue Brief: Deciphering the Manufacturing Landscape for COVID-19 Vaccines, Duke Global Health Innovation Center (19 March 2021), see <https://launchandscalefaster.org/sites/default/files/documents/Speedometer%20Issue%20Brief-COVID%20Manufacturing%20Landscape%2019%20March%2021.pdf>.

of November 15, 2021, people living in Global North countries continue to receive disproportionate amounts of the vaccine with more than 66 percent of the population in high-income countries fully vaccinated as opposed to only 2.3 percent in the low-income countries.[19] Global North countries such as the United Kingdom which oppose the waiver have administered booster shots to around 20 percent of their populations while less than 7 percent of the population in the entire African continent is vaccinated.[20] Tedros Adhanom Ghebreyesus, the Director-General of the WHO and Winne Byanyima, the Executive Director of UNAIDS have termed this divide “vaccine apartheid.”[21]

In opposing the proposed waiver of applicable provisions of the TRIPS waiver at the WTO, Global North-based pharmaceutical corporations and allies, including wealthy host states, have marshalled a variety of arguments as to why intellectual property monopolies over COVID-19 vaccine technology do not impede vaccine access for Global South populations.[22] However, these arguments are undermined by actions of the pharmaceutical corporations themselves and by numerous scientific, humanitarian, news and intergovernmental sources. On the whole, these arguments are red herrings obscuring the unwillingness of pharmaceutical corporations and related interests to give up their monopoly controls over the supply of COVID-19 healthcare at the expense of at-risk populations living in the Global South.

Below is a table of the myths perpetuated by pharmaceutical monopoly-holding corporations, their state allies and other TRIPS waiver opponents versus the reality grounded in facts. Each of the points made is further substantiated by scientific, humanitarian, news and non-governmental sources and by the actions of corporate actors themselves.

[18] Pg. 3, *A Dose of Reality, Dose of Reality: How Rich Countries and Pharmaceutical Corporations are Breaking their Vaccine Promises, The People's Vaccine* (21 October 2021), see <https://peoplesvaccine.org/g20/>.

[19] Hannah Ritchie, Edouard Mathieu, Lucas Rodés-Guirao, Cameron Appel, Charlie Giattino, Esteban Ortiz-Ospina, Joe Hasell, Bobbie Macdonald, Diana Beltekian and Max Roser (2020) - "Coronavirus Pandemic (COVID-19)". Published online at [OurWorldInData.org](https://ourworldindata.org/coronavirus). Retrieved from: <https://ourworldindata.org/coronavirus>.

[20] Hannah Ritchie, Edouard Mathieu, Lucas Rodés-Guirao, Cameron Appel, Charlie Giattino, Esteban Ortiz-Ospina, Joe Hasell, Bobbie Macdonald, Diana Beltekian and Max Roser (2020) - "Coronavirus Pandemic (COVID-19)". Published online at [OurWorldInData.org](https://ourworldindata.org/coronavirus). Retrieved from: <https://ourworldindata.org/coronavirus>.

[21] World has Entered the Stage of “Vaccine Apartheid”- WHO Head, Reuters (May 17, 2021), see <https://www.reuters.com/business/healthcare-pharmaceuticals/world-has-entered-stage-vaccine-apartheid-who-head-2021-05-17/>; A Global Vaccine Apartheid is Unfolding. People's Lives Must Come Before Profit, *The Guardian* (29 January, 2021), see <https://www.theguardian.com/global-development/2021/jan/29/a-global-vaccine-apartheid-is-unfolding-peoples-lives-must-come-before-profit>.

[22] 10 Arguments Against a Waiver of Intellectual Property Rights, *Oxford University Business Law Blog* (29 June 2021), see <https://www.law.ox.ac.uk/business-law-blog/blog/2021/06/10-arguments-against-waiver-intellectual-property-rights>; COVID-19 and the Role of Intellectual Property: Position Paper of the Max Planck Institute for Innovation and Competition of 7 May 2021. Max Planck Institute for Innovation and Research (7 May 2021), see https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3841549.

WHY A TRIPS WAIVER IS NEEDED TO JUSTLY AND EFFECTIVELY END THE PANDEMIC: MYTHS V/S REALITY

REALITY

- Significant manufacturing capacity and technical expertise exists in the Global South to produce generic COVID-19 medical technologies.
- Competition from generic manufacturers entering the market for manufacturing COVID-19 medical technologies will stimulate the supply of required raw materials and components.
- Intellectual property monopolies stifle supply of lifesaving COVID-19 healthcare technologies and deprive Global South populations of their right to the benefits of scientific progress and advancement.
- Voluntary licensing of intellectual property monopolized COVID-19 medical technologies, also referred to as the “Third Way”, is inadequate to meet global needs.
- Compulsory licensing provisions in the TRIPS Agreement place undue procedural burdens on Global South countries and do not cover the full scope of the medical technologies required for control of the COVID-19 pandemic globally.
- Alternatives such as COVAX/donations are insufficient and do not support a human-rights based approach to making COVID-19 medical technologies accessible for Global South populations.

MYTH

- There is not enough technical expertise in the Global South to allow for the manufacture of COVID-19 medical technologies.
- Generic manufacturers entering the market will further strain the supply of raw materials and components required for manufacturing COVID-19 medical technologies.
- Intellectual property monopolies are necessary for scientific advancement and development of lifesaving healthcare technologies.
- Voluntary licensing provisions in TRIPS / “Third Way” are sufficient to meet global needs for COVID-19 medical technologies.
- Compulsory licensing provisions in the TRIPS agreement are sufficient to meet global needs for COVID-19 medical technologies.
- COVAX/donations are sufficient to make COVID-19 medical technologies accessible to at-risk Global South populations.

KEY POINTS ON COVID-19 VACCINE AND OTHER HEALTHCARE ACCESS INEQUITY

1. Significant manufacturing capacity and technical expertise exists in the Global South to produce generic COVID-19 medical technologies.[23]

The intellectual property monopolies of Global North corporations over COVID-19 medical technologies prevent them from being accessible as public goods and allow corporations to exercise control over amount, price and other terms of production, impeding various efforts to increase the availability of COVID-19 healthcare technologies globally.[24] Pre-existing grants of licenses and contracts are inadequate to meet the needs of the Global South. This is in part because licensing agreements often limit production to the formulation of medicines, their bottling, freeze drying or testing (“fill and finish” agreements), while the core ingredients and processes remain controlled by the monopoly holders, including in terms of quantity and pricing.[25] Moreover, pharmaceutical industry-friendly arguments[26] regarding lack of requisite expertise or manufacturing capacity in the Global South obscure commercial prerogatives in not sharing information with competitor manufacturers. Such arguments also risk alignment with racist notions connecting the lack of Global South-based local production with a supposed general lack of scientific knowledge in these countries.

Global North-based pharmaceutical corporations have stressed the lack of requisite technical expertise elsewhere in setting up new plants as a primary impediment to global vaccine access.[27] Thomas Cueni, the Director-General at

[23] Generic drugs are versions of brand-name drugs that contain the same active ingredient(s) and in the same dosage but are made by a different manufacturer. After a regulatory authority certifies that a given generic drug is the equivalent of a brand-name drug, the two can be used interchangeably. Manufacturers of generic drugs are not required to repeat clinical trials to establish safety which rapidly reduces the time for approval. Pg. 19, Hit Hard, Hit Fast Globally, A Model for Global Vaccine Access, PrEP4All (19 March 2021), see <https://www.prep4all.org/news/hit-hard-hit-fast-hit-globally>.

