

THE TRIPS AGREEMENT AND COVID-19

INFORMATION NOTE¹

Key points

- A full response to the COVID-19 crisis requires wide access to an extensive array of medical products and other technologies, ranging from protective equipment to contact tracing software, medicines and diagnostics, as well as vaccines and treatments that are yet to be developed. The way in which the intellectual property (IP) system is designed – and how effectively it is put to work – can be a significant factor in facilitating access to existing technologies and in supporting the creation, manufacturing and dissemination of new technologies. This is framed by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) which represents the most comprehensive multilateral agreement on IP.
- Collaboration and cooperation among health technology developers, governments and other stakeholders can be positively supported by the IP system as well as by guidance on lawful cooperation among competitors under a country's domestic competition policy regime.
- From the beginning of the crisis, governments and stakeholders have considered how innovation is promoted, regulated and managed, including through the IP system, and the contribution that this could make to address the pandemic. A number of initiatives have addressed the voluntary sharing and pooling of IP rights (IPRs), thus responding to the spirit of collaboration that is required for any global effort to tackle the COVID-19 pandemic. Equally, a range of policy options confirmed under the TRIPS Agreement, as implemented in domestic law, remains available to WTO members as tools to deal with public health issues where needed.
- For example, the TRIPS Agreement allows compulsory licensing and government use of a patent without the authorization of its owner under a number of conditions aimed at protecting the legitimate interests of the patent holder. All WTO members may grant such licences and government-use orders for health technologies, such as medicines, vaccines and diagnostics, as well as any other product or technology needed to address COVID-19. One member has already issued a government-use licence for a potential treatment. In some other members, the parliament has requested the government to issue compulsory licences to ensure access to medicines, vaccines or diagnostics for COVID-19 and others have updated or clarified their laws in the light of the pandemic.
- The need for an urgent response to the COVID-19 pandemic has led national and regional IP offices to take initiatives to expedite or simplify their administration of the IP system, especially concerning patents and trademarks, and to provide practical support for firms seeking to develop products of potential benefit in combating the pandemic.
- Transparency and the availability of up-to-date information is an immediate and critical need that embraces both trade and health-related legal and policy areas. Ensuring maximum transparency of legal and policy measures taken by WTO members in the field of IP to address the pandemic is in the mutual interest of all stakeholders. It supports governments and economic operators to keep up to date in a rapidly evolving trade landscape, provides much-needed clarity and enables mutual learning. Updated lists of IP measures undertaken

¹ This document has been prepared under the WTO Secretariat's own responsibility as a factual overview and is without prejudice to the positions of WTO members or to their rights and obligations under the WTO.

by governments in the context of COVID-19 are available on the WTO's COVID-19 webpage² and the WIPO COVID-19 IP Policy Tracker.³

1 INTRODUCTION

This note sets out the role and key contributions that the global IP system, including its policy options and flexibilities as implemented in domestic law, can make to address COVID-19. It also provides an overview of measures taken by WTO members within this framework since the start of the crisis.

The WTO's TRIPS Agreement is the most comprehensive multilateral agreement on IP. It provides for certain basic principles (such as non-discrimination), situates the IP system in terms of promoting innovation and disseminating technology for the public's welfare, sets forth minimum standards of protection in respect of each of the areas of IP covered by the TRIPS Agreement, contains provisions that deal with domestic procedures and remedies for IP enforcement, and makes disputes between members about respect for TRIPS obligations subject to the WTO's dispute settlement procedures.

The global IP system provides a framework in which urgently needed innovation in relation to COVID-19 can be encouraged, shared and disseminated. Innovation in health can be seen as a cycle: it covers the stages from initial invention to the supply to the public of a product or service. Within a balanced IP system, the exclusive rights conferred by IPRs can serve as an incentive for investment at each stage of the innovation cycle, and as a mechanism for combining and trading in technology inputs from different sources. Policy choices with respect to the design and implementation of the IP system made at the regional and national levels, along with the management of IP, can also directly influence research and development (R&D) outcomes and access.

Article 7 of the TRIPS Agreement describes the objectives of the IP system in terms of a balance of rights and obligations. The objectives refer to the protection and enforcement of IPRs in a manner which contributes to "the promotion of technological innovation", "the transfer and dissemination of technology" to the mutual advantage of both "producers and users of technological knowledge", and also "social and economic welfare". Article 8 states that members may adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development that are consistent with the provisions of the TRIPS Agreement.

