

Promoting Access to Medical Technologies and Innovation

SECOND EDITION

Intersections between public health, intellectual property and trade

Updated extract: integrated health,
trade and IP approach to respond
to the COVID-19 pandemic,
30 August 2021



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Introduction

The second edition of the joint WHO, WIPO and WTO publication “Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade” (the Trilateral Study),* published in 2020, included a special insert mapping the challenges posed by the COVID-19 pandemic in relation to the integrated health, trade and IP policy framework set out in the study. The Trilateral Study and the special insert were designed to serve as background reference for policy-makers in the widest sense – lawmakers, government officials, delegates to international organizations, non-

governmental organizations (NGOs) and researchers who seek a comprehensive presentation of the full range of issues, including institutions and legal concepts with which they may be unfamiliar. It is also designed to serve as a factual resource for the three organizations’ technical cooperation activities.

This update revises the information contained in that insert in the light of more recent developments as of 30 August 2021. Further updates will be made to reflect subsequent developments.

* Available at: <https://www.who.int/publications/i/item/9789240008267>; <https://www.wipo.int/publications/en/details.jsp?id=4511> and https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm.

A dramatic impact on health systems and responses at the global level

The coronavirus disease 2019 (COVID-19) pandemic constitutes an extraordinary global public health crisis. It has created a pressing need for intensified global cooperation. The pandemic has, from its outset, raised issues at the crossroads of public health, trade, intellectual property (IP) policy, and the framework for and management of innovation and access, including issues related to technology transfer.

The total number of excess deaths in 2020 worldwide may have amounted to at least 3 million, as compared to the reported 1.8 million excess deaths in 2020. There is probably a significant undercount of total deaths directly and indirectly attributed to COVID-19.¹ According to the WHO Coronavirus Dashboard,² globally, as of 27 August 2021, there had been 214,468,601 confirmed cases of COVID-19, including 4,470,969 deaths, reported to WHO. As of 25 August 2021, a total of 4,953,887,422 vaccine doses had been administered.

COVID-19 disproportionately impacts vulnerable populations. It has exposed persistent inequalities by income, age, race, sex and geographic location. Despite recent global health gains, across the world people continue to face complex interconnected threats to their health and well-being rooted in social, economic, political and environmental determinants of health.³

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) – the newly emergent coronavirus first recognized in December 2019 – causes COVID-19. According to evidence available as of 18 May 2021, most people with COVID-19 are asymptomatic or develop mild (40 per cent) or moderate (40 per cent) disease. Approximately 15 per cent develop severe disease that requires oxygen support and 5 per cent have critical disease.⁴ The WHO interim guidance document also reports that country data point to 14-19 per cent of SARS-CoV-2 infections requiring hospitalization while 3-5 per cent develop severe disease requiring admission to an intensive care unit (ICU) for complications.

Based on the information notified to the WHO under the International Health Regulations (IHR) 2005, the WHO Director-General on 30 January 2020 declared a public health emergency of international concern. The WHO subsequently issued temporary recommendations relating to trade, including recommendations pertaining to travel, cargo and goods. The WHO Director-General on 11 March 2020 characterized the COVID-19 outbreak as a pandemic.

United Nations General Assembly (UNGA) resolutions A/RES/74/270 “Global solidarity to fight the coronavirus disease 2019 (COVID-19)”⁵ and A/RES/74/274 “International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19”,⁶ as well as World Health Assembly resolutions WHA73.1 “COVID-19 response”⁷ and WHA73.8 “Strengthening preparedness for health emergencies: implementation of the International Health Regulations (IHR) (2005)”⁸ recognized the dramatic impact on health systems of the global outbreak, which has, in some cases, entirely overwhelmed existing capacity and, in others, placed systems under immense strain and underscored the need for cooperation and collaboration in the spirit of unity and solidarity.

UNGA resolutions A/74/L.92 “Comprehensive and coordinated response to the coronavirus disease (COVID-19) pandemic”,⁹ and A/74/L.57, “United response against global health threats: combating COVID-19”,¹⁰ further highlighted the need to step up WHO-led collaborative efforts for mitigating the repercussions of the global health emergency, including by creating partnerships and sharing requisite materials and data. Human Rights Council resolution A/HRC/46/L.25/Rev.1, “Ensuring equitable, affordable, timely and universal access for all countries to vaccines in response to the coronavirus disease (COVID-19) pandemic,” calls upon states and other relevant stakeholders to take appropriate measures to guarantee the fair, transparent, equitable, efficient, universal and timely access and distribution of safe, quality, efficacious, effective, accessible and affordable COVID-19 vaccines and to enable international cooperation, among other actions.¹¹

International Health Regulations and COVID-19

A review of the performance of the International Health Regulations (IHR) during the COVID-19 response sought an understanding of what did and did not function in its implementation and of any shortcomings.¹² In its report, the Review Committee provided 40 recommendations to improve the functioning of the IHR in 10 key areas:

- 1) Role and function of national IHR focal points;
- 2) Core capacity requirements for preparedness, surveillance and response;
- 3) Legal preparedness;
- 4) National notification and alert system;
- 5) Risk assessment and information-sharing;

- 6) COVID-19 Emergency Committee and the determination of a public health emergency of international concern;
- 7) Travel measures;
- 8) Digitalization and communication;
- 9) Collaboration, coordination and financing; and
- 10) Compliance and accountability.

Independent Panel for Pandemic Preparedness and Response

An Independent Panel for Pandemic Preparedness and Response was established by the WHO Director-General to provide an impartial, independent and comprehensive review of the international health response to COVID-19. The panel reviewed experiences gained and lessons learned. Among the recommendations of the panel in its 12 May 2021 report was the adoption of a Pandemic Framework Convention using the powers under the WHO Constitution.¹³ The findings of the report were presented to the 74th World Health Assembly during which a special session was held to consider developing a WHO convention, agreement or other international instrument on pandemic preparedness and response.¹⁴ The special session followed a 30 March 2021 call from the WHO Director-General, 25 heads of government and the President of the European Council upon the international community to work together towards a new international treaty for pandemic preparedness and response to build a more robust global health architecture that will protect future generations.¹⁵

Public health and social and economic measures

Governments around the globe have implemented restrictions to economic and social activities in an effort to slow the spread of the virus, including through policies of confinement, physical distancing and restrictions on travel. These restrictions have sought to reduce pressure on health systems and to allow sufficient time to improve health infrastructure and develop diagnostics, vaccines and treatments to effectively respond to the virus. The WHO publishes a regularly updated interim guidance document on “Considerations for implementing and adjusting public health and social measures in the context of COVID-19”, which provides guidance to help WHO member states assess the situation at national and sub-national levels, and provides key recommendations about the implementation of public health and social measures.¹⁶

Monitoring variants of concern

On 29 March 2021, the WHO held global consultations with a view to proposing an integrated approach to monitoring and assessing SARS-CoV-2 variants of concern and outlining a decision-making process to

inform policy recommendations, with a specific focus on the impact of COVID-19 vaccines.¹⁷ It is normal for viruses to mutate. However, the more a virus spreads, the more opportunities it has to change. The emergence of viral variants has triggered renewed calls for global collaboration to slow the spread of the virus universally, and necessitates continuing monitoring and adaptation of the collective response. Accordingly, the WHO, in collaboration with national authorities, institutions and researchers, routinely assesses whether variants of SARS-CoV-2 alter transmission or disease characteristics, or impact vaccines, therapeutics, diagnostics or the effectiveness of public health and social measures to control the spread of the disease.