[24] Pg. 2, Waiver of the WTO's Intellectual Property Rules (TRIPS): An Indispensable Tool to Fight the COVID-19 Pandemic, Public Citizen (5 April 2021), see <https://www.citizen.org/article/waiver-of-the-wtos-intellectual-property-rules-existing-trips-flexibilities-unworkable-for-scale-up-of-covid-19-medicines-production/>.

[25] Explainer, Vaccine Licenses for COVID-19, Health Justice Initiative (23 August 2021), see <https://healthjusticeinitiative.org.za/2021/08/23/explainer-on-vaccine-licenses-for-covid-19/>.

[26] 10 Arguments Against a Waiver of Intellectual Property Rights, Oxford University Business Law Blog (29 June 2021), see <https://www.law.ox.ac.uk/business-law-blog/blog/2021/06/10-arguments-against-waiver-intellectual-property-rights>; Pg. 2, COVID-19 and the Role of Intellectual Property: Position Paper of the Max Planck Institute for Innovation and Competition of 7 May 2021. Max Planck Institute for Innovation and Research (7 May 2021), see https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3841549.

[27] 10 Arguments Against a Waiver of Intellectual Property Rights, Oxford University Business Law Blog (29 June 2021), see <https://www.law.ox.ac.uk/business-law-blog/blog/2021/06/10-arguments-against-waiver-intellectual-property-rights>; Pg. 2, COVID-19 and the Role of Intellectual Property: Position Paper of the Max Planck Institute for Innovation and Competition of 7 May 2021. Max Planck Institute for Innovation and Research (7 May 2021), see https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3841549.

the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) has said Global South manufacturers looking to partner with Global North corporations “underestimate the challenge” of quality control.[28] Pfizer’s Chief

Executive Officer, Albert Bourla, said that teaching Global South manufacturers the requisite expertise would take “years.”[29] Chief Executive of Moderna, Stéphane Bancel, said finding people with expertise to produce vaccines in the Global South was impossible because such people “don’t exist.”[30]

However, the actions of pharmaceutical corporations themselves indicate that there already exists significant manufacturing capacity in the Global South for certain types of vaccines and therapeutics. The world’s largest vaccine manufacturer, the Serum Institute, is located in India and has been contracted to supply COVID-19 vaccines.[31] Global-North pharmaceutical corporations themselves have also contracted with certain manufacturers and licensees to manufacture COVID-19 medical technologies around the world, including manufacturers in India, South-Korea, Brazil, China, Argentina and Thailand, sometimes setting up production in a matter of months.[32]

Furthermore, several pharmaceutical manufacturers around the world have said they have production capacity to meet the demand for vaccine production for both the mRNA and other types of vaccines. Specifically, The Washington Post and The Intercept report that factories in Canada, Bangladesh and Pakistan have expressed an interest in producing the vaccine.[33] Further, Reuters reports that at least two

[29] *The Fight to Manufacture COVID Vaccines in Lower-Income Countries*, *Nature* (15 September 2021), see <https://www.nature.com/articles/d41586-021-02383-z>; *Drug Companies Defend Vaccine Monopolies in the Face of Global Outcry*, *The Washington Post* (20 March 2021), see

<https://www.washingtonpost.com/business/2021/03/20/covid-vaccine-global-shortages/>

[30] *Developing Countries Can Make mRNA Covid Vaccines*, *New York Times* (22 Oct 2021), see <https://www.nytimes.com/interactive/2021/10/22/science/developing-country-covid-vaccines.html>

[31] *The World’s Largest Vaccine Maker Took a Multimillion Dollar Pandemic Gamble*, *NPR* (18 March 2021), see

<https://www.npr.org/sections/goatsandsoda/2021/03/18/978065736/indias-role-in-covid-19-vaccine-production-is-getting-even-bigger>.

[32] *Drug Companies Defend Vaccine Monopolies in the Face of Global Outcry*, *The Washington Post* (20 March 2021), see

<https://www.washingtonpost.com/business/2021/03/20/covid-vaccine-global-shortages/>; *South Korea’s SK Bioscience in Deal with AstraZeneca on Vaccine*, *Reuters* (July 21, 2020), see <https://www.reuters.com/article/us-health-coronavirus-southkorea-astraze/south-koreas-sk-bioscience-in-deal-with-astrazeneca-on-vaccine-idUSKCN24M0ZF>; *COVID-19: Fiocruz Will Sign an Agreement To Produce Vaccines by the University of Oxford*, *FIOCRUCZ*, (30 June 2020), see

[https://portal.fiocruz.br/en/news/covid-19-fiocruz-will-sign-agreement-produce-vaccines-university-oxford#:~:text=The%20Oswaldo%20Cruz%20Foundation%20\(Fiocruz,by%20the%20University%20of%20Oxford.&text=Combined%20with%20other%20actions%2C%20it,fight%20the%20Covid%2D19%20pandemic](https://portal.fiocruz.br/en/news/covid-19-fiocruz-will-sign-agreement-produce-vaccines-university-oxford#:~:text=The%20Oswaldo%20Cruz%20Foundation%20(Fiocruz,by%20the%20University%20of%20Oxford.&text=Combined%20with%20other%20actions%2C%20it,fight%20the%20Covid%2D19%20pandemic;);

AstraZeneca Signs First COVID-19 Vaccine Deal with China’s Shenzhen Kangtai, *BioSpace* (6 August 2020), see <https://www.biospace.com/article/astrazeneca-inks-covid-19-vaccine-deal-with-china-s-shenzhen-kangtai/>;

Mabxience Enters into an Agreement with AstraZeneca to Produce COVID-19 Vaccine, *Mabxience* (17 August 2020), see <https://www.mabxience.com/mabxience-enters-into-an-agreement-with-astrazeneca-to-produce-covid-19-vaccine/>;

Thailand to Make, Supply AstraZeneca’s COVID-19 vaccine, *Reuters* (12 October 2020), see <https://www.reuters.com/article/us-health-coronavirus-astrazeneca-thaila/thailand-to-make-supply-astrazenecas-covid-19-vaccine-idUSKBN26X1GC>

[33] *Factor Owners Around the World Stand Ready to Manufacture COVID-19 Vaccines*, *The Intercept* (29 April 2021), see <https://theintercept.com/2021/04/29/covid-vaccine-factory-production-ip/>.

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[29] *The Fight to Manufacture COVID Vaccines in Lower-Income Countries*, *Nature* (15 September 2021), see <https://www.nature.com/articles/d41586-021-02383-z>; *Drug Companies Defend Vaccine Monopolies in the Face of Global Outcry*, *The Washington Post* (20 March 2021), see <https://www.washingtonpost.com/business/2021/03/20/covid-vaccine-global-shortages/>

[30] *Developing Countries Can Make mRNA Covid Vaccines*, *New York Times* (22 Oct 2021), see <https://www.nytimes.com/interactive/2021/10/22/science/developing-country-covid-vaccines.html>

[31] *The World’s Largest Vaccine Maker Took a Multimillion Dollar Pandemic Gamble*, *NPR* (18 March 2021), see <https://www.npr.org/sections/goatsandsoda/2021/03/18/978065736/indias-role-in-covid-19-vaccine-production-is-getting-even-bigger>.