The Doha Declaration on the TRIPS Agreement and Public Health, a landmark declaration adopted at the WTO Ministerial Conference in 2001, reaffirmed the objectives and principles of the Agreement as guidance for the implementation of TRIPS provisions in a manner that is responsive to public health objectives. WTO members affirmed that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of Members' right to protect public health and, in particular, to promote access to medicines for all". The Doha Declaration also clarified certain policy options, or "flexibilities", within the framework of the TRIPS Agreement. It is thus a well-established principle that the TRIPS Agreement can be interpreted and implemented in line with public health policy objectives and that it provides wide latitude for members to take action to protect public health.

While much public health policy attention has focused on the patent system as a key element of the system for innovation and dissemination of medical technologies, other areas of IP covered by the TRIPS Agreement are also significant.⁴ Trade secrets and clinical trial data are subject to protection, and the way that this is applied by members can be critical in ensuring that new technologies are carried forward without overly burdening generic followers. A well-run trademark system has a valuable role in ensuring accurate information for medical practitioners and consumers, while safeguarding against potential confusion with critical terms such as the international non-proprietary

² www.wto.org/covid

³ www.wipo.int/covid19-policy-tracker

⁴ The delegations of South Africa and India have called for a holistic approach that takes account of TRIPS flexibilities in the area of patents, copyright, design rights and trade secrets. See the minutes of the TRIPS Council meeting held on 30 July 2020, WTO official document no. IP/C/M/95/Add.1 (all WTO official documents are available at <https://docs.wto.org/>); see also the Communication from South Africa on Intellectual Property and the Public Interest: Beyond Access to Medicines and Medical Technologies Towards a More Holistic Approach to TRIPS Flexibilities, WTO official document no. IP/C/W/666, and the Communication from South Africa and India on Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, WTO official document no. IP/C/W/669.

names that are used to identify pharmaceutical substances and ingredients. A balanced copyright system that takes due account of the interests of rights-holders and the public at large to access copyright-protected works can support R&D activities and enable the development of digital solutions to support diagnostics and treatment.

IP systems are only one element of the innovation cycle that includes the discovery, development and delivery of new health technologies. An integrated approach to respond to the COVID-19 pandemic implicates numerous policy areas, including tariffs and import licensing, government procurement, regulatory standards, health services and competition policy.⁵ A standalone section in the 2020 study jointly published by the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the WTO, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (second edition),⁶ on COVID-19 was added at the start of the publication to map the multiple challenges posed by the pandemic in relation to the integrated health, trade and IP policy frameworks set out in the study.

2 VOLUNTARY COLLABORATION

Most new health technologies entail the incorporation of multiple inputs from different sources. They must also be rigorously tested for safety and efficacy before being distributed to the public. In this light, collaboration and cooperation among health technology developers, governments and other stakeholders can be positively supported by the IP system.

IPRs generally take the form of a limited "exclusive" right granted under national law to a creator over the use of the creation for a certain period of time. This allows the right-holder to extract economic value from the IPRs by using them directly or by authorizing others to do so. For example, an owner of a patent can allow its use voluntarily with third parties through licensing agreements. A licence is a contract in which the patent-holder allows another party to use the IP, either in return for a payment of royalties (or some other consideration) or free of charge. The licence may be limited to a certain field of use or in a certain territory. It also allows the right-holder to exercise control over the quality of the production. Non-commercial players, such as academic institutions and philanthropic initiatives, have used patent licences to leverage specific public interest applications of their technology, thus not limiting licensing strategies to economic interests alone.

Where collaborative arrangements are taking place between firms that would normally compete against each other, competition policy and principles apply. The Organisation for Economic Co-operation and Development (OECD) recommends that governments provide guidance on lawful cooperation between competitors to maximize efficiencies in arrangements between competitors for the development of key health products (e.g. vaccines or essential drugs) on the one hand, and to ensure that relevant arrangements are limited in time and do not include hardcore restrictions on competition, such as price fixing, on the other hand.⁷ Where IP rights are involved, members may take appropriate measures against practices which unreasonably restrain trade or adversely affect the international transfer of technology in line with Article 8.2 of the TRIPS Agreement. Article 40 provides expressly for scope for members to address anticompetitive licensing practices.