The WHO publishes a COVID-19 “Weekly Epidemiological Update”¹⁸ that provides the most up-to-date information on the impact of COVID-19 virus variants on the effectiveness of the different vaccines. This is an area in which the evidence remains preliminary, although it is developing quickly. Measures to reduce transmission continue to work against new variants by reducing the amount of viral transmission and therefore also reducing opportunities for the virus to mutate. Such measures apply not only to threats posed by epidemics and pandemics, but also to the ongoing threat of antimicrobial resistance.

The importance of effective national infection prevention and control programmes is a shared priority of the international community for addressing public health threats of international concern. Scaling up vaccine manufacturing and rolling out vaccines as quickly and as widely as possible are also critical to protect people before they are exposed to the virus and from the risk of new variants.¹⁹ Inequitable access to vaccines and other health products and vaccine nationalism have contributed to the continued spread of the virus and the emergence of new variants, reducing the efficacy of current tools and threatening progress everywhere.²⁰

The WHO “Disease Outbreak News” provides up-to-date information on the impact of COVID-19 virus variants on the effectiveness of the different vaccines.²¹ The 6 July 2021 WHO COVID-19 “Weekly Epidemiological Update” summarized vaccine performance against variants of concern, including for Alpha, Beta, Gamma and Delta variants.²² While current research indicates that protection is retained against all outcomes for the Alpha variant, there may be reduced protection against symptomatic disease for Beta and Delta variants. Protection, however, appears to be retained against severe disease for Beta and Delta variants, although the available evidence remains limited. There is very limited evidence regarding overall vaccine efficacy against the Gamma variant.²³

Policy challenges posed by the pandemic

The COVID-19 pandemic has generated sudden, far-reaching impacts on health systems, with significant social and economic repercussions around the world. The International Monetary Fund (IMF) Chief warned that, while there has been strong economic growth in wealthy countries, developing countries are being held back by slow vaccination rates, and that this is a: “[...] danger for the coherence of growth and it is also a danger for global stability and security.”²⁴ World Bank data indicate that the pandemic has resulted in a steep increase in debt, especially in emerging markets and developing economies.²⁵ Statistical briefs published by the UN Committee for the Coordination of Statistical Activities analysing the social and economic impact of the pandemic suggest that 71 to 100 million people are being pushed into extreme poverty by the pandemic.²⁶

This extraordinary threat to people’s health and livelihoods has required urgent action to:

- monitor and contain the spread of the virus and new variants;
- understand relevant virology and epidemiology;
- mobilize and coordinate the requisite resources;
- deploy the necessary healthcare system infrastructure;
- ensure that healthcare products, technologies and protective equipment are available and can be accessed equitably in sufficient quantities worldwide;
- develop, test, manufacture and ensure equitable access to diagnostics, vaccines and therapeutics, medical devices and other relevant technologies;
- ensure the free flow of vaccines and inputs; and
- address the economic repercussions resulting from the pandemic, as well as the impacts on people’s health.

Meeting the demand for health technologies and medical services

The pandemic continues to trigger a massive global demand for vaccines, as well as for existing health technologies to respond to COVID-19, including diagnostics, medicines, ventilators and other medical devices, and consumables used in hospitals, such as personal protective equipment (PPE). This has put pressure on public procurement systems and led to shortages and other supply and access challenges for certain products in developed and developing countries.²⁷ WHO provides information about the global response, such as R&D landscapes, regulatory approval status, and the manufacturing and distribution of vaccines.²⁸

Government priorities have included ensuring sufficient access to vaccines and to intensive care equipment such as ventilators, ensuring sufficient PPE to minimize infection risks to front-line workers, and ensuring access to testing services and products. Governments in a number of countries have taken steps to enhance and adapt manufacturing capacity to meet a surge in demand for hospital equipment and PPE, including by redirecting production lines to manufacture essential products. For example, Bangladesh is producing a generic version of remdesivir, a pharmaceutical that is patented in a number of other countries, to treat COVID-19,²⁹ thus benefitting from the transition period under the WTO Agreement on Trade-Related Aspects of Intellectual Property

Rights (TRIPS Agreement), which currently exempts least-developed countries (LDCs) from implementing patent protection for pharmaceutical products and from protecting clinical trial data.³⁰

Eighteen generic manufacturers, in a joint statement, have announced a collaboration with the Medicines Patent Pool to boost capacity for developing countries and have pledged to deliver affordable COVID-19 treatments for low- and middle-income countries.³¹

Manufacturing capacity for vaccines has been a key part of the debate around global equitable access to COVID-19 health products. A number of governments have invested in ensuring that sufficient manufacturing capacity is available to produce the necessary volumes of vaccines for COVID-19. Publicly available data and information on global manufacturing capacity has been compiled by various organizations.³² To ensure adequate access to diagnostics, health systems have, among other things, set up contact-tracing systems and “drive-through” testing facilities, and have organized new laboratory networks to utilize capacity in smaller labs.

Facilitating the movement of health workers, for example through visas or work permits and recognition-of-qualifications programmes, has been considered

by certain governments as instrumental to keeping health systems operational.³³ Equally, the international movement of skilled personnel has been identified as a key contribution to the pressing need to expand the transfer and dissemination of critical vaccine technologies. While some states have considered the idea of implementing COVID-19 vaccine passports as a condition of travel, WHO does not promote the use of vaccine passports as a precondition for travel.³⁴ The Review Committee on the Functioning of the International Health Regulations (2005) During the COVID-19 Response recommends that a risk-based approach should be promoted in relation to travel measures. The focus should be on protecting health, sharing essential information and specimens, and accepting that travel and trade restrictions may be required. The effectiveness of travel measures depends on their timing. However, precautionary measures should still be proportional to the perceived threat, non-discriminatory, continuously reviewed in the light of new knowledge, and applied in accordance with the IHR.³⁵ Telemedicine may be used to overcome geographical limitations and physical distancing requirements.³⁶