[32] *Drug Companies Defend Vaccine Monopolies in the Face of Global Outcry*, *The Washington Post* (20 March 2021), see <https://www.washingtonpost.com/business/2021/03/20/covid-vaccine-global-shortages/>; *South Korea’s SK Bioscience in Deal with AstraZeneca on Vaccine*, *Reuters* (July 21, 2020), see <https://www.reuters.com/article/us-health-coronavirus-southkorea-astraze/south-koreas-sk-bioscience-in-deal-with-astrazeneca-on-vaccine-idUSKCN24M0ZF>; *COVID-19: Fiocruz Will Sign an Agreement To Produce Vaccines by the University of Oxford*, *FIOCRUZ*, (30 June 2020), see [https://portal.fiocruz.br/en/news/covid-19-fiocruz-will-sign-agreement-produce-vaccines-university-oxford#:~:text=The%20Oswaldo%20Cruz%20Foundation%20\(Fiocruz,by%20the%20University%20of%20Oxford.&text=Combined%20with%20other%20actions%2C%20it,fight%20the%20Covid%2D19%20pandemic](https://portal.fiocruz.br/en/news/covid-19-fiocruz-will-sign-agreement-produce-vaccines-university-oxford#:~:text=The%20Oswaldo%20Cruz%20Foundation%20(Fiocruz,by%20the%20University%20of%20Oxford.&text=Combined%20with%20other%20actions%2C%20it,fight%20the%20Covid%2D19%20pandemic);

AstraZeneca Signs First COVID-19 Vaccine Deal with China’s Shenzhen Kangtai, *BioSpace* (6 August 2020), see <https://www.biospace.com/article/astrazeneca-inks-covid-19-vaccine-deal-with-china-s-shenzhen-kangtai/>; *Mabxience Enters into an Agreement with AstraZeneca to Produce COVID-19 Vaccine*, *Mabxience* (17 August 2020), see <https://www.mabxience.com/mabxience-enters-into-an-agreement-with-astrazeneca-to-produce-covid-19-vaccine/>; *Thailand to Make, Supply AstraZeneca’s COVID-19 vaccine*, *Reuters* (12 October 2020), see <https://www.reuters.com/article/us-health-coronavirus-astrazeneca-thaila/thailand-to-make-supply-astrazenecas-covid-19-vaccine-idUSKBN26X1GC>

[33] *Factor Owners Around the World Stand Ready to Manufacture COVID-19 Vaccines*, *The Intercept* (29 April 2021), see <https://theintercept.com/2021/04/29/covid-vaccine-factory-production-ip/>.

with AstraZeneca and Novovax, potentially have capacity to manufacture the COVID-19 vaccine.[34] According to interviews done by The New York Times with dozens of scientists and executives at vaccine and medical technology companies, there are ten strong manufacturers in six countries across three continents in the Global South with capacity to produce COVID-19 mRNA vaccines, including Brazil-based Bio-Manguinhos and Instituto Butantan, Thailand-based BioNet-Asia, South Africa-based Aspen Pharmacare and Biovac Institute, Argentina-based Sinergium Biotech and Indonesia-based BioFarma.[35]

Additionally, evidence indicates technology transfers to produce COVID-19 healthcare technologies can take place quickly, in places with limited resources and even remotely without in-person assistance.[36]

Global North pharmaceutical manufacturers have stressed the time required to set up production in the Global South as a substantial factor against regional/local manufacture of vaccines. However, according to experts, manufacturers of COVID-19 vaccines typically began production within a mere six months after technology transfer began.[37] For example, J&J partnered with an Indian company – Biological E, in an effort which took seven months – to produce more than 40 million doses of its COVID-19 vaccine, all of which was originally designated for export to Europe (until the Indian government imposed restrictions on the export of vaccine in April 2021 following a devastating surge of the Delta variant of the virus in India).[38] Further, J&J also partnered with a pharmaceutical company in Durban, South Africa to manufacture shots, exporting the vaccine to Europe, even as some 90 percent of South Africans received no vaccine at all (after public outcry, the South African government put export control measures into place).[39]

[34] South Korea's SK Bioscience in Deal with AstraZeneca on Vaccine, Reuters (July 21, 2020), see <https://www.reuters.com/article/us-health-coronavirus-southkorea-astraze/south-koreas-sk-bioscience-in-deal-with-astrazeneca-on-vaccine-idUSKCN24MOZF>.

[35] Developing Countries Can Make mRNA Covid Vaccines, New York Times (22 Oct 2021), see <https://www.nytimes.com/interactive/2021/10/22/science/developing-country-covid-vaccines.html>

[36] Sharing the Knowledge: How President Joe Biden Can Use the Defense Production Act to End the Pandemic Worldwide, Health Affairs Blog (August 6, 2021), see <https://www.healthaffairs.org/doi/10.1377/hblog20210804.101816/full/>.

[37] The Fight to Manufacture COVID Vaccines in Lower-Income Countries, Nature (15 September 2021), see <https://www.nature.com/articles/d41586-021-02383-z>.

[38] The Fight to Manufacture COVID Vaccines in Lower-Income Countries, Nature (15 September 2021), see <https://www.nature.com/articles/d41586-021-02383-z>; COVID Vaccines' Export May Not Resume Before 2022, Hindustan Times (4 September, 2021), see <https://www.hindustantimes.com/india-news/covid-vaccines-export-may-not-resume-before-2022-101630688785979.html>.

[39] J&J Vaccine Shipments from S. Africa to Europe Halted, AU Says, Reuters (2 September 2021), see <https://www.reuters.com/world/jj-deal-ship-covid-19-shots-safrica-europe-halted-au-says-2021-09-02/>

Russia's partnership with Global South manufacturers to produce the Sputnik V vaccine (as yet unauthorized by the WHO despite authorization in many countries) shows that technology transfer is crucial. Russian scientists gave willing drug companies the essential ingredients for the vaccine, taught them the manufacturing process, knowledge of equipment and supplies allowing for the vaccine to be commercially available in eight months in India.[40] On account of similarities in the vector used to produce the J&J vaccine and Sputnik V, manufacturers in India say they could produce J&J's vaccine faster.[41]

The WHO has described the technology involving the use of mRNA vaccines of the kind developed by Pfizer-BioNTech and Moderna as "very flexible", allowing for rapid adaptation of the vaccine to different variants of the COVID-19 virus.[42] For instance, Moderna readied a new mRNA vaccine for a variant of the COVID-19 virus in 30 days for clinical trials.[43] Medical experts regard mRNA vaccines as having the best scope for global scale up due to relative ease of manufacture – global commercial capacity for manufacturing the vaccine grew from zero in February 2020 to over a billion doses in December 2020, with most production lines being built from pre-existing pharmaceutical plants becoming operational in six months or less.[44] Martin Friede, coordinator of the Initiative for Vaccine Research at the WHO, has suggested manufacturing redesign via the use of process intensification techniques to help make vaccine production cheaper and overcome limitations in resource poor locations.[45]

While production of the most effective messenger mRNA vaccines outside of fill and finish agreements takes place in the Global North, it appears that the shortage of mRNA vaccine manufacturing in Global South countries is not on account of lack of expertise but attributable in significant part to Global North intellectual

[40] *The Fight to Manufacture COVID Vaccines in Lower-Income Countries*, Nature (15 September 2021), see <https://www.nature.com/articles/d41586-021-02383-z>.

[41] *The Fight to Manufacture COVID Vaccines in Lower-Income Countries*, Nature (15 September 2021), see <https://www.nature.com/articles/d41586-021-02383-z>.

[42] *Establishment of a COVID-19 mRNA Vaccine Technology Transfer Hub to Scale up Global Manufacturing*, World Health Organization (16 April 2021), see <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing>.

[43] Pg. 1, *Share mRNA Technology, Save Lives: MSF Briefing Note*, Médecins Sans Frontières (August 2021), see https://msfaccess.org/sites/default/files/2021-09/COVID19_TechnicalBrief_MSf_mRNA_vaccines_ENG_20.9.2021_0.pdf

[44] Pg. 17, *Hit Hard, Hit Fast Globally, A Model for Global Vaccine Access*, PrEP4All (19 March 2021), see <https://www.prep4all.org/news/hit-hard-hit-fast-hit-globally>.