Sharing IP and clinical trial data

The sharing of relevant IP and the exchange of clinical trial data can facilitate cooperation for research and development of COVID-19-related health technologies. In particular, it can help expedite the development, manufacturing and marketing of tests, treatments and vaccines. Many examples of action undertaken in support of such voluntary collaborative efforts have been witnessed by stakeholders, including governments, private sector actors and international bodies (see Box 1).

⁵ WTO reports related to COVID-19 and world trade are available at www.wto.org/covid.

⁶ https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm.

⁷ See OECD (2020), "COVID-19: Competition policy actions for governments and competition authorities," available at <https://www.oecd.org/daf/competition/COVID-19-competition-policy-actions-for-governments-and-competition-authorities.pdf>.

Box 1: Examples of voluntary collaborative efforts

Permissive licences to allow open access to design files and software for ventilators and transfer of know-how

Medtronic, a medical device company, made freely available the design specifications and software for their Puritan Bennett™ 560 (PB560) ventilator. It also launched the Ventilator Training Alliance to transfer know-how required for the use of ventilator technology.⁸

Non-enforcement or waiver of patent rights

AbbVie, a biopharmaceutical company, waived patent rights relating to lopinavir/ritonavir (LPV/r), a second-line treatment recommended by the WHO for the human immunodeficiency virus (HIV), being studied as a coronavirus treatment.⁹

Moderna, a company developing a messenger RNA vaccine against COVID-19 and holding a number of patents relevant to the vaccine, announced that it will not enforce those patents during the pandemic to allow other COVID-19 vaccines in development to use the technology. For the period after the pandemic, it also stated its willingness to license the company's intellectual property for COVID-19 vaccines to competitors upon request.¹⁰

Free global licences to use IP

Under the Open COVID Pledge, several multinational technology companies including Microsoft, Amazon, IBM, Intel, Hewlett Packard and Facebook, among others, have committed to grant time-limited licenses for some or all of their IP for the purposes of ending and mitigating the COVID-19 pandemic.¹¹

Sharing of IP to develop vaccines

A potential vaccine developed at Oxford University in the United Kingdom was 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), which finances independent research projects to develop vaccines against emerging infectious diseases, and Gavi, the Vaccine Alliance. The 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.¹²

Initiatives to transfer technology and know-how to make, adapt or use COVID-19-related technologies

The COVID-19 Clinical Research Coalition, a coalition of scientists, physicians, funders and policymakers, promotes open sharing of research knowledge and data and advocates for equitable and affordable access to COVID-19-related health technologies.¹³

Free access to COVID-19 publications protected by copyright

Over 30 publishers make their COVID-19 and coronavirus-related publications freely accessible in public repositories.¹⁴

Free availability of standards protected by copyright

The European Committee for Standardization and the European Committee for Electrotechnical Standardization, in collaboration with their members, agreed to make freely available certain copyrighted European standards for certain medical devices and personal protective equipment.¹⁵

⁸ <http://newsroom.medtronic.com/news-releases/news-release-details/medtronic-shares-ventilation-design-specifications-accelerate> and <https://www.medtronic.com/covidien/en-us/ventilator-training-alliance.html>.

⁹ <https://www.medspal.org/licence/?uuid=4e7317ed-ed68-4167-84c2-62309223fdb1>.

¹⁰ See Statement on Intellectual Property Matters During the COVID-19 Pandemic, 8 October 2020, <https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19>.

¹¹ <https://opencovidpledge.org/>.

¹² <https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-covid-19-vaccine.html>.

¹³ <https://covid19crc.org/>.

¹⁴ <https://wellcome.ac.uk/press-release/publishers-make-coronavirus-covid-19-content-freely-available-and-reusable>.

¹⁵ Further details, including links to official sources, are available at: https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm.

ASTM International, an international standards developing organization, is providing no-cost public access to some copyrighted ASTM standards used in the production and testing of personal protective equipment, including face masks, medical gowns, gloves and hand sanitizers.¹⁶

Open-source licensing and open access initiatives

During the health crisis, some IPR owners have turned to open-source licensing. This is the practice of licensing IPRs, possibly free of charge, for use by third-parties in commercial applications for a specific purpose, such as using, modifying or sharing the source code, blueprint or design, typically on the condition that any improvements that are developed are made available on the same terms (see Box 2).

