An integrated health, trade and IP approach to respond to the COVID-19 pandemic

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 the management of innovation, including those relating to intellectual property (IP) rights.

The text of the second edition of this publication had been completed prior to the COVID-19 outbreak. This special insert maps myriad challenges posed by the outbreak in relation to the integrated health, trade and IP policy frameworks set out in this study. It provides cross-references to the relevant sections of the main text.

A dramatic impact on health systems

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) – a newly emergent coronavirus first recognized in December 2019 – causes COVID-19. According to evidence available as of 27 May 2020, most people with COVID-19 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.¹

Based on the information notified to the World Health Organization (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.

UN General Assembly resolutions A/RES/74/270 "Global solidarity to fight the coronavirus disease 2019 (COVID-19)"² and A/RES/74/274 "International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19",³ as well as World Health Assembly resolution WHA73.1 "COVID-19 response",⁴ recognized the dramatic impact of the global outbreak on health systems, 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.

Governments around the globe have implemented restrictions to economic and social activities in an effort

to slow the virus's spread, including through policies of confinement, physical distancing and restrictions on travel. These restrictions have sought to reduce pressure on health systems, allow sufficient time to improve health infrastructure and develop diagnostics, vaccines and treatments to effectively respond to the virus.

Policy challenges posed by the pandemic

The COVID-19 pandemic has generated sudden, farreaching impacts on health systems, and has prompted significant social and economic repercussions around the world. This extraordinary threat to peoples' health and livelihoods has required urgent action:

- to monitor and contain the spread of the virus;
- to understand relevant virology and epidemiology;
- to mobilize and coordinate the requisite resources;
- to deploy the necessary health care system infrastructure;
- to ensure that health care products, technologies and protective equipment are available and can be accessed equitably in sufficient quantities worldwide;
- to develop, test, manufacture and ensure equitable access to diagnostics, vaccines and therapeutics, medical devices and other relevant technologies.

Meeting the demand for health technologies and medical services

The pandemic triggered a massive global demand for existing health technologies to combat COVID-19, including diagnostics, medicines, ventilators and other medical devices, as well as for 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.

Determinants of access: Chapter II, section A and Chapter IV

Government priorities have included ensuring sufficient access to intensive care equipment such as ventilators, ensuring sufficient PPE to minimize infection risk to frontline 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 through redirecting production lines to manufacture essential products. To date, generic manufacturers in Bangladesh have begun producing a generic version of remdesivir to treat COVID-19, which is patented in a number of other countries, benefitting from the transition period under the World Trade Organization (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.

LDC TRIPS transition periods: Chapter II, section B.1(g)(v)

To ensure adequate access to diagnostics, health systems have, among other things, set up contact tracing systems and "drive-through" testing facilities as well as organized new laboratory networks to utilize capacity in smaller labs. Although vaccines for COVID-19 are still early in their development, a number of governments have invested in ensuring that sufficient manufacturing capacity is available to produce the necessary volumes if and when an effective vaccine is found.

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.

 Health services under the WTO General Agreement on Trade in Services (GATS): Chapter II, section B.3(c)

Telemedicine may be used to overcome geographical limitations and physical distancing requirements.

Software licensing and eHealth: Chapter II, section B.1(e)(v)

Authorities in many jurisdictions have expedited 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.

Procurement mechanisms: Chapter II, section B.4 and Chapter IV, section A.8

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. 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 in order to enhance testing capacities in the Netherlands.⁵ Several competition authorities have issued guidance⁶ on the application of competition policy in times of urgency and limited supply and clarified whether and when coordination between firms in order to respond to crisis needs could be permitted, at least temporarily.

Competition law and policy: Chapter II, section B.2 and Chapter IV, section D.2

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.

International trade in health-related products: Chapter IV, section D.1(a)

Preserving the integrity of global trade is critical to ensure equal access to needed health technologies and will support countries in recovering from the crisis and building health systems that foster greater resilience against future pandemics. While recognizing that governments may take emergency measures to address public health challenges, including shortages of COVID-19 technologies, G20 Trade Ministers⁷ have called upon countries to ensure that any trade-restrictive measure taken to promote public health be "targeted, proportionate, transparent and temporary".8 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.9 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.

Governments have concomitantly implemented both trade-restrictive measures (e.g. restrictions on exports of key products) and trade-facilitating ones to reduce costs and delays (e.g. facilitation and simplification of customs procedures).

WTO Trade Facilitation Agreement: Chapter IV, section D.1(b) Some countries have reduced or eliminated tariffs on certain imported health technologies or deferred payment deadlines for the same.