[45] *Process intensification is a manufacturing technique designed to reduce time and space required to make vaccines while also reducing processing complexity to some degree. Vaccines produced in this process would still need to be tested in clinical trials and need regulatory approval. Intensifying Vaccine Production*, Bulletin of the World Health Organization, World Health Organization, see <https://www.who.int/bulletin/volumes/98/5/20-020520.pdf>

property monopolies.[46] A recent set of events illustrates the connection between vaccine monopolies exercised by the Global North pharmaceutical industry and the limited global supply of vaccines. In April 2021, the WHO established a technology transfer hub focused on mRNA vaccine technology to allow for the production, export and distribution of generic versions of the vaccine. [47] In a few weeks after the launch of the hub, it had received interest from some fifty manufacturers, some of whom have expertise in vaccine manufacturing.[48] Meanwhile, on September 14 2021, the WHO announced it would begin efforts to replicate Moderna's mRNA vaccine in a manufacturing facility located in South Africa in collaboration with two South African companies. The WHO said it had chosen Moderna on account of the large volume of publicly available information about its vaccine and Moderna's recent statements saying it would not enforce its patents, demonstrating the link between monopolization of vaccine technology and the reduced supply of the vaccine.[49] Further, South Africa emerged as the location of choice after due diligence revealed there was no patent application for an mRNA vaccine in the country.[50] Nevertheless, further illustrating the supply constraints posed by intellectual property monopolies, this effort is expected to take considerable time because Moderna has not actually made publicly available its vaccine recipe.[51]

[46] *The Fight to Manufacture COVID Vaccines in Lower-Income Countries*, *Nature* (15 September 2021), see <https://www.nature.com/articles/d41586-021-02383-z>.

[47] *Establishment of a COVID-19 mRNA Vaccine Technology Transfer Hub to Scale up Global Manufacturing*, *World Health Organization* (16 April 2021), see <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing>.

[48] *Factor Owners Around the World Stand Ready to Manufacture COVID-19 Vaccines*, *The Intercept* (29 April 2021), see <https://theintercept.com/2021/04/29/covid-vaccine-factory-production-ip/>

[49] *Exclusive WHO-backed Vaccine Hub to Copy Moderna COVID-19 Shot*, *Reuters* (15 September 2021), see <https://www.reuters.com/world/africa/exclusive-who-backed-vaccine-hub-africa-copy-moderna-covid-19-shot-2021-09-14/>; *Africa Wants to Produce a Coronavirus Vaccine – and Big Pharma's not Happy*, *Politico* (July 26, 2021), see <https://www.politico.eu/article/as-africa-tries-to-tap-promise-of-mrna-vaccines-coronavirus-covid19-pharma-pushes-back/>.

[50] *Africa Wants to Produce a Coronavirus Vaccine – and Big Pharma's not Happy*, *Politico* (July 26, 2021), see <https://www.politico.eu/article/as-africa-tries-to-tap-promise-of-mrna-vaccines-coronavirus-covid19-pharma-pushes-back/>.

[51] *Exclusive WHO-backed Vaccine Hub to Copy Moderna COVID-19 Shot*, *Reuters* (15 September 2021), see <https://www.reuters.com/world/africa/exclusive-who-backed-vaccine-hub-africa-copy-moderna-covid-19-shot-2021-09-14/>.

2. Competition from generic manufacturers entering the market for manufacturing COVID-19 medical technologies will stimulate the supply of required raw materials and components.

Global North-based pharmaceutical intellectual property monopoly holders often frame their own raw-materials requirements as genuine global needs deserving of government aid/funding, while delegating potential shortage of vaccine components and raw materials to the realm of the “free-market,” to be managed by forces of supply and demand. Accordingly, they have argued that potential generic manufacturers entering the market for production of the COVID-19 vaccine will put undue pressure on the already limited global supply of hard-to-manufacture vaccine raw materials/components and cause global supply chain disruptions.[52]

U.S. pharmaceutical manufacturers, such as Pfizer, have substantially relied on the US government to assist them in meeting their raw material/component requirements. Reports from April 2021 point to two kinds of raw material shortages: 1) of sterile, single-use plastic bags used for insides of the metal reactors used in making mRNA (the suppliers of these plastic liners ramped-up production, so this shortage is not expected to have long-term impacts on supply); and 2) of difficult-to-manufacture cationic lipids – nano fat particles used to carry the mRNA into the cell, manufactured by a small number of companies.[53]

At the same time, pharmaceutical corporations like Pfizer had anticipated shortages of cationic lipids as early as December 2020 and increased production capacity such that by July 2021, just one of Pfizer’s facilities in Michigan was manufacturing lipids sufficient for millions of doses of its vaccine each week.[54] Moreover, since May 2020, the U.S. has through Operation Warp Speed and the Defense Production Act funded the U.S. Biomedical Advanced Research and Development Authority (BARDA) to help guarantee requisite supply of cationic lipids for pharmaceutical manufacturers using funding provided by the U.S.

[52] Drug Companies Defend Vaccine Monopolies in the Face of Global Outcry, *The Washington Post* (20 March 2021), see <https://www.washingtonpost.com/business/2021/03/20/covid-vaccine-global-shortages/>.

[53] The World is Hungry for mRNA Vaccines Like Pfizer’s. But We Are Short of Vital Components, *The Conversation* (27 April 2021), see <https://theconversation.com/the-world-is-hungry-for-mrna-covid-vaccines-like-pfizers-but-were-short-of-vital-components-159143>.

[54] Shot of a Lifetime: How Pfizer Developed its Own Raw Material to Ensure a Steady Supply for the COVID-19 Vaccine, Pfizer (Undated), see https://www.pfizer.com/news/hot-topics/shot_of_a_lifetime_how_pfizer_developed_its_own_raw_materials_to_ensure_a_steady_supply_for_the_covid_19_vaccine.

U.S. Congress under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (CARES Act), with the goal of increasing US-based manufacturing capacity of vaccine raw materials and components.[55]

Thus, recent examples show that input supply shortages have been dealt with by a mixture of government support and increased production. The U.S. government has assisted corporations in meeting anticipated raw materials needs, and, accordingly, such government support could also be provided to generic manufacturers entering the market. Finally, competition from generic manufacturers would increase incentives to supply raw materials, allowing for heightened access and lower costs.

3. Intellectual property monopolies stifle supply of lifesaving COVID-19 healthcare technologies.

On the one hand, the Global North-based pharmaceuticals industry has claimed that proprietary control over COVID-19 medical technologies is an essential part of their innovation model and that development of generic versions of the vaccine will ultimately impede future medical technological progress.[56] On the other, they argue that the Global South does not have the manufacturing capacity or technical expertise to manufacture the vaccine in numbers sufficient to substantially increase global supply. These arguments are plainly contradictory because long-term impact of generic manufacturing on the future of medical innovation in the bio-pharma sector would likely not occur without substantial success of generic manufacturing in increasing vaccine supply in the first place.

Second, Big Pharma's arguments hide the history of Global North corporations' use of intellectual property monopolies to impede wider access to medical technologies, even during situations of emergency.[57] Furthermore, research suggests intellectual property monopolies may encourage pharmaceutical

[55] *Pharmaceutical Manufacturing in America: BARDS's Commitment to Expanding Pharmaceutical Manufacturing the United States*, U.S. Department of Health & Human Services (2021), see <https://www.medicalcountermeasures.gov/barda/influenza-and-emerging-infectious-diseases/coronavirus/pharmaceutical-manufacturing-in-america/>.