Box 2: Examples of open-source or open-access initiatives

Open-source software for contact-tracing technology

Singapore has made copyrighted software related to a contact-tracing solution for COVID-19 freely available under an open-source licence.¹⁷

Open-source hardware to resolve supply-chain weaknesses

Open-source hardware projects include testing material, open lung ventilators, etc.¹⁸

Open access to research results

Medicines for Malaria Venture created the COVID Box, which contains a set of 80 marketed drugs or compounds in development with known or predicted activity against COVID-19 in research publications. Recipients of the Box will be asked to publish their findings in the public domain.¹⁹

Technology pools

Solutions for pooling technologies have found increased attention during the COVID-19 pandemic. A technology pool is an agreement between at least two IPR owners to group their rights relating to a specific technology and to license the rights to use these rights to each other and to third parties, subject to certain conditions, such as the payment of royalties.

The Solidarity Call to Action, signed by the WHO Director-General and the President of Costa Rica on 29 May 2020 and initially endorsed by nearly 40 WHO member states, calls upon governments and other key stakeholders to pool knowledge, IP and data relevant for the development of medicines, vaccines and diagnostics to combat COVID-19.²⁰ To operationalize the Solidarity Call to Action, the COVID-19 Technology Access Pool (C-TAP) will compile pledges of commitment made under the Solidarity Call to Action to voluntarily share COVID-19 health technology-related knowledge, IP and data. To do so, it collaborates with existing mechanisms, such as the Medicines Patent Pool (see Box 3).²¹

Box 3: Example of a technology pooling initiative

The Medicines Patent Pool (MPP) was established in 2010 by Unitaid, a global health initiative, as a public health patent pool. The MPP negotiates IP licence agreements with patent-holding pharmaceutical companies, wherein the patent-holder allows the MPP to grant sublicences to manufacturers in low and middle-income countries to make and sell generic versions in a certain territory. The MPP's mandate was initially focused on HIV, then expanded to include tuberculosis (TB) and hepatitis C, and, in 2018, was expanded to include patented essential medicines more broadly.²²

¹⁶ <https://www.astm.org/COVID-19/>.

¹⁷ <https://bluetrace.io/>.

¹⁸ <https://opensource.com/article/20/3/open-hardware-covid19>.

¹⁹ <https://www.mmv.org/mmv-open/covid-box/about-covid-box>.

²⁰ <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool/solidarity-call-to-action>

²¹ <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool>.

²² <https://medicinespatentpool.org/who-we-are/strategy/>.

On 3 April 2020, MPP's Board decided to temporarily expand MPP's mandate to include any health technology that could contribute to the global response to COVID-19 and where licensing could facilitate innovation and access.²³

3 GOVERNMENT ADMINISTRATIVE OPTIONS

Acquisition and maintenance under the TRIPS Agreement

Some IPRs – notably patents, trademarks and registered designs – are only granted after going through administrative procedures such as examination. The TRIPS Agreement establishes general principles concerning the acquisition and maintenance of such IPRs. Part IV of the Agreement is to ensure that unnecessary procedural difficulties in acquiring or maintaining IPRs do not impair protection if and when required by the Agreement. It provides (in Article 62) that compliance with reasonable procedures and formalities may be required for the acquisition and maintenance of IP rights, and that these should not be too costly or protracted. But neither the TRIPS Agreement nor the Paris Convention²⁴ mandates specific procedures or lays down detailed procedural requirements. As a result, members have room to manoeuvre in developing an approach to IPR acquisition and maintenance procedures tailored to their specific needs and circumstances.

Within this framework, national and regional IP offices have taken initiatives to expedite or simplify their administration of the IP system, especially concerning patents and trademarks, and to provide practical support for firms seeking to develop products of potential benefit in combating the pandemic.

Patent examination or application procedures

Some IP or patent offices have expedited the patent examination process of inventions that contribute to a public policy objective. The goal of accelerated patent examination procedures, or so-called "fast-track" procedures, is to facilitate the development and eventual dissemination of certain types of technology, such as technologies with healthcare impacts.