Authorities in many jurisdictions have expedited the procurement of essential products via emergency procedures, such as shortening public procurement timelines and issuing direct contract awards. A number of countries have put in place transparency mechanisms with regard to emergency procurement, following best international practices in this regard. Some countries and regional groupings have used pooled procurement for select goods.³⁷ To safeguard essential supply chains during the COVID-19 pandemic, numerous competition authorities exceptionally allowed some level of cooperation between manufacturers, distributors and purchasers. Among others, the European Commission and competition agencies from Canada, China, Japan, the Russian Federation and the United Kingdom published COVID-19-related guidance on permissible collaboration.³⁸ Some competition authorities have eased the rules applicable to specific sectors by issuing “comfort letters”³⁹ or introducing sector exemptions which apply to entire industries.⁴⁰ The European Competition Network (ECN), has issued guidance⁴¹ on the application of competition policy in times of urgency and limited supply and clarified whether and when coordination between firms to respond to crisis needs can be permitted, at least temporarily.⁴²

At the same time, to ensure that companies are not taking advantage of the exceptional market situation, competition agencies have made it clear that they will be vigilant for cartels, i.e., where firms may collude to avoid “ruinous” competition or to take advantage of increased demand and emergency public purchasing, by engaging in bid-

rigging. For example, the United Kingdom competition authority has emphasized that it “will not tolerate unscrupulous businesses exploiting the crisis as a ‘cover’ for non-essential collusion”, and the US Department of Justice has reminded firms that they could be prosecuted for collusion, especially where it relates to the provision of public health products to government agencies.⁴³

Furthermore, to ensure that essential products remain available at competitive prices, a number of competition authorities across the globe have launched investigations relating to COVID-19 health products, including into price hikes for health products and diagnostic manufacturing information held as a trade secret.⁴⁴ For example, the Greek competition authority conducted an investigation into the market for healthcare materials, following numerous consumer complaints regarding price increases.⁴⁵ Based on econometric analysis of the collected data, the interim results indicated that the price increases were consistent with competitive behaviour.⁴⁶ In the Netherlands, an investigation was started into Roche’s dominant position regarding COVID-19 test equipment and materials. Roche committed to release all the relevant know-how and to scale up production to enhance testing capacities in the Netherlands. The competition authority indicated that it saw no reason for taking any further steps at that moment, but that it would remain vigilant to ensure that, even in these special circumstances, businesses compete fairly.⁴⁷ Supermarkets and enterprises were investigated over excessive or “unjust” prices for medical protective equipment, oxygen and sanitary supplies in a number of jurisdictions, including Argentina, China, Brazil, Fiji, Kenya and Nigeria.⁴⁸ In a number of cases, breaches of competition laws were found and remedial orders were issued.⁴⁹

Some authorities amended legal rules to tackle pricing abuses more effectively during the pandemic, or adjusted their economic analyses to take into account the temporary nature of the crisis. For example, South Africa amended its competition and consumer protection legislation to introduce anti-price-gouging provisions.⁵⁰ The Chinese competition authority issued warnings against price increases and guidelines for swift enforcement against increases in the prices of facemasks.⁵¹ The governments of Argentina⁵² and Morocco⁵³ issued decrees setting maximum pricing for surgical masks, hand sanitizers and other products. A number of competition authorities have also created a specific task force or have been involved in competition advocacy and active monitoring of price hikes. In the United Kingdom, the competition authority launched a task force to tackle the negative impact of the pandemic.⁵⁴ Turkey established a new Unfair Price Evaluations Board.⁵⁵

Preserving effective international trade

While low- and middle-income countries face particular challenges caused by the global scarcity of key health technologies, the vast majority of countries are net importers of all categories of health technologies, including those needed to address COVID-19.⁵⁶

While total world trade declined by 7.6 per cent in 2020 compared to 2019, imports and exports of medical goods increased by 16 per cent, reaching US\$ 2,343 billion in value.⁵⁷ Preserving the integrity of global trade is therefore critical to ensure equal access to needed health technologies and to support countries in recovering from the crisis and building health systems that foster greater resilience against future pandemics.⁵⁸

While recognizing that governments may take emergency measures to address public health challenges, including shortages of COVID-19 technologies, G20 Trade Ministers⁵⁹ have repeatedly called upon countries to ensure that any trade-restrictive measure taken to promote public health be “targeted, proportionate, transparent and temporary”, points echoed by leaders of the WHO, WTO and the World Customs Organization (WCO).⁶⁰ Ensuing declarations and statements by a wide range of WTO members have underscored the importance of a predictable, transparent, non-discriminatory and open global trading system for pandemic response and recovery. In particular, they have emphasized the importance of well-functioning supply chains and the need to facilitate cross-border flows of vital medical supplies and services.⁶¹ Countries and international organizations work closely together to facilitate the smooth cross-border flow of vital medical supplies and to avoid unnecessary disruptions to global trade and supply chains.

To support those efforts, a WTO Secretariat note explored the way in which trade policy can play a role in order to ensure the rapid roll-out of COVID-19 vaccines.⁶² This was followed in July 2021 by several practical tools:

- “An Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measures on Critical Products to

Combat COVID-19”,⁶³ facilitating access to granular information on inputs used in vaccine manufacturing, vaccine distribution and approval, therapeutics and pharmaceuticals, diagnostics and medical devices. As a living list, it is open to development through stakeholder input.

- “A Joint Indicative List of Critical COVID-19 Vaccine Inputs for Consultation”,⁶⁴ which compiles information on the critical inputs for the manufacture, distribution and administration of COVID-19 vaccines, and has been produced by several organizations and prepared in collaboration with key stakeholders. It is a living document open to development through stakeholder input.
- “Improving Trade Data for Products Essential to Fight COVID-19: A Possible Way forward”,⁶⁵ an information note on data problems and on how to monitor trade in products essential to combat the COVID-19 pandemic and future health crises.

In addition to the above practical tools, activities undertaken at the WTO in close coordination with partners have examined issues such as what the multilateral trading system can contribute to COVID-19 and vaccine equity, main trade-related challenges to vaccine supply chain and regulatory transparency and how international trade can be leveraged to expand COVID-19 vaccine manufacture to promote equitable access.⁶⁶

From the outset of the pandemic, governments have concomitantly implemented both trade-restrictive measures (e.g. restrictions on exports of key products) and trade-facilitating measures to reduce costs and delays (e.g. facilitation and simplification of customs procedures).⁶⁷ Some countries have reduced or eliminated tariffs on certain imported health technologies or deferred payment deadlines for the same.⁶⁸ Regulatory conformity checks have been streamlined through international cooperation and standards, as well as through mutual or unilateral recognition of third-country or WHO Emergency Use approvals.⁶⁹

Intellectual property aspects

The global IP system provides an incentive framework in which urgently needed innovation in relation to COVID-19 can be encouraged. It covers the stages from invention to supply of a product or service.⁷⁰ The impact of patents on access is complex and an area of particular focus. Other IP rights, including trade secrets, are also being discussed.