[56] *10 Arguments Against a Waiver of Intellectual Property Rights*, Oxford University Business Law Blog (29 June 2021), see <https://www.law.ox.ac.uk/business-law-blog/blog/2021/06/10-arguments-against-waiver-intellectual-property-rights>; Pg. 3, *COVID-19 and the Role of Intellectual Property: Position Paper of the Max Planck Institute for Innovation and Competition* of 7 May 2021. Max Planck Institute for Innovation and Research (7 May 2021), see https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3841549.

companies to hide harmful impacts of clinical trials and falsify data on the efficacy of their formulations.[58]

Additionally, recent studies show that the much-touted linkage between intellectual property law systems and increased innovation is questionable, in part because of substantial incentives for innovation provided by public funding of certain types of research in the Global North.[59] Research indicates that private corporations were primary recipients of public funding of COVID-19 vaccine research and development funding. Further, Global North states and institutions were the largest providers of funding to private corporations. Finally, with the exception of China, India, Nigeria and Indonesia, Global North corporations were the primary recipients of public and institutional funding directed towards COVID-19 vaccine development.[60]

The top-five privately owned vaccine manufacturers in the Global North have each received between \$957 million and \$2.1 billion in public funding connected to the development, production, scaling and clinical trials of their COVID-19 vaccines. [61] For example, the U.S. government invested \$11 billion in late stage vaccine development and increased manufacturing capacity of COVID-19 vaccines through Operation Warp Speed and BARDA.[62] The U.S. government also entered into pre-purchase agreements worth millions of dollars with Moderna, Pfizer, AstraZeneca, J&J and Novovax.[63] Specifically, as of February 2021, Moderna received \$957 million in government and non-profit funding for its vaccine, including from the U.S. government; Pfizer/BioNTech received \$445 million from the German government; Astrazeneca/Oxford received \$1.7 billion in government and non-profit funding including from the United Kingdom government; J&J received \$1.5 billion from the U.S. government for the development of its vaccine.[64] The U.S. government also made substantial investments in therapeutics, including in the prominent mono-clonal antibody

[57]Global North-based pharmaceutical corporations used intellectual property rules to control the amount as well as price of medical technologies, such as during the HIV/AIDS epidemic, which was controlled only by overcoming intellectual property monopolies and producing generic anti-retroviral medications at prices affordable in Global South countries through the issuance of compulsory licenses. Pg. 4, *Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies*, MSF Briefing Document, Médecins Sans Frontières (May 2021), see https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSFAccess_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf.

[58]Patents and the Pandemic: Can We Learn Anything? Center for Economic and Policy Research (12 April 2021), see <https://cepr.net/patents-and-the-pandemic-can-we-learn-anything/>.

[59] Baker, Dean et. al., Pg. 70, *Innovation, Intellectual Property and Development: A Better Set of Approaches for the 21st Century*, AccessIBSA: Innovation & Access to Medicines in India, Brazil & South Africa (July 2017), see <https://www8.gsb.columbia.edu/faculty/jstiglitz/sites/jstiglitz/files/IP%20for%2021st%20Century%20-%20EN.pdf>.

[60] COVID-19 Vaccine R&D Investments, Global Health Centre (Last Updated 8 July 2021), see <https://www.knowledgeportal.org/covid19-r-d-funding>.

[61] Challenges in Ensuring Global Access to COVID-19 Vaccines: Production, Affordability, Allocation, and Deployment, *The Lancet* (February 12 2021), see [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00306-8/fulltext/](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00306-8/fulltext/),

therapies brought to the market by Regeneron and Lilly.[65]

All this is in addition to the investments made by the U.S. government in the funding of underlying research that led to the making of the current set of vaccines and therapeutics brought to the market by Global North-based corporations. For instance, in 2016, Moderna received \$125 million from BARDA for development of a Zika vaccine (Moderna admits it uses the same underlying mRNA technology in both its Zika and COVID-19 vaccines).[66]

Beyond public funding, pharmaceutical manufacturers' intellectual property monopolies limit supply and control prices in ways that drive revenues and profits. For instance, the Swiss pharmaceutical manufacturer Roche is the world's sole producer of a therapeutic Tocilizumab, recommended by the WHO for the treatment of severe COVID-19. However, accessibility is hampered due to Roche's astronomically high prices enabled by its secondary patents on the drug, with prices per dose ranging from \$410 in Australia, \$646 in India and \$3625 in the U.S., while cost of manufacture is estimated to be below \$40 per dose.[67]

Moreover, the harmful impacts of the current international intellectual property system are amplified in the Global South due to the lack of public investment in critical research and healthcare, even as Global South populations face severe crises, including in healthcare, climate change and related to the harmful outcomes of the global political economy.[68] In fact, research suggests the pharmaceutical industry has a history of under-investing in the research and development of safe, effective and affordable treatments for "neglected diseases" such as malaria and tuberculosis which cause high mortality in poor people in the Global South because such investment is not considered profitable.[69]

[62] Funding of Pharmaceutical Innovation During and After COVID-19 Pandemic, JAMA Network (14 January 2021), see <https://jamanetwork.com/journals/jama/fullarticle/2775400>.

[63] Funding of Pharmaceutical Innovation During and After COVID-19 Pandemic, JAMA Network (14 January 2021), see <https://jamanetwork.com/journals/jama/fullarticle/2775400>.

[64] Figures include pre-purchase agreements between governments and manufacturers where substantial portions of the funding went to late-stage development or scaling of production before completion of clinical trials. Challenges in Ensuring Global Access to COVID-19 Vaccines: Production, Affordability, Allocation, and Deployment, *The Lancet* (February 12 2021), see [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00306-8/fulltext/](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00306-8/fulltext/).

[65] Funding of Pharmaceutical Innovation During and After COVID-19 Pandemic, JAMA Network (14 January 2021), see <https://jamanetwork.com/journals/jama/fullarticle/2775400>.

[66] BARDA-Rapidly Advancing a Zika mRNA Vaccine, Moderna (Undated), <https://www.modernatx.com/ecosystem/strategic-collaborators/mrna-strategic-collaborators-government-organizations>; CEO Stéphane Bancel Presents at Goldman Sachs' 42nd Annual Healthcare Conference Transcript, Seeking Alpha (Jun. 9, 2021), <https://tinyurl.com/52r3t7s4> ("What's important to note here, and I'll remind everyone, because I know that we did probably mention this earlier, but the technologies, the mRNA technologies and the lipid nanoparticle technologies that are used in all of those vaccines that I just mentioned, are exactly the same as that that's being used in our mRNA-1273 COVID-19 vaccine." - Lavina Talukdar, Moderna Senior VP).

On the whole, it is clear that a “one size fits all” approach as it relates to intellectual property is not conducive to global public health.[70] The human rights obligations of states – including extraterritorial obligations – to fulfil the rights of all persons to the highest attainable standard of healthcare, to a share in scientific progress and advancement based on the use of maximum available resources, requires that they eliminate intellectual property monopolies with respect to the critical healthcare needs of Global South countries, including in countries where there exists production capacity for manufacturing COVID-19 medical technologies.[71]

[67] Tocilizumab, Second Drug Ever Recommended by the WHO for COVID-19, Will Remain Unaffordable and Inaccessible for Most of the World, Médecins Sans Frontières (6 July 2021), see <https://msfaccess.org/tocilizumab-second-drug-ever-recommended-who-covid-19-will-remain-unaffordable-and-inaccessible>.

[68] Baker, Dean et. al., Pg. 28, *Innovation, Intellectual Property and Development: A Better Set of Approaches for the 21st Century*, Access/BSA: Innovation & Access to Medicines in India, Brazil & South Africa (July 2017), see <https://www8.gsb.columbia.edu/faculty/jstiglitz/sites/jstiglitz/files/IP%20for%2021st%20Century%20-%20EN.pdf>.

[69] Trouiller P et. al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, *Lancet* (22 June 2002), see <https://pubmed.ncbi.nlm.nih.gov/12090998/>.