Some members have adopted accelerated patent examination or fee deferral or waiver procedures for COVID-19-related technologies (see Box 4).

Box 4: Example of patent examination or application procedures²⁵

In **Brazil**, under Ordinance (Portaria, in Portuguese) No. 149/2020, the Brazilian National Institute of Industrial Property (INPI) will prioritize the examination of patent applications related to innovations that can be used to fight COVID-19 from 7 April 2020 to 30 June 2021.

In the **United States**, the United States Patent and Trademark Office (USPTO) launched the COVID-19 Prioritized Patent Examination Pilot Program, under which it will grant requests for prioritized patent examination for applicants which qualify for small and micro-entity status with respect to applications that cover a product or process that is subject to US Food and Drug Administration (FDA) approval for use in the prevention and/or treatment of COVID-19. The USPTO has also implemented a deferred-fee provisional patent application pilot programme and collaboration database to promote the expedited exchange of information about inventions designed to combat COVID-19. Under this programme, the USPTO permits applicants to defer payment of the provisional application filing fee until the filing of a corresponding non-provisional application. In turn, applicants must agree that the technical subject matter disclosed in their provisional applications will be made available to the public via a searchable collaboration database maintained on the USPTO website.

In the **Russian Federation**, a Decision of the Russian Federal Service was taken for IP on accelerated consideration of applications for inventions and utility models in the field of technologies for combating viruses and associated diseases (such as pneumonia) without charging an additional fee.

²³ <https://medicinespatentpool.org/what-we-do/our-work/covid-19/>.

²⁴ The TRIPS Agreement incorporates by reference provisions of various WIPO-administered IP treaties, including Articles 1 to 12 and Article 19 of the Paris Convention for the Protection of Industrial Property (1967).

²⁵ Further details, including links to official sources, are available at: https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm.

Trademark examination or application procedures

According to Article 15.1 of the TRIPS Agreement, any sign, or any combination of signs, capable of distinguishing the goods and services of one undertaking from those of other undertakings must be eligible for trademark protection. Article 15.2 recognizes that members may also refuse the registration of a trademark in their territory on grounds other than those addressed in Article 15.1 – for example, lack of distinctiveness or contrary to morality or public order, provided they do not derogate from the provisions of the Paris Convention.

To monitor COVID-19-related trademark applications, some members have introduced guidance for IP offices. Other members are offering assistance to trademark registration applicants (see Box 5).

Box 5: Example of trademark examination procedures²⁶

In **Australia**, the Trade Mark COVID-19 Helpline supports and assists small to medium Australian businesses that are having to quickly adapt to changing circumstances due to COVID-19 in exploring use of their trade mark/s on different goods and services to those currently covered under the respective trademark application or registration.

In **China**, the Notice of the Office of the State Intellectual Property Office (SIPO) on Strictly Fighting the Act of Acting on Abnormal Trademark Application Related to the New Coronary Pneumonia Epidemic Guozhiban Hanyunzi [2020] No. 149 introduced guidance to increase the monitoring or investigation of certain trademark applications related to COVID-19.²⁷

SIPO statistics reportedly show that more than 1,500 trademark applications pertaining to COVID-19 have been received since the beginning of the pandemic.²⁸

In **Chinese Taipei**, to help companies to apply quickly for trademark registration while lowering marketing risks, the IP office has produced a list of the names of pandemic prevention products and services and is offering a fee reduction with respect to trademark applications which designate goods or services identical to those on the list. In addition, the IP office launched a trademark consultation hotline in order to assist applicants with trademark searches.

In the **United States**, the USPTO launched the Prioritized Examination Program for certain trademark and service mark applications, which allows COVID-19-related trademark applications to be prioritized and immediately assigned for examination.

IP office measures to ease requirements

Some members have taken measures to ease procedural requirements, deadlines or fees with respect to administrative IP matters. Generally, such measures appear to have been taken into account any difficulties caused by COVID-19 which applicants, right-holders or other stakeholders may encounter. Examples of measures that have been taken include extending deadlines, organizing hearings through videoconferencing, waiving fees or requiring an original handwritten signature. WIPO is tracking the measures taken by IP offices in certain jurisdictions within its COVID-19 IP Policy Tracker.²⁹ In addition, some of those measures are listed on the WTO's COVID-19 webpage³⁰ and mentioned in the 2020 WTO Trade Monitoring Report, which gathers together information on trade-facilitating and trade-restricting measures introduced by WTO members.³¹

²⁶ Further details, including links to official sources, are available at:

https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm.