IP policy and the administration and enforcement of IP laws aim to balance and accommodate a range of interests in a way that promotes overall public welfare. A wide range of policy options and flexibilities are built into the international IP regime and can be used to promote access to health products and other public health objectives.⁷¹

Disclosure and patent information

The disclosure requirement is considered one of the important rationales of the patent system, as it enables dissemination of information and an increase in the public stocks of knowledge.⁷²

The World Intellectual Property Organization (WIPO) has established a COVID-19 search facility⁷³ within its global PATENTSCOPE database. The tool offers predefined search strings that support searches for COVID-19-related patent information. The European Patent Office (EPO)⁷⁴ and a number of national patent authorities have developed similar tools, as well as databases of COVID-19-related patents. For example, China launched a freely accessible database for COVID-19-related patents; the Republic of Korea has made available patent information on technology relating to the diagnosis and treatment of COVID-19, including patent analysis and trend reports; and, as part of the PROSUR/PROSUL regional technical cooperation initiative, Argentina, Brazil, Chile, Colombia, Ecuador, Peru and Uruguay have published patent reports on technologies relevant to COVID-19.⁷⁵ The United States Patent and Trademark Office (USPTO) has created a COVID-19 Prioritized Examination Pilot Program that fast-tracks examination of COVID-19-related applications filed by small and micro enterprises.⁷⁶ The Brazilian National Institute of Industrial Property prioritizes the examination of patent applications related to innovations that can be used to fight COVID-19 from 7 April 2020 to 30 June 2021.⁷⁷

The Medicines Patent Pool provides patent information in its Medicines Patents and Licences database (MedsPaL), in response to the call for user-friendly databases in the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI).⁷⁸ At the time of writing, the database included information about a number of medicines in trials to treat COVID-19, including AT-527, baricitinib, dapagliflozin, darunavir/cobicistat, favipiravir, imatinib, lopinavir/ritonavir, molnupiravir, remdesivir, ruxolitinib, sarilumab, sofosbuvir/daclatasvir, tocilizumab, bevacizumab, rivaroxaban, siltuximab and sofosbuvir/daclatasvir.⁷⁹ The MPP has also compiled and published patent information on COVID-19 vaccines in the newly created VaxPaL Database. In the coming months, VaxPaL will be turned into a user-friendly, fully searchable online database, similar to MedsPaL.⁸⁰

Innovation and access: flexibility in the IP system

Well-functioning IP systems should consider the interests of a wide range of stakeholders, such as start-ups, R&D institutions, both public and private, universities and corporations, as well as the interests of funders, whether public or private, and of the public at large, including patients, who ultimately benefit from innovation that meets

their needs. To achieve this delicate balance, each country can tailor its domestic IP system to its particular needs and circumstances, including through the implementation of the provisions of the TRIPS Agreement, which provide flexibility for public health purposes and the application under national law.⁸¹

The IP system has a number of features that support and facilitate R&D and access, including certain exclusions from patentable subject matter and limited exceptions to patent rights. Those options are available to support countries' access to medical technology and innovation policies.⁸² For example, national IP systems have certain options with respect to patenting material that exists in nature. Patentability may have relevance for biotechnological R&D on the SARS-CoV-2 virus.⁸³

Domestic IP laws frequently provide for research exceptions. Where a research exception is available, R&D on patented COVID-19-related technologies does not constitute patent infringement.⁸⁴ In countries where a regulatory review exception exists, a patented invention can be used without the consent of the patent holder for the purposes of developing information to obtain regulatory marketing approval.⁸⁵ A number of national patent systems provide options addressing the further development, and repurposing, of existing medicines, including incremental innovation, medical indication claims and limiting evergreening.⁸⁶

Available policy measures include compulsory licences and government-use licences.⁸⁷ Legislation has been passed in some countries to ensure that mechanisms for expedient compulsory licensing and government-use licensing are in place if needed in order to facilitate access to COVID-19 therapies, for example, in Canada and Hungary.⁸⁸ In Germany, legislation has authorized the Federal Ministry for Health to order the competent authority to allow the use of patent-protected inventions to ensure the supply of various health technologies, including medicines, diagnostics and personal protection equipment, on the grounds of public interest or national security.⁸⁹ In Israel, a government-use licence has been issued for the import of generic lopinavir/ritonavir in COVID-19 treatment.⁹⁰ In November 2020, the Hungarian Intellectual Property Office issued three compulsory licences for domestic use of remdesivir.⁹¹ On 31 December 2020, the Russian Federation granted a compulsory licence for the production of remdesivir for a duration of one year, on the grounds of national security.⁹²

On 26 May 2021, the Indian pharmaceutical company, Bajaj Healthcare submitted a request to the Indian Patent Office for the grant of a compulsory licence to produce baricitinib, a medicine which is patented by Incyte and licensed for commercialization to Eli Lilly.⁹³ The treatment is under investigation for use in treating COVID-19 in combination with remdesivir.⁹⁴

The TRIPS Council's regular review of the Special Compulsory Licensing System for manufacture and export of pharmaceutical products⁹⁵ in October 2020 made reference to the relevance of the System for the global health crisis.⁹⁶ However, questions have also been raised as to whether the System can provide an effective and expeditious response to the COVID-19 pandemic,⁹⁷ and concerning the choice of developed-country WTO members to exclude themselves from using the System as importers.⁹⁸

According to the information note on the "TRIPS Agreement and COVID-19", while it remains a challenging task to forecast the System's role to help addressing the pandemic, its mere existence may be helpful in facilitating access, whether or not a compulsory licence is ultimately issued to procure the needed vaccines or treatments. For example, by notifying the WTO of the expected needs at an early stage of the procurement of a COVID-19 health technology, a member would open up the widest possible range of suppliers, including through, but not limited to, the System; this would also facilitate groups of members to aggregate demand and benefit from economies of scale and exercise joint leverage to secure access.⁹⁹

In early 2021, Bolivia as well as Antigua and Barbuda notified to the TRIPS Council their respective intentions to use the System for the importation of pharmaceutical products, in particular vaccines.¹⁰⁰ On 11 May 2021, Bolivia notified its specific need to import 15 million doses of COVID-19 vaccines to the TRIPS Council.¹⁰¹ The Canadian pharmaceutical company, Biolyse Pharma, expressed its intention to produce and export a generic version of the Johnson & Johnson vaccine and signed an agreement with the Government of Bolivia to manufacture and export COVID-19 vaccines. This was subject to the necessary regulatory approvals and voluntary and compulsory licences through the Canadian Access to Medicines Regime (CAMR),¹⁰² Canada's law to implement the System domestically. CAMR requires medicines to be positively scheduled before being considered for a compulsory licence and links regulatory approval with the System¹⁰³ – so that the product intended for export meets the same safety, efficacy and quality standards applicable to drugs destined for Canada's domestic market.¹⁰⁴ Internal discussions as to whether COVID-19 vaccines should be scheduled under CAMR reportedly cover the question of whether Biolyse has the capacity to manufacture vaccines that meet regulatory standards.¹⁰⁵