> Tariffs: Chapter IV, section D.1(b)

Regulatory conformity checks have been streamlined through international cooperation and standards, as well as through mutual or unilateral recognition of third-country approvals.

WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and WTO Agreement on Technical Barriers to Trade (TBT Agreement): Chapter II, section B.3(b)

Intellectual property and the pandemic

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. Given their particular importance, patents are the focus of this section, while other aspects of IP are discussed further in the main study.

IP system: Chapter II, section B.1, Chapter III, section D and Chapter IV, section C

The disclosure requirement and dissemination of patent information ensure access to technical information, which can support research and development (R&D) needs. The World Intellectual Property Organization (WIPO) has established a COVID-19 search facility¹⁰ within its global PATENTSCOPE database. The tool offers predefined search strings that support the searching of COVID-19related patent information. The European Patent Office (EPO)11 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-19.12 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. 13 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 2021.14

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).¹⁵ As of writing, the database includes information about a number of medicines in trials to treat COVID-19: remdesivir, lopinavir/ritonavir, favipiravir and ruxolitinib, as well as biotherapeutics tocilizumab, sarilumab and siltuximab.

- > Patent information: Chapter II, section B.1(b)(viii)-(xi)
- Disclosure requirement: Chapter II, section B.1(b)(iii)

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 TRIPS flexibilities.

IP policy options and flexibilities in the IP system: Chapter II, section B.1(g)

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.

IP exclusions and exceptions: Chapter II, section B.1(b) (vii) and Chapter IV, sections C.1 and C.3

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.

Patentable subject matter: Chapter III, section D.4(a)

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.

> Research exceptions: Chapter III, section D.5(a)-(b)

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.

Regulatory review exception: Chapter IV, section C.3(a)(i)

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.

Further development and repurposing: Chapter III, section D.4(b)-(c)

Available policy measures include compulsory licences and government-use licences. 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. 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. In Israel, a government-use licence has been issued for the import of generic lopinavir/ritonavir in COVID-19 treatment.

Compulsory licences and government-use licences: Chapter IV, section C.3(a)(ii)

As regards the Special Compulsory Licensing System for manufacture and export of pharmaceutical products, ¹⁹ questions have been raised regarding the response that the system can provide to the COVID-19 pandemic²⁰ and the fact that developed country WTO members excluded themselves from using the System as importers.²¹

Special Compulsory Licensing System: Chapter IV, section C.3(a)(iii) and Annex III

Civil society organizations have submitted oppositions against patents on technologies that could be potentially used in a new COVID-19 medicine; some have requested patent revocation.²² Such measures have traditionally been used more often by commercial competitors.

Pre-grant and post-grant patent review: Chapter IV, section C.2

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.

> Exceptions to copyright: Chapter II, section B.1(e)(ii)

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.

Software licensing and eHealth: Chapter II, section B.1(e)(y)

Many organizations, corporations and other rights holders have undertaken voluntary actions and initiatives during the COVID-19 crisis. Open licensing models have been used collaboratively to develop and manufacture hardware to resolve supply chain weaknesses. Numerous private sector companies have taken access-oriented actions that include: (i) committing to non-exclusive and royalty-free licensing or issuing non-enforcement declarations of patent rights in some or all jurisdictions;²³ (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.²⁴

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, ²⁵ and the making available of standards protected by copyright. ²⁶ 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-19.²⁷

Licensing approaches: Chapter III, sections C.5(g),
 D.1, D.2 and D.5(c) and Chapter IV, section C.3(b),
 (c) and (e)

Governments and the private sector have also undertaken initiatives to transfer technology and know-how to make, adapt or use COVID-19-related technologies.

Manufacturing and technology transfer: Chapter IV, section A.10

A concrete example of IP management for a new COVID-19 technology is seen in a vaccine candidate developed at Oxford University in the United Kingdom and licensed to an originator pharmaceutical company for manufacture. Development and manufacture are supported by US\$ 750 million in funding from the Coalition for Epidemic Preparedness Innovations (CEPI) (see below) and Gavi, the Vaccine Alliance. While exact contract terms are not public, the originator company has committed to supplying the vaccine globally on a no-profit basis and has signed an agreement with an Indian-based manufacturer allowing the latter to supply low- and middle-income countries.²⁸

 Socially responsible licensing: Chapter IV, section C.3(c)

International initiatives to support R&D of, and equitable access to, COVID-19 technologies

Since the outbreak 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 simultaneously address both R&D and access needs. Collaborative efforts include substantial investments in product development partnerships (PDPs) to support non-commercial development of a vaccine and large multi-stakeholder R&D initiatives.