²⁷ http://www.gov.cn/zhengce/zhengceku/2020-03/06/content_5488018.htm and <http://english.sipo.gov.cn/news/localipinformation/1146950.htm>.

²⁸ See <https://news.cctn.com/news/2020-04-23/Can-COVID-19-related-terms-be-registered-as-trademarks--PVvkAFu968/index.html>.

²⁹ <http://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/ipo-operations> and https://www.wipo.int/about-wipo/en/offices/singapore/news/2020/news_0003.html.

³⁰ https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm.

³¹ https://www.wto.org/english/tratop_e/tpr_e/trade_monitoring_e.htm (e.g. see pages 111-115 of WTO official document no. WT/TPR/OV/W/14).

4 GOVERNMENT POLICY OPTIONS

The global IP system as a framework for innovation and technology diffusion

The way in which the IP system is designed – and how effectively it is put to work – can be a significant factor in facilitating access to existing technologies and in supporting the creation, manufacturing and dissemination of new technologies. The policy choices made at the regional and national levels within the international legal framework are key to incentivizing research and development (R&D) investments, collaboration and outcomes, as well as to securing access to treatments, diagnostics, vaccines and other health technologies.

The initiatives for voluntary sharing and pooling of IPRs represent one set of responses to the spirit of collaboration that dominates the global effort to tackle COVID-19. Equally, a range of policy options confirmed under the TRIPS Agreement, as implemented in domestic law, remain available to WTO member governments as tools to deal with public health issues where needed. This section reviews these options, which are available already in the laws of most WTO members.

Exceptions to patent rights

Patent rights are not absolute, and it is well established that they can be constrained by policy considerations and the broader public interest. For instance, in the absence of voluntary collaboration, patent exceptions and limitations define to what extent proprietary technologies can be used by others for research or the development of compatible products, and thus often determine to what extent existing technologies can be used for further innovation.

Article 30 of the TRIPS Agreement states that members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Two types of TRIPS Article 30 exceptions to patent rights which may be of particular relevance in the context of the current health crisis are the research and experimental use exception and the regulatory review (or "Bolar") exception.³²

The research exception or experimental use exception is one of the most commonly used types of exceptions to national patent laws pursuant to Article 30 of the TRIPS Agreement. Under this exception, use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement. This exception enables researchers to examine the patented inventions and to conduct research on improvements without having to fear that they are infringing the patent.

Another key exception to patent rights, confirmed in TRIPS dispute settlement practice, is the regulatory review (or "Bolar") exception.³³ It allows potential competitors to use a patented invention during the patent term without the consent of the patent owner for the purpose of obtaining marketing approval for a prospective generic product. Because marketing approval may take several years, the inability to use the patented invention during the approval process, prior to patent expiration, would delay market entry of generic versions. The regulatory review exception mitigates this situation by entitling use of a patented invention during the patent term without the consent of the patent holder for the purposes of developing information to obtain marketing approval. In the context of COVID-19, this may be important in cases where the term of patent protection of possible treatments is approaching expiry.

³² Further details regarding certain aspects of national or regional patent laws are available at https://www.wipo.int/patents/en/topics/exceptions_limitations.html and https://www.wipo.int/scp/en/annex_ii.html (hyperlink not enabled) and <https://www.wipo.int/scp/en/>.

³³ Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, adopted on 7 April 2000, DSR 2000:V, page 2,289.

Compulsory or government-use licences

The role of compulsory or government-use licences to address COVID-19

The TRIPS Agreement allows compulsory licensing as part of the Agreement's overall balance between promoting access to existing technologies and promoting research and development into new technologies. Article 31 of the Agreement allows compulsory licensing and government use of a patent without the authorization of its owner under a number of conditions aimed at protecting the legitimate interests of the patent-holder. Patent-owners are, in principle, entitled to receive remuneration. The option to grant a compulsory licence under Article 31 for the purpose of manufacturing or import is available to all members. While there has been particular attention paid to use of compulsory licensing for pharmaceuticals, it applies to patents in any field. All members may grant such licences for health technologies, such as medicines, vaccines and diagnostics, as well as any other product or technology needed to combat COVID-19.