Civil society organizations have opposed the granting of certain patents on technologies that could potentially be used in a new COVID-19 medicine;¹⁰⁶ some have also requested revocation of certain patents in India.¹⁰⁷ Such measures have traditionally been used more often by commercial competitors.¹⁰⁸ For example, Moderna sought to invalidate a US patent on an mRNA delivery system owned by Arbutus Biopharma, which Moderna uses for

its COVID-19 vaccines. In July 2020, the United States Patents Trial and Appeal Board rejected Moderna's petition that the subject matter was obvious and therefore not patentable.¹⁰⁹

A balanced copyright system that supports the interests of rights holders and allows access to copyright-protected works can support R&D activities and enable the development of digital solutions to support diagnostics and treatment. Text- and data-mining exceptions have been used in initial research into COVID-19, including for tracking and predicting its spread, and are being used in the search for treatments.¹¹⁰

Software licensing schemes can also support the development of eHealth products and digital processes that may allow easier diagnosis and treatment of COVID-19 patients.¹¹¹

Voluntary actions and initiatives

Many organizations, corporations and other rights-holders undertook voluntary actions and initiatives during the COVID-19 crisis.¹¹² Open licensing models have been used collaboratively to develop and manufacture hardware to resolve supply chain weaknesses.¹¹³ A number of private sector companies took access-oriented actions that included:

- (i) committing to non-exclusive and royalty-free licensing or issuing non-enforcement declarations of patent rights in some or all jurisdictions;¹¹⁴
- (ii) publishing scientific data on a free-to-use basis;
- (iii) publishing technical specifications of vital equipment (e.g. ventilators); and
- (iv) sharing knowledge to enable others to manufacture and use such technologies.¹¹⁵

In addition, among other voluntary actions in support of R&D that have been observed are the permission to use text- and data-mining and machine-learning technologies and to freely access and reuse COVID-19-related scientific literature protected by copyright,¹¹⁶ and to make available standards protected by copyright.¹¹⁷ For example, as part of the Open COVID Pledge, a number of private companies and universities are granting free access to patented technologies and protected designs related to diagnosing, preventing, containing and treating COVID-19.¹¹⁸ According to the US University Report Card for Global Equity and Biomedical Research in April 2020, half of the surveyed universities made no commitments to equitable COVID-19 biomedical licensing practices, and none made commitments to the Open COVID Pledge.¹¹⁹

Governments and the private sector have also undertaken initiatives to transfer technology and know-how to make, adapt or use COVID-19-related technologies.¹²⁰ A concrete example of IP management for a new

COVID-19 technology is seen in a vaccine developed at Oxford University in the United Kingdom and licensed to an originator pharmaceutical company for manufacture. While the exact contract terms are not public, the originator company has committed to supplying the vaccine globally on a non-profit basis and has signed an agreement with an India-based manufacturer allowing the latter to supply low- and middle-income countries.¹²¹ Publicly available data and information on licensing or other agreements for manufacture and transfer of technology for COVID-19 vaccines and vaccine candidates are available from a number of sources.¹²²

Despite voluntary actions and initiatives taken by certain stakeholders, there have been strong calls from a broad range of key actors for transfer of technology and know-how,¹²³ as well as urgently needed additional voluntary

licences,¹²⁴ in particular, from the holders of key vaccines, therapeutics or diagnostics to prevent, detect and treat COVID-19 and achieve equitable global access.

Given the enormity of the COVID-19 challenge, all mechanisms, including voluntary licences, technology pools and the use of TRIPS flexibilities and of the proposed waiver of obligations of WTO members to implement or apply certain provisions of the TRIPS agreement, should be explored carefully. All these different initiatives have different characteristics and could be implemented in different ways, and there are also existing challenges for the implementation of each of them. That is why they should be explored simultaneously according to the different needs of the countries and their ability to implement them at the national level.

COVID-19 technologies: international initiatives to support R&D and equitable access

Since the start of the COVID-19 pandemic, myriad public and private actors have launched collaborative global efforts to develop treatments, vaccines and diagnostics with the aim of guaranteeing equitable access to those technologies. Many such efforts strive to address R&D and access needs simultaneously. Collaborative efforts include substantial investments in product development partnerships (PDPs)¹²⁵ to support the non-commercial development of vaccines and large multi-stakeholder R&D initiatives.¹²⁶

The “2019 Novel Coronavirus (2019-nCoV): Strategic preparedness and response plan” includes actions to coordinate international R&D efforts. Such actions include use of the R&D Blueprint Global Coordination Mechanism and the convening of expert consultations that have resulted in a Coordinated Global Research Roadmap.¹²⁷ The “Strategic preparedness and response plan 2021” builds on achievements and lessons learned from 2020 with strategic actions that aim to address new challenges such as new viral variants.¹²⁸ The WHO R&D Blueprint for COVID-19 highlights the importance of a collaborative approach, stating that “virus materials, clinical samples and associated data should be rapidly shared for immediate public health purposes and that fair and equitable access to any medical products or innovations that are developed using the materials must be part of such sharing”.¹²⁹ Genetic sequences of viral samples are being shared openly, worldwide. Timely sharing of epidemiological and other data is also crucial.¹³⁰

WHO held a COVID-19 Global Research & Innovation Forum from 13-14 May 2021 to provide information as to the development of a revised COVID-19 Global Research and Innovation Roadmap with clear goals, priority actions and milestones.¹³¹

To ensure efficiency in testing potential treatments, WHO launched “Solidarity I”, an international clinical trial platform for COVID-19 treatments, which enrolls patients in one single randomized trial to facilitate the rapid worldwide comparison of unproven treatments.¹³² Since end-2020, the Solidarity Trial has recruited over 15,000 patients in 500 hospitals globally. The Solidarity Trial is ongoing in 30 participating countries, and an additional 13 countries have received approval to commence recruitment. Overall, 116 countries have joined or expressed an interest in joining the Trial.