[70] Baker, Dean et. al., Pg. 70, *Innovation, Intellectual Property and Development: A Better Set of Approaches for the 21st Century*, Access/BSA: Innovation & Access to Medicines in India, Brazil & South Africa (July 2017), see <https://www8.gsb.columbia.edu/faculty/jstiglitz/sites/jstiglitz/files/IP%20for%2021st%20Century%20-%20EN.pdf>.

[71] *Supporting the TRIPS COVID-19 Waiver is an Essential Step to Support International Human Rights*, Open Global Rights (last accessed November 30, 2021), <https://www.openglobalrights.org/supporting-the-trips-covid-waiver-is-essential-to-support-international-human-rights/?lang=English>.

4. The current system of voluntary licensing of intellectual property monopolized COVID-19 medical technologies, also referred to as the “Third Way,” is inadequate to meet global needs.

Pharmaceutical companies claim that the voluntary licensing agreements containing non-disclosure terms are necessary for the protected transfer of know-how beyond what is covered by patents and other forms of intellectual property, [72] and they further argue that current voluntary licensing of intellectual property-protected technology is sufficient to meet global needs.[73] This claim has also found the support of WTO’s most recent Director-General, the economist Ngozi Okonjo-Iweala, countries of the European Union and the Gates Foundation, and is now labelled the “Third Way”.[74]

Voluntary licensing/Third Way arguments are unconvincing for two reasons. First, pharmaceutical manufacturers’ claim of the intellectual property monopolies being necessary to technology transfer has little substantiation in empirical data. Cross-country data suggests that factors such as market size, infrastructure and better business regulation are much more important in regulating flows of investment and information to generic manufacturers than licensing agreements.[75] Second, pharmaceutical companies can enter into voluntary licensing agreements while still restricting access to information and technology with a potential competitor with whom they are compelled to share certain know-how to meet demand for their product. The Director-General of the WHO, Tedros Adhanom Ghebreyesus, stated that voluntary licensing agreements tend to be “nontransparent, compromising equitable access.”[76] Voluntary licensing agreements also enable Global North-based pharmaceutical intellectual property holders to control the amount, price and location of manufacture.[77]

[72] Voluntary licenses are agreements between the holder of intellectual property and another manufacturer to allow use of a product protected as intellectual property. 10 Arguments Against a Waiver of Intellectual Property Rights, Oxford University Business Law Blog (29 June 2021), see <https://www.law.ox.ac.uk/business-law-blog/blog/2021/06/10-arguments-against-waiver-intellectual-property-rights>; Pg. 3, COVID-19 and the Role of Intellectual Property: Position Paper of the Max Planck Institute for Innovation and Competition of 7 May 2021. Max Planck Institute for Innovation and Research (7 May 2021), see https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3841549.

[73] Drug Companies Defend Vaccine Monopolies in the Face of Global Outcry, The Washington Post (20 March 2021), see <https://www.washingtonpost.com/business/2021/03/20/covid-vaccine-global-shortages/>.

[74] Pg. 2, Third-Way Proposals from Big Pharma and the WTO are the Same-Old Way – Commercial Control of Supply, Price, and Distribution, The People’s Vaccine Alliance (April 2021), see <http://infojustice.org/wp-content/uploads/2021/05/Baker-April-2021.pdf>.

[75] Baker, Dean et. al., Pg. 30, Innovation, Intellectual Property and Development: A Better Set of Approaches for the 21st Century, AccessIBSA: Innovation & Access to Medicines in India, Brazil & South Africa (July 2017), see <https://www8.gsb.columbia.edu/faculty/jstiglitz/sites/jstiglitz/files/IP%20for%2021st%20Century%20-%20EN.pdf>.

[76] I Run the W.H.O. and I Know That Rich Countries Must Make a Choice, The New York Times (April 22, 2021) <https://www.nytimes.com/2021/04/22/opinion/who-covid-vaccines.html>.

[77] Pg. 2, Waiver of the WTO’s Intellectual Property Rules (TRIPS): An Indispensable Tool to Fight the COVID-19 Pandemic, Public Citizen (5 April 2021), <https://www.citizen.org/article/waiver-of-the-wtos-intellectual-property-rules-existing-trips-flexibilities-unworkable-for-scale-up-of-covid-19-medicines-production/>.

A crucial factor in determining the adequacy of voluntary licensing as a method to control the current pandemic is assessing whether pharmaceutical manufacturers have in fact entered into voluntary licensing agreements with Global South manufacturers in sufficient numbers to meet local demand for COVID-19 medical technologies. The answer to this question is no, they have not. Far from issuing licenses to as many manufacturers as possible, as of April 2021, AstraZeneca's licensing deal with one vaccine manufacturer in India, the Serum Institute, was providing vaccines for 92 of the poorest countries in the world.[78] An illustration of the limitations of the voluntary licensing system are the failed efforts of Canadian pharmaceutical manufacturer Biolyse Pharma to obtain a voluntary license to produce a COVID-19 vaccine. In March 2021, Biolyse Pharma requested a voluntary license from J&J to manufacture its COVID-19 vaccine in Canada for export to Bolivia to meet the urgent needs for the vaccine there under TRIPS rules which authorize exports to WTO members under the provisions of Article 31bis of the TRIPS Agreement.[79] J&J rejected its request for a license and refused to negotiate, despite the Biolyse Pharma's claims of having sufficient manufacturing capacity.[80] Even where voluntary licenses are entered into, such as in J&J's license with the Indian pharmaceutical manufacturer Biological E, decisions about where to export and price are "under the purview of J&J completely.[81]"

Further, the reluctance of Big Pharma to share technology is manifest in limited engagement with the multiple information and technology sharing platforms that have been set up in hopes for voluntary technology sharing. For instance, the WHO launched the COVID-19 Technology Access Pool (C-TAP) program in May 2020 to facilitate "timely, equitable and affordable" to COVID-19 medical products via sharing of "knowledge, intellectual property and data." [82] The only example of a fully published voluntary license between a Global North pharmaceutical corporation with a C-TAP affiliate is Merck's voluntary licensing agreement with the UN-backed Medicines Patent Pool (MPP) granting the MPP

[78] *The World's Poorest Countries at India's Mercy for Vaccines. It's Unsustainable*, *The Guardian* (2 April 2021), see

<https://www.theguardian.com/commentisfree/2021/apr/02/india-in-charge-of-developing-world-covid-vaccine-supply-unsustainable>.

[79] Pg. 10, *Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case*, *The South Centre* (September, 2021), see https://www.southcentre.int/wp-content/uploads/2021/09/RP136_Canadas-Political-Choices-Restrain-Vaccine-Equity-The-Bolivia-Biolyse-Case_EN-1.pdf.

[80] *The Canadian government, for its part, did not take the necessary steps to enable the compulsory licensing process*. Pg. 10-11, *Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case*, *The South Centre* (September, 2021), see https://www.southcentre.int/wp-content/uploads/2021/09/RP136_Canadas-Political-Choices-Restrain-Vaccine-Equity-The-Bolivia-Biolyse-Case_EN-1.pdf.

[81] *The Fight to Manufacture COVID Vaccines in Lower-Income Countries*, *Nature* (15 September 2021), see <https://www.nature.com/articles/d41586-021-02383-z>.