To be prepared to respond to the pandemic, some members have eased procedures to grant compulsory or government use licences (see Box 6). One member has issued a government use licence for a potential treatment. In some other members, the parliament has requested the government to issue compulsory licences to ensure access to medicines, vaccines, or diagnostics for COVID-19. Compulsory licensing may serve as a useful policy tool to increase access to eventual treatments or vaccines for COVID-19, in particular in situations in which from a member's perspective access to affordable health technologies in sufficient quantities cannot be otherwise secured.

Box 6: Examples of members which have undertaken actions relating to compulsory licences for COVID-19-related technology³⁴

Bill C-13 amends **Canada's** Patent Act to empower the Commissioner of Patents, on the application of the Minister of Health, to authorize the Government of Canada or another specified person to supply a patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern. These amendments include safeguards to protect the interests of patent-holders; for example, ensuring that a patent-holder receives adequate remuneration for the use of the patent, placing limitations on the duration of the authorization, providing the patent-owner with notice of the authorization, and ensuring that the patent-owner has recourse to the courts if any person authorized acts outside the scope of the authorization.

Germany passed amendments to the German Act on the Prevention and Control of Infectious Diseases in Humans. Among other things, it authorizes the Ministry of Health to issue use orders in the context of an epidemic situation of national importance with respect to patented inventions related to medical products.

Hungary declared special legal order (State of Danger). During this period, the government may adopt decrees by means of which it may, as provided for by a cardinal Act, suspend the application of certain Acts, derogate from the provisions of Acts and take other extraordinary measures.

The Government Decree 212/2020 (16 May) on public health compulsory licences for exploitation within Hungary (hereinafter mentioned as Government Decree 212/2020), based on Article 31 of the TRIPS Agreement, created a public health compulsory licence for exploitation within Hungary.

The special legal order (State of Danger) was terminated on 18 June 2020, and thus Government Decree 212/2020 ceased to have effect on that day.

On 18 March 2020, **Israel's** Minister of Health issued a permit allowing the government to import generic versions of lopinavir/ritonavir from India for the purpose of exploring the possibility of treating COVID-19 patients.

Regarding the basis for a compulsory or government use licence, the TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing and thus leaves members the freedom to define the grounds for issuing a compulsory licence. Many laws include national emergency as one of the grounds for issuing a compulsory licence. A number of members

³⁴ Further details, including links to official sources, are available at: https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm.

have declared a national emergency in the context of the COVID-19 pandemic. For example, the patent law in New Zealand includes national emergency as grounds for the issuance of a government use licence. On 25 March 2020, New Zealand declared a nationwide state of emergency.

Special compulsory licensing for export

First introduced in 2003 by means of a waiver decision and now permanently incorporated in Article 31*bis* of the amended TRIPS Agreement, the Special Compulsory Licensing System has been conceived to facilitate access to affordable medicines for countries that rely on import of medicines to deal with a public health problem. For this purpose, it removes the condition in Article 31(f) that a compulsory licence be predominantly used for the supply of the domestic market. The trade-related compulsory licence under the Special Compulsory Licensing System is specifically designed to enable export to countries that are especially dependent on imports for medicines. It ensures a legal pathway for a country to permit the manufacturing of patented medicines under compulsory licence exclusively for export to countries with insufficient or no local manufacturing capacities in the pharmaceutical sector.

All members may export medicines under the Special Compulsory Licensing System. Least-developed countries are automatically entitled to import under the system, and other countries can import by giving a simple notification. A number of industrialized countries elected not to use the system for imports.³⁵ Several other members have said they would use it only for imports in situations of national emergency or other circumstances of extreme urgency. These positions were put on record at the time the system was established.

As set out in the amended TRIPS Agreement, the Special Compulsory Licensing System covers pharmaceutical products, including medicines, vaccines and diagnostics, needed to address public health problems as set out in the Doha Declaration on the TRIPS Agreement and Public Health. Because of the wide range of products covered, the system therefore has potential as one tool among others in ensuring equitable access to COVID-19-related health technologies. As a mechanism designed to facilitate trade to countries in need, it can serve as a practical platform for WTO Members to strengthen their cooperation on facilitating affordable access to medical products by the most vulnerable countries.