The Trial compares four promising treatment options (remdesivir, lopinavir/ritonavir, lopinavir/ritonavir with interferon beta and chloroquine) against the standard of care. In line with the “Policy Statement on Data Sharing by the World Health Organization in the Context of Public Health Emergencies”, interim results from the Trial were published in October 2020 and found that all four treatments had little or no effect on overall mortality, initiation of ventilation and duration of hospital stay for patients who had been hospitalized.¹³³ Through the Trial, WHO has facilitated access to thousands of treatment courses for the trial through donations from a number of manufacturers.¹³⁴

The WHO data-sharing policy further clarifies the WHO position in providing access to data for: 1) surveillance, epidemiology and emergency responses, including health facilities, 2) genetic sequences, and 3) observational studies and clinical trials. On 23 June 2021, a WHO *ad hoc* Ethics Review Committee for COVID-19 approved a protocol titled “Solidarity Trial PLUS: An international randomized trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care” which signals that the Trial may evaluate other treatments in future studies.¹³⁵

WHO is also leading a global collaboration that promotes the implementation of serological surveys on SARS-CoV-2, “Solidarity II”. The global platform allows governments and academic collaborators to carry out seroepidemiological, risk factor and severity studies.¹³⁶ WHO plans to launch “Solidarity III” as a large, international, randomized clinical trial for evaluation of the efficacy and safety of several candidate COVID-19 vaccines and facilitate regulatory and deployment decisions through the Access to COVID-19 Tools Accelerator (ACT-A) and the COVAX facility (the Vaccines Pillar of ACT-A).¹³⁷

UNGA resolution A/RES/74/274¹³⁸ underscored that equitable access to health products is a global priority and that the availability, accessibility, acceptability and affordability of health products of assured quality are fundamental to tackling the pandemic.

World Health Assembly resolution WHA73.1¹³⁹ is concerned, *inter alia*, about the continued functioning of the health system and universal health coverage, promotion of R&D, including through open innovation, as well as timely, equitable and affordable access to health technologies. It called on “international organizations and other stakeholders [...] to work collaboratively at all levels to develop, test and scale-up production of safe, effective, quality, affordable diagnostics, therapeutics, medicines and vaccines for the COVID-19 response, including, existing mechanisms for voluntary pooling and licensing of patents in order to facilitate timely, equitable and affordable access to them, consistent with the provisions of relevant international treaties, including the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the flexibilities within the Doha Declaration on the TRIPS Agreement and Public Health”.¹⁴⁰ It also called for restrictions on the movement of medical equipment and medicines to be temporary and specific; for the sharing of knowledge, lessons learned, experiences, best practices, data, materials and commodities; and for collaboration to promote both private-sector and government-funded research and development.

Resolution WHA74.6 on “Strengthening local production of medicines and other health technologies to improve access” signals WHO member states’ commitment to distribute production capacity more equitably.

Decision WHA74(16) agreed on a special session of the World Health Assembly to consider developing a WHO convention, agreement or other international instrument on pandemic preparedness and response more recently followed.¹⁴¹

WHO, together with private sector partners and other stakeholders, has launched the Access to COVID-19 Tools Accelerator (ACT-A), a collaboration to accelerate the development, production and equitable global access to new COVID-19 essential health technologies.¹⁴² ACT-A is organized around four main pillars of work: diagnostics, treatment, vaccines and a cross-cutting pillar on strengthening health systems. As of 19 July 2021, COVAX, the vaccines pillar of ACT-A, has shipped more than 129 million vaccines to more than 136 economies.¹⁴³ Major achievements of the diagnostics pillar include the procurement of over 27 million molecular tests and 12 million rapid antigen tests for low- and middle-income countries.¹⁴⁴

In response to an initiative of the Government of Costa Rica, the WHO on 29 May 2020 launched the Solidarity Call to Action and the COVID-19 Technology Access Pool (C-TAP). The Call has been endorsed by 44 other member states as well as UN agencies and other stakeholders.¹⁴⁵ It states that “the COVID-19 pandemic has revealed the fallibility of traditional ways of working when it comes to equitable access to essential health technologies” and “sets out an alternative, in line with WHO’s efforts to promote global public health goods, based on equity, strong science, open collaboration and global solidarity”. Key elements of the Solidarity Call to Action include:

- public disclosure of gene sequences and data;
- timely publication of all clinical trial results;
- encouragement of governments and R&D funders to include clauses in funding agreements with pharmaceutical companies and other innovators concerning equitable distribution, affordability and transparency, including the publication of trial data;
- use of global non-exclusive licensing for relevant health technologies, including through licensing to the Medicines Patent Pool;¹⁴⁶ and
- promotion of open innovation models and technology transfer that increase local manufacturing and supply capacity, including through joining the Open COVID Pledge and the United Nations (UN) Tech Access Partnership.¹⁴⁷

To operationalize the Solidarity Call to Action, WHO and partners launched the COVID-19 Technology Access Pool (C-TAP) to facilitate timely, equitable and affordable access of COVID-19 health products. C-TAP, working through its implementing partners – the Medicines Patent Pool, the Open COVID Pledge and the UN Technology

Bank – provides a global one-stop shop for developers of COVID-19 therapeutics, diagnostics, vaccines and other health products to share their intellectual property, knowledge and data with quality-assured manufacturers through public health-driven voluntary, non-exclusive and transparent licences. With the support of WHO and Unitaid, the Medicines Patent Pool temporarily expanded its mandate to cover any COVID-19-related health technologies, including vaccines and diagnostics.¹⁴⁸

By licensing intellectual property and know-how through the pooling and voluntary agreements, developers of COVID-19 health products can facilitate scaling up production through multiple manufacturers that currently have untapped capacity to scale up production. Among other actions, the Solidarity Call to Action promotes the fact that all COVID-19 publicly-funded and donor-funded research outcomes are affordable, available and accessible to all on a global scale through appropriate provisions in funding agreements, and include specific provisions regarding accessibility to and affordability of resulting COVID-19 related health products through global non-exclusive voluntary licensing, transparency and, when necessary, other commitments to expand access by sharing, for example, other intellectual property rights, know-how and data. During a special press conference to mark the first anniversary of C-TAP, the President of the Republic of Costa Rica and the Director-General of WHO called once again on all WHO member states to actively support C-TAP.¹⁴⁹ C-TAP has engaged technology holders in bilateral discussions and the Spanish National Research Council (CSIC) announced its intention to make its COVID-19 serological test technology available to C-TAP.

The UN Technology Bank for LDCs is dedicated to enhancing the contribution of science, technology and innovation for sustainable development in the world's 46 LDCs and former LDCs for up to five years after their graduation from the category. Its headquarters location is based in Gebze, Turkey. The UN Technology Bank actively engages with national, regional and international partners to deliver its programme and projects which strengthen science, technology and innovation capacity in LDCs. It supports national and regional technological efforts, reinforces partnerships across sectors and helps nations identify and use appropriate technologies to transform their economies and improve livelihoods.