[82] *WHO COVID-19 Technology Access Pool*, *World Health Organization* (Last Accessed 29 October 2021), see <https://www.who.int/initiatives/covid-19-technology-access-pool/take-action-now>.

permission to sub-license the experimental antiviral molnupiravir to manufactures in low and middle-income countries. However, the license is restrictive as it excludes nearly half the world's population and important countries with national manufacturing capacity such as Brazil and China.[83] Recently, Pfizer too announced a voluntary license with MPP for its experimental anti-viral ritonavir (Paxlovid). Again, this license excludes Global South countries such as Brazil, Argentina, China, Malaysia and Thailand from its agreement with MPP.[84] Additionally, Pfizer did not disclose its prices for this experimental treatment.[85]

ACT Accelerator is another initiative, supported by the WHO, Gavi, the World Bank and a number of other public and private organizations, offering a potential alternative to C-TAP but with a commitment to the protection of intellectual property monopolies.[86] Although there exist reports of companies supporting ACT Accelerator, an independent review of ACT Accelerator recommended the setting up of a data-sharing framework, suggesting inadequacies in the data sharing has taken place so far.[87] Finally, no Global North pharmaceutical corporations have engaged with the WHO's technology transfer hub in South Africa, which was set up with the aim of reproducing Moderna's mRNA vaccine technology.[88]

Furthermore, licensing (rather than direct manufacturing or sharing) can delay greater supply. Medical experts say that bridge trials – clinical trials that licensees of medical technology are often required to run – increase manufacturing times dramatically, even though technically there are no intellectual property barriers. In contrast to licensing, contract manufacturing of vaccines enables rapid production by eliminating the need for repeated clinical trials.[89] For instance, more than 80 percent of Moderna's vaccine drug substance is made by another company.[90] Similarly, Moderna also contracts with other manufacturers for vialing, packaging

[83] License Between Merck and Medicines Patent Pool for Global Production of Promising New COVID-19 Drug Molnupiravir Disappoints in its Limitations, *Médecins Sans Frontières* (27 October 2021), see <https://msfaccess.org/license-between-merck-and-medicines-patent-pool-global-production-promising-new-covid-19-drug>.

[84] MSF Response to License Between Pfizer and Medicines Patent Pool for new COVID-19 treatment Paxlovid, *Médecins Sans Frontières* (16 November 2021), see <https://msfaccess.org/msf-response-license-between-pfizer-and-medicines-patent-pool-new-covid-19-treatment-paxlovid>.

[85] MSF Response to License Between Pfizer and Medicines Patent Pool for new COVID-19 treatment Paxlovid, *Médecins Sans Frontières* (16 November 2021), see <https://msfaccess.org/msf-response-license-between-pfizer-and-medicines-patent-pool-new-covid-19-treatment-paxlovid>.

[86] How Bill Gates Impeded Global Access to Covid Vaccines, *The New Republic* (12 April 2021), see <https://newrepublic.com/article/162000/bill-gates-impeded-global-access-covid-vaccines>.

[87] Pg. 72, ACT-Accelerator Strategic Review: An Independent Report Prepared by Dahlberg, World Health Organization (8 October 2021), see <https://www.who.int/publications/m/item/act-now-act-together-2020-2021-impact-report>.

[88] The Fight to Manufacture COVID Vaccines in Lower-Income Countries, *Nature* (15 September 2021), see <https://www.nature.com/articles/d41586-021-02383-z>.

[89] Pg. 20, Hit Hard, Hit Fast Globally, A Model for Global Vaccine Access, *PrEP4All* (19 March 2021), see <https://www.prep4all.org/news/hit-hard-hit-fast-hit-globally>.

[90] Pg. 20, Hit Hard, Hit Fast Globally, A Model for Global Vaccine Access, *PrEP4All* (19 March 2021), see <https://www.prep4all.org/news/hit-hard-hit-fast-hit-globally>.

and freezing for distribution.[91] Public health experts have suggested public ownership of vaccine manufacturing facilities utilizing efficiencies of the contract manufacturing framework as one of the strategies for achieving epidemic control. [92]

5. Compulsory licensing provisions in the TRIPS Agreement place undue procedural burdens on Global South countries and do not cover the full scope of the medical technologies required for control of the COVID-19 pandemic globally.

Pharmaceutical corporations and the European Union argue that current flexibilities in the TRIPS Agreement, most prominently compulsory licensing, allow governments to meet global public health needs adequately in the ongoing COVID-19 pandemic.[93] Under the terms of the TRIPS Agreement, states have the authority to use compulsory licenses to produce generic versions of patented medical products for a number of public health related reasons, including when there are public health emergencies, to remedy monopolistic policies, to address failures of patent-rights holders to license to qualified producer or on account of the lack of accessibility of a protected medical product.[94] Although compulsory licenses have been used successfully in the past for medical products, they are procedurally difficult to obtain and may have negative consequences for license issuing countries.

Compulsory licensing provisions of the TRIPS Agreement are also limited in their scope to increase global supply of COVID-19 medical technologies. First, the TRIPS Agreement covers compulsory licenses only for patented medical products and not for other intellectual property protections, such as trade secret-protected knowledge (e.g. data related to manufacturing, quality control, and biological

[91] Pg. 20, Hit Hard, Hit Fast Globally, A Model for Global Vaccine Access, PrEP4All (19 March 2021), see <https://www.prep4all.org/news/hit-hard-hit-fast-hit-globally>.

[92] Pg. 20, Hit Hard, Hit Fast Globally, A Model for Global Vaccine Access, PrEP4All (19 March 2021), see <https://www.prep4all.org/news/hit-hard-hit-fast-hit-globally>.

[93] The European Union's Position on Compulsory Licensing and the TRIPS Waiver in the COVID-19 Pandemic, Médecins Sans Frontières (May 2021), see <https://msfaccess.org/analysis-eu-position-compulsory-licensing-and-trips-waiver-covid-19-pandemic>.

[94] A compulsory license is a government permit allowing a manufacturer to produce a generic version of a medical product otherwise protected by intellectual property rules without an agreement from the holder of intellectual property. Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies, MSF Briefing Document, Médecins Sans Frontières (May 2021), see https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf.

resources) or copyright protected information (e.g. manuals, industrial blue prints and software for equipment/medical devices).[95] Under the existing terms of the TRIPS Agreement, the TRIPS Council decides on use of compulsory licenses on a country-by-country basis and on individual merits, meaning it takes a case-by-case approach for each medical product and compulsory license application.

Proponents of the TRIPS waiver have pointed out how hard-to-navigate intellectual property monopolies across different jurisdictions impede access to COVID-19 healthcare technologies for large portions of the world. For example, Merck has filed for patents for the experimental anti-viral COVID-19 therapy molnupiravir in nearly fifty jurisdictions making challenging each patent application extremely burdensome.[96]

Further, TRIPS terms require governments first engage in voluntary licensing efforts on reasonable commercial terms with the corporation and issue a compulsory license (with royalties) only if such negotiations fail. [97] There must also be grounds for review of the compulsory license and the royalty rate. Such processes are time consuming and can result in unfair diplomatic pressure on countries issuing the licenses. For instance, in past years Global North-based pharmaceutical manufacturers have sued governments and leveraged international corporate forums to threaten Global South countries, such as Brazil, Chile, India, South Africa and Thailand with sanctions over the issuing compulsory licenses.[98] Besides, under the terms of the TRIPS Agreement, the use of compulsory licensing must be for domestic supply alone and exports are allowed only in limited situations where the license is in remedy of competition violations. [99] For instance, after the pharmaceutical manufacturer Gilead sued the Russian government in the Supreme Court of Russia challenging Russia's grant of compulsory license to produce generic versions of the therapeutic remdesivir used in the treatment of COVID-19, Russia was unable to export its generic versions to India on account of export limitations, even as India faced a massive wave of

[95] *Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies*, MSF Briefing Document, Médecins Sans Frontières (May 2021), see https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSFAAC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf.

[96] *Examples of IP Issues and Barriers in COVID-19 Pandemic*, Communication from South Africa, World Trade Organization (23 November 2020), see <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W670.pdf&Open=True>.

[97] *Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies*, MSF Briefing Document, Médecins Sans Frontières (May 2021), see https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSFAAC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf.