Frameworks for urgent innovation to address pandemics: Chapter III, section C.3 and section E

The WHO Strategic Preparedness and Response Plan for 2019 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.²⁹ The WHO's 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".³⁰ Genetic sequences of viral samples are being shared openly, worldwide. Timely sharing of epidemiological and other data is also crucial.

- Sharing of health-related data: Chapter IV, section A.4(f)
- Access and benefit-sharing for genetic resources: Chapter II, section D and Chapter III, section E.4

To ensure efficiency in testing potential treatments, WHO launched the "Solidarity" clinical trial, which enrols patients in one single randomized trial to facilitate the rapid worldwide comparison of unproven treatments. As of 3 June 2020, more than 3,500 patients have been recruited in 35 countries, with over 400 hospitals actively recruiting patients. The WHO is facilitating access to thousands of treatment courses for the trial through donations from a number of manufacturers.³¹

UN General Assembly resolution A/RES/74/274³² 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 WHA73.1³³ 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".34 It also called for restrictions on the movement of medical equipment and medicines to be temporary and specific; for 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.

The WHO, together with a group of other global health actors, private sector partners and other stakeholders, has launched the Access to COVID-19 Tools (ACT) Accelerator, a collaboration to accelerate the development, production and equitable global access to new COVID-19 essential health technologies.³⁵

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. The Call has been endorsed by 39 other member states as well as other stakeholders. 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; 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.³⁷

To operationalize the Solidarity Call to Action, the COVID-19 Technology Access Pool (C-TAP), working through its implementing partners, will compile in a single compendium of commitments to voluntarily share COVID-19 health technology-related knowledge, IP and data.³⁸

Additionally, with the support of WHO and Unitaid, the Medicines Patent Pool has temporarily expanded its mandate to cover any COVID-19-related health technologies, including vaccines and diagnostics.³⁹

Patent pools in the area of health: Chapter III, section C.5(α)

The UN Tech Access Partnership, hosted by the UN Technology Bank, aims to support developing countries scale up local production of critical health technologies. It does so by facilitating connections between experienced manufacturers and local manufacturers in developing countries to share key data, knowledge and other relevant support through a coordinated network.⁴⁰

Manufacturing and technology transfer: Chapter IV, section A.10

The need for rapid development of new technologies has spurred unprecedented government investment in R&D. 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, diagnostics, treatments and vaccines against coronavirus.⁴¹ The 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.⁴²

The CEPI, a PDP created in the wake of the 2014 Ebola virus outbreak by philanthropies and a number of governments, has to date received US\$ 1.4 billion from governments for COVID-19-related work, an unprecedentedly large investment in a PDP.⁴³ CEPI requires that producers 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.⁴⁴

Product development partnerships: Chapter III, section C.6

To support research on COVID-19 as well as on future threats to health, Medicines for Malaria Venture (MMV) has compiled 80 compounds, including ones in development and marketed drugs that have a known or predicted

activity against SARS-CoV-2, in its "COVID Box". ⁴⁵ The MMV offers free access to the COVID Box for research purposes. Researchers who use it are expected to place any resulting data in the public domain.

Regulatory responses

Regulatory assessment and approval of health technologies are essential in every health system to ensure product quality, safety and efficacy. As an effective COVID-19 treatment has not yet been found, researchers are exploring the repurposing of older medicines, and "compassionate use" of medicines (clinical use before approval) is taking place in specific cases.

Regulation of health technologies: Chapter II, sections A.6 and D.3 and Chapter IV, section A.11

The WHO's Emergency Use Listing (EUL) procedure aims to streamline the process by which new or unlicensed products can be used during public health emergencies. 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. The EUL provides a time-limited listing for unlicensed products in an emergency context when limited data are available and products are not yet ready for application for WHO prequalification. The EUL is currently open to candidate in vitro diagnostics (IVDs) to detect SARS-CoV-2.46

WHO prequalification: Chapter IV, section A.11

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 of this publication.

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. An 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 to it 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, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.

Transparency in COVID-19 R&D and access initiatives is also an essential part of the WHO Solidarity Call to Action.

The WIPO COVID-19 IP Policy Tracker⁴⁸ 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, hence is 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.⁴⁹ It has issued a number of information notes and reports on trade in the context of COVID-19, including on trade in medical goods, transparency, export prohibitions and restrictions, the treatment of medical

products in regional trade agreements, standards and regulations, and trade in services.⁵⁰

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 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 this trilateral study is of relevance to the global response to COVID-19.

The Directors-General of the three organizations emphasized in the foreword to this study: "the COVID-19 pandemic has brought extraordinary challenges to peoples' health, economies and societies at large. Global collaborative efforts are required now more than ever before".

Endnotes

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