The Open COVID Pledge calls upon organizations around the world to make their patents and copyrights freely available in the fight against the COVID-19 pandemic. The Pledge was originally developed by an international group of researchers, scientists, academics and lawyers seeking to accelerate the rapid development and deployment of diagnostics, vaccines, therapeutics, medical equipment and software solutions in this urgent public health crisis. The project is now led and stewarded by Creative Commons, a non-profit organization that

helps overcome legal obstacles to the sharing of knowledge and creativity to address the world's pressing challenges.

WHO and partners established the COVAX Manufacturing Task Force as a proposed pathway to increasing supply and ensuring regional health security.¹⁵⁰ The task force aims to increase the immediate supply of existing vaccines, to ensure that vaccines coming onto the market can be produced at maximum scale and are not constrained by existing contracts, and to enable low- and middle-income countries to acquire COVID-19 vaccine production technology and establish sustainable outbreak response capacity for regional health security. As part of the task force, WHO established in April 2021 a COVID-19 mRNA vaccine technology transfer hub to scale up global manufacturing.¹⁵¹ WHO and its COVAX partners are working with a South African consortium to establish the first COVID mRNA vaccine technology transfer hub.¹⁵² Future hubs for other technologies, such as viral vectors and proteins, are foreseen.¹⁵³ The WTO is actively contributing to the workstreams of the COVAX Manufacturing Task Force.

The need for the rapid development of new technologies has spurred unprecedented government investment in R&D.¹⁵⁴ Launched by the European Commission in May 2020, "Coronavirus Global Response" pledging events reached a total of EUR 15.9 billion by the end of June 2020 to fund collaborative development and universal deployment of and access to COVID-19 diagnostics, treatments and vaccines.¹⁵⁵ The European Commission has also instituted a "temporary framework" to allow state aid to go to COVID-19-related R&D, if beneficiaries commit to grant non-exclusive licences under non-discriminatory market conditions to third parties in the European Economic Area.¹⁵⁶

The Coalition for Epidemic Preparedness Innovations (CEPI), a product development partnership created in the wake of the 2014 Ebola virus outbreak by philanthropists and a number of governments, by 9 June 2020 had received US\$ 1.4 billion from governments for COVID-19-related work, an unprecedentedly large investment in a PDP.¹⁵⁷ CEPI requires producers to provide equitable access to any vaccine developed through its funding. It further requires product developers to be willing to undertake technology transfer to enable production by a global network of manufacturers.¹⁵⁸ It is playing a key role in the work of COVAX.

As of 9 July 2021, the Access to COVID-19 Tools Accelerator (ACT-A) reported a funding gap of US\$ 16.7 billion for 2021.¹⁵⁹ Proposals to address the funding gap have been put forward including a financial share proposal across the 89 high and upper-middle countries for financing ACT-A. A US\$ 50 billion proposal from the IMF aims at generating new investments to bring the pandemic to an end, including funding to ACT-A.¹⁶⁰

It has become increasingly evident that collaborative multi-stakeholder engagement is key to resolving issues of vaccine scarcity and equitable access. Numerous multi-stakeholder initiatives are under way to help identify the challenges and practical steps needed to help scale up manufacturing capacity for and facilitate equitable distribution of COVID-19 vaccines; these include:

- The November 2020 launch by the President of the UN General Assembly of #Vaccines4All, calling on UN member states to support global, multilateral efforts to achieve fair and equitable access;
- The January 2021 call to action issued by the WHO for vaccine equity and working together in solidarity to accelerate the equitable rollout of vaccines in every country, starting with health workers and those at highest risk for COVID-19;¹⁶¹
- The April 2021 World Bank event on “Vaccines for Developing Countries”;
- The WTO high-level meeting in April 2021 on “COVID-19 and Vaccine Equity: What Can the WTO Contribute?”¹⁶² and technical workshop in June 2021 on “COVID-19 vaccine supply chain and regulatory transparency”;¹⁶³
- The April 2021 ECOSOC event on “A Vaccine for All”, focusing on scaling up manufacturing and financing;
- The WHO-WTO High Level Dialogue on Expanding COVID-19 vaccine manufacture to promote equitable access in July 2021.¹⁶⁴

Regulatory responses

Regulatory assessment and approval of health technologies are essential in every health system to ensure product quality, safety and efficacy. An effective COVID-19 treatment has not yet been found. Clinical trials are ongoing for new treatments as well as for repurposed medicines.¹⁶⁵ “Compassionate use” of medicines (i.e., their clinical use before approval) is taking place in specific cases.¹⁶⁶

The WHO Emergency Use Listing (EUL) procedure aims to streamline the process by which new or unlicensed products can be used during public health emergencies. The EUL provides a time-limited listing for unlicensed products in an emergency context when limited data are available and when products are not yet ready to apply for WHO pre-qualification.¹⁶⁷ In this context, products are still undergoing development, but are not yet licensed. WHO assesses the quality, safety and efficacy of the data generated during development and conducts a risk-benefit assessment to determine use outside of clinical trials. Certain eligibility criteria apply to EUL for COVID-19 products, including: whether the disease may cause an outbreak, epidemic or pandemic; whether there are no products available capable of eradicating or preventing the disease; whether products are manufactured in compliance with good manufacturing practices; and whether the applicant undertakes to complete the development of the product and apply for prequalification once it is licensed.

The EUL is currently open to candidate *in vitro* diagnostics (IVDs) to detect SARS-CoV-2, including for assays for the detection of SARS-CoV-2 nucleic acid, immunoassays for the detection of SARS-CoV-2 specific antibodies and rapid diagnostic tests for the

detection of SARS-CoV-2 antigens.¹⁶⁸ The up-to-date status of COVID-19 vaccines within WHO EUL/PQ evaluation process is available on the WHO website.¹⁶⁹ The list assists interested UN procurement agencies and member states in determining the acceptability of specific products, based on an essential set of available quality, safety and efficacy and performance data. As of 7 May 2021, WHO has listed the Pfizer/BioNTech vaccine for emergency use; two AstraZeneca/Oxford COVID-19 vaccines, produced by AstraZeneca-SKBio (Republic of Korea) and the Serum Institute of India; and COVID-19 vaccine Ad26.COVS.2 developed by Janssen (Johnson & Johnson) and Sinopharm COVID-19 vaccine for emergency use. For Brazil’s health regulatory authority ANVISA, the EUL has served as the basis for the exemption of market and emergency use authorization and the procedure for the import and monitoring of vaccines acquired by the Ministry of Health within the scope of the COVAX Facility for the tackling of the COVID-19 pandemic.¹⁷⁰

Together in close collaboration with international partners, recent WTO activities (e.g. the Vaccine Supply Chain and Regulatory Transparency Technical Symposium¹⁷¹ and the Webinar on Regulatory Cooperation during the COVID-19 Pandemic¹⁷² in June 2021) have examined how to increase transparency in the regulatory approval process and how to strengthen regulatory cooperation. These events explored the main challenges to vaccine supply chain and regulatory transparency in the context of COVID-19, and discussed cooperation towards finding practical solutions to scale up the global COVID-19 response and address gaps in the global production and distribution of vaccines, diagnostics and other medical technologies.