[98] *Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies*, MSF Briefing Document, Médecins Sans Frontières (May 2021), see https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSFAAC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf.

[99] *Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies*, MSF Briefing Document, Médecins Sans Frontières (May 2021), see https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSFAAC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf.

COVID-19 cases.[100] Finally, the implementation of compulsory licenses is limited by national or multi-national level agreements such as by European Union legislation on medicinal products, which impedes the effective use of compulsory licenses by prohibiting registration of generic equivalents for a period of time determined by the medicine regulator.[101] Another illustration of the limitations of compulsory licensing is Canada-based Biolyse Pharma's (also referenced earlier) attempts to acquire a compulsory license from the Canadian government for the manufacturer of J&J's COVID-19 vaccine in March 2021 under Canada's Access to Medicines Regime (CAMR) after its efforts to secure a voluntary license from J&J failed. The consequent bureaucratic process has since unveiled layers of red tape as Canada's fears of alienating a powerful pharmaceutical like J&J on whom it is dependent for vaccines impedes vaccine access for Bolivia.[102] Consequently, Biolyse Pharma has been unable to get the CAMR process started at all.[103]

On the whole, given the scale of the pandemic across Global South countries and the need for medical protection, a TRIPS waiver, and accompanying technology transfers, involving the suspension of intellectual property on essential COVID-19 technologies, materials and know-how required to control the pandemic is essential for giving the majority of the world access to COVID-19 medical technologies.

[100] *Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies*, MSF Briefing Document, Médecins Sans Frontières (May 2021), see https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf. [101] Pg. 3, *The European Union's Position on Compulsory Licensing and the TRIPS Waiver in the COVID-19 Pandemic*, Médecins Sans Frontières (May 2021), see <https://msfaccess.org/analysis-eu-position-compulsory-licensing-and-trips-waiver-covid-19-pandemic>.

[102] Pg. 14, *Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case*, The South Centre (September, 2021), see https://www.southcentre.int/wp-content/uploads/2021/09/RP136_Canadas-Political-Choices-Restrain-Vaccine-Equity-The-Bolivia-Biolyse-Case_EN-1.pdf.

[103] Pg. 14, *Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case*, The South Centre (September, 2021), see https://www.southcentre.int/wp-content/uploads/2021/09/RP136_Canadas-Political-Choices-Restrain-Vaccine-Equity-The-Bolivia-Biolyse-Case_EN-1.pdf.

6. Alternatives such as COVAX/donations are insufficient and do not support a human-rights based approach to making COVID-19 medical technologies accessible for Global South populations.

COVAX is an multistakeholder entity led by the Center for Epidemic Preparedness and Innovation (CEPI) and Gavi, with some ties to the United Nations system (to WHO and the United Nations Children’s Fund (UNICEF)).^[104] It was set up in April 2020 with the stated goal of making vaccines accessible to unprotected populations in the Global South with funding from Global North countries.^[105] COVAX says it does this by purchasing vaccines directly from Global North manufacturers in a manner as to allow smaller and low-income countries to purchase vaccines at the same prices as large, high-income countries. However, COVAX does not support a human-rights centered approach to vaccine access. COVAX’s core constituents are Global North entities like CEPI and Gavi (funded by private foundations, investors, states), instead of states with the clearest human rights obligations and corresponding accountability mechanisms at the international level.^[106] While COVAX’s stated partnership with the United Nations has helped it gain broad legitimacy, the role of the United Nations Organizations in the running of COVAX is limited. Healthcare experts are concerned that COVAX functions more like a merchant or an international financing institution than a healthcare institution, and its operation is pivoted around the conception of healthcare as a market good rather than a public utility.^[107]

Second, COVAX is not designed to make equitable and timely vaccine access a reality for Global South populations. Although most countries in the Global North and South have signed up for COVAX, the initiative has not yet met its own goal of vaccinating 20 percent of the world’s population in 2021 owing to shortages of

[104] COVAX: A Global Multistakeholder Group That Poses Political and Health Risks to Developing Countries and Multilateralism, *Transnational Institute* (1 April 2021), see <https://longreads.tni.org/covax>.

[105] What is This COVAX Program That the U.S. is Pouring Millions of Vaccines Into? *NPR* (May 19, 2021), see <https://www.npr.org/sections/goatsandsoda/2021/05/19/998228372/what-is-this-covax-program-that-the-u-s-is-pouring-millions-of-vaccines-into>.

[106] COVAX: A Global Multistakeholder Group That Poses Political and Health Risks to Developing Countries and Multilateralism, *Transnational Institute* (1 April 2021), see <https://longreads.tni.org/covax>.

[107] COVAX: A Global Multistakeholder Group That Poses Political and Health Risks to Developing Countries and Multilateralism, *Transnational Institute* (1 April 2021), see <https://longreads.tni.org/covax>.

supply of vaccines.[108] As of 21 October 2021, of the 1.8 billion COVID vaccine donation promised by high-income countries, only 261 million doses (14 percent) were delivered and of those promised by pharmaceutical companies to COVAX, only 12 percent were delivered. [109] Both J&J and Moderna are yet to deliver a single dose they promised to COVAX. [110] Further, under COVAX, no country will receive enough doses to vaccinate more than 20 percent of its population until all countries have been offered doses to vaccinate 20 percent of their populations, meaning that it could take years before populations in the Global South are protected if relying on COVAX.[111] Public health experts say there appears to be little medical rationale governing COVAX's goal of vaccinating 20 percent of the world's population. [112]

Lastly, despite COVAX's stated goals of making high-quality vaccines accessible to the Global South, it has mostly delivered less efficacious vaccines to them.[113] Beyond the systemic issues with COVAX and vaccine shortages that have crippled it, the initiative is limited in scope to the procurement of vaccines, while the healthcare rights of Global South populations impacted by COVID-19 must include access to therapeutics and other medical technologies used for the diagnosis, containment, treatment and prevention of COVID-19.

The human rights obligations of states – including extraterritorial obligations – to fulfil the rights of people to the highest attainable standard of healthcare, to share in global scientific progress and advancement based on the use of maximum available resources and international assistance/cooperation, require them to eliminate intellectual property monopolies with respect to the critical health care needs of Global South countries.[114]A comprehensive TRIPS waiver would provide a valuable first step in access for Global South populations to not only vaccines but also therapeutics, medicines and other medical technologies vital for the treatment, prevention and control of COVID-19 on a global level.

[108] Joint COVAX Statement on Supply Forecast for 2021 and Early 2022, WHO (8 September 2021),

<https://www.who.int/news/item/08-09-2021-joint-covax-statement-on-supply-forecast-for-2021-and-early-2022>.

[109] Pg. 3, A Dose of Reality, Dose of Reality: How Rich Countries and Pharmaceutical Corporations are Breaking their Vaccine Promises, *The People's Vaccine* (21 October 2021), see <https://peoplesvaccine.org/g20/>.

[110] Pg. 3, A Dose of Reality, Dose of Reality: How Rich Countries and Pharmaceutical Corporations are Breaking their Vaccine Promises, *The People's Vaccine* (21 October 2021), see <https://peoplesvaccine.org/g20/>.

[111] COVAX Explained, Gavi: The Vaccine Alliance, <https://www.gavi.org/vaccineswork/covax-explained>.

[112] COVAX: A Global Multistakeholder Group That Poses Political and Health Risks to Developing Countries and Multilateralism, *Transnational Institute* (1 April 2021), see <https://longreads.tni.org/covax>.

[113] How to Vaccinate the World, Yale GHJP and LPE Vaccine Access Webinar, *Health Justice Initiative* (13 October 2021), see <https://healthjusticeinitiative.org.za/2021/10/13/yale-ghjp-and-lpe-vaccine-access-webinar-how-to-vaccinate-the-world/>.