Ensuring transparency

Transparency and the availability of up-to-date information on measures taken by governments are of critical importance and cut across both legal and policy areas addressed in the Trilateral Study.¹⁷³

The International Health Regulations (2005) include a broad notification requirement, which aims at detecting, early on, all public health events that could have serious and international consequences, and preventing or containing them at source through an adapted response before they spread across borders.¹⁷⁴ Notifiable events must be reported to the WHO immediately, i.e., within 24 hours after having carried out the assessment of public health information related to the event. Following notification, state parties shall also:

- continue to communicate to the WHO sufficiently detailed public health information available on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease, and the health measures employed;
- submit information about health measures taken in addition to those recommended by WHO; and
- report, where necessary, the difficulties faced and the support needed in responding to the potential public health emergency of international concern.

Transparency in COVID-19 R&D and access initiatives is an essential principle in the WHO Solidarity Call to Action and C-TAP.¹⁷⁵ The WHO Director-General has noted that lack of transparency is the main disadvantage of bilateral technology transfer through voluntary licensing.¹⁷⁶ In addition, World Health Assembly resolution WHA72.8

on “Improving the transparency of markets for medicines, vaccines, and other health products”, adopted in 2019, urges WHO member states and the WHO Director-General to take a number of actions toward improving transparency, including toward improving public reporting of patent status information and the marketing approval status of health products.

The WIPO COVID-19 IP Policy Tracker¹⁷⁷ online listing provides information on measures adopted by IP offices in response to the COVID-19 pandemic, such as the extension of deadlines to ensure continued operations. In addition, the Policy Tracker provides information on legislative and regulatory measures taken by governments, as well as on voluntary actions of a broad range of stakeholders, to improve access. It relies on information provided by IP offices, member states and other entities, and is therefore not an exhaustive list of all actions taken regarding COVID-19.

To promote transparency, the WTO monitors and reports on trade-related measures pertaining to goods, services and IP rights implemented by its members in response to the pandemic.¹⁷⁸ The WTO has issued a number of information notes and reports on trade in the context of COVID-19, including updated notes on trade in medical goods, transparency, export prohibitions and restrictions, the treatment of medical products in regional trade agreements, standards and regulations, trade in services and how WTO members have used trade measures to expedite access to COVID-19 critical medical goods and services.¹⁷⁹ A further information note on “Developing and delivering COVID-19 vaccines around the world”¹⁸⁰ looks at issues with trade impact and explores how trade policy can play its part in ensuring the rapid roll-out of vaccine against COVID-19.¹⁸¹

The way forward

The COVID-19 pandemic has placed immense pressure on health systems and trade systems around the world. The urgent search for technologies that may help to control the pandemic has mobilized unprecedented research efforts and investments. It has given rise to new models of working. Rapid and efficient innovation is needed more than ever, and global equitable access to new technologies is of paramount importance. Adequate management of IP is central to achieving these goals.

National and international responses to the pandemic reflect policymakers' growing experience in tackling pressing health needs, with initiatives considering health, trade and IP elements in a holistic manner. Responses to the pandemic span such a wide range of technical areas that nearly every section of the Trilateral Study is of relevance to the global response to COVID-19.

The Directors-General of the three organizations emphasized in the foreword to the Trilateral Study that “the COVID-19 pandemic has brought extraordinary challenges to people’s health, economies and societies at large. Global collaborative efforts are required now more than ever before”. They underscored in their meeting of 15 June 2021 their commitment to universal, equitable access to COVID-19 vaccines, therapeutics, diagnostics and other health technologies – a commitment anchored in the understanding that this is an urgent moral imperative in need of immediate practical action. In this spirit, they agreed to build further on the long-standing commitment to WHO-WIPO-WTO Trilateral Cooperation.¹⁸²

On September 27, 2021, the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) jointly organized the first in a series of Workshops on Innovation in, and Access to, COVID-19 Technologies. The workshop focused on intellectual property licensing, technology transfer, and sharing of know-how and clinical trial information.¹⁸³

WTO members are discussing proposals regarding trade-related measures to address the pandemic. Among

the proposals is the Trade and Health Initiative, which aims to contain the pandemic and support economic recovery through a coordinated global response.¹⁸⁴ This draft initiative covers the elimination of existing export restrictions and due restraint in the imposition of new restrictions, trade facilitating measures, regulatory alignment and removal or reduction of tariffs.¹⁸⁵ Another proposal specifically proposes a Ministerial Declaration on trade and health, underscoring the role of WTO to foster coordination and transparency in international trade, taking into consideration the imperatives of public health.¹⁸⁶ Groups of WTO members have also put forward proposals covering export restrictions, customs, services and technical regulations, tariffs, transparency and the role of the WTO more broadly in the global effort toward the production and distribution of COVID-19 vaccines and other medical products.

A group of WTO members has submitted a proposal to the TRIPS Council for a decision by the WTO General Council that would waive WTO members' obligation to protect and enforce certain IP rights in relation to the prevention, containment or treatment of COVID-19. It is proposed that the waiver remains in force for at least three years from the date of decision and until a decision of the General Council determines the date of termination of the waiver. As an alternative proposal, the European Union, on 18 June 2021, submitted a Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic which has also been considered at subsequent TRIPS Council meetings.¹⁸⁷ A key question has been whether a solution to access problems in developing countries can be found by operating within the IP system, including by making full use of the flexibilities in the TRIPS Agreement, or whether such a solution would require waiving certain obligations under the TRIPS Agreement during the pandemic in order to allow for a rapid scaling up of manufacturing capacities. At the General Council meeting on 27–28 July, the TRIPS Council Chair reported that the TRIPS Council would continue its consideration of the revised waiver request and other related proposals and report back to the General Council.¹⁸⁸

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Promoting Access to Medical Technologies and Innovation

SECOND EDITION

Intersections between public health, intellectual property and trade

Updated extract: integrated health, trade and IP approach to respond to the COVID-19 pandemic, 30 August 2021

The coronavirus disease 2019 (COVID-19) pandemic constitutes an extraordinary global public health crisis. It has created a pressing need for intensified global cooperation. The pandemic has from its outset raised issues at the crossroads of public health policy, trade policy and the framework for and management of innovation, including those relating to intellectual property rights.

The second edition of the joint WHO, WIPO and WTO publication "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade", published in 2020, included a special insert mapping the challenges posed by the COVID-19 pandemic in relation to the integrated health, trade and IP policy framework set out in the study. This update revises the information contained in that insert in the light of more recent developments as of 30 August 2021.



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