The System addresses a specific problem identified in the Doha Declaration: a member (importing member) lacks a specific patented pharmaceutical product, which cannot be produced locally, and hence has to be imported from a generic producer in another member (exporting member); the product is subject to patent protection in the exporting member; and thus there is a need to issue a compulsory licence in the exporting member enabling generic producers to manufacture the product exclusively for export to the importing member. Because of the plurality of development pipelines and the wide range of national needs and circumstances, it is very difficult to speculate in advance whether or when this specific problem would arise in relation to COVID-19 medical treatments and vaccines which are currently under development.

Nevertheless, as indicated in the Doha Declaration itself, the very purpose of the system is to enable vulnerable countries to make "effective use" of compulsory licensing. The very identification of the potential for the system's use may be helpful in facilitating access, whether a compulsory licence is ultimately issued or exercised in any particular procurement scenario. As with conventional compulsory licensing, the system serves as a reminder that patent rights are not absolute and that public interest considerations can prevail.

One way for a member to use this system would be for it to send a simple, brief notification to the WTO Secretariat of its expected requirements at a very early stage in its procurement of a COVID-19 vaccine or treatment; this would open up the widest possible range of potential suppliers, including through the System, if that was the avenue that yielded the preferred access to affordable and sustainable supply of the vaccine or treatment.

³⁵ Footnote 3 of the Annex to the Amended TRIPS Agreement https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm#fnt-3 and footnote 3 of the 2003 waiver decision https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm. It should be noted that the option to grant a standard compulsory licence under Article 31 is available to all members for the purpose of local manufacturing or import.

Policy options and flexibilities regarding other IPRs

As mentioned in the introduction, the role of policy options in other areas of IP rights has also been raised in discussions about IP and COVID-19.³⁶

Copyright

Copyright, like other forms of IP, has to consider the balance between the rights of authors and owners and the larger public interest. Copyright provides exceptions and limitations that allow access to those works under certain special cases. Both copyright, on the one hand, and exceptions and limitations to copyright, on the other hand, are of particular importance when considering the question of access to medical technology and innovation. To aid responses to the COVID-19 pandemic, some copyright-holders have taken action to make copyright-protected content freely available to help address the pandemic.³⁷

Article 13 of the TRIPS Agreement permits limitations or exceptions to copyright if they are confined to certain special cases; they do not conflict with a normal exploitation of the work; and they do not unreasonably prejudice the legitimate interests of the right-holder. In the context of health technology development, text and data mining (TDM) exceptions to copyright, for example, can be an invaluable technique for researchers to develop new technologies in health care. A company may apply technology to analyse thousands of molecules that might serve as drug candidates and predict their suitability for blocking the mechanism of a pathogen, or to mine large data sets of genetic information and medical records to identify linkages between genetic mutations and disease. New research techniques and diagnostic methods that involve TDM can be developed, due to the application of balanced copyright flexibilities for the development of medical innovations.

Trademarks

The trademark rules under the TRIPS Agreement also aim to provide for a balance between the rights of trademark-owners and the public interest. Article 17 of the TRIPS Agreement provides that members may provide for exceptions to the rights conferred by a trademark, provided that such exceptions are limited; take account of the legitimate interests of the owner of the trademark and of those third parties. Article 17 cites "fair use of descriptive terms" as an illustrative example of a limited exception.

Industrial designs

The protection of industrial designs, which are generally understood to refer to the ornamental or aesthetic aspect of an article rather than its technical features, may apply to a wide variety of products in the health industry. According to Article 26.2 of the TRIPS Agreement, exceptions to the rights conferred on the owner of industrial designs are allowed if these are limited, do not unreasonably conflict with the normal exploitation of protected industrial designs, and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking account of the legitimate interests of third parties. Some members' laws provide for exceptions such as private use, use for experimental or teaching purposes or prior use of a protected design.

Clinical trial data and undisclosed information

Access to clinical trial data can be particularly relevant to the development and marketing of COVID-19 critical health technologies. Article 39.3 of the TRIPS Agreement requires WTO members to protect such data against unfair commercial use and disclosure, subject to certain conditions. It also provides for an exception to the obligation to protect such data against disclosure when this is necessary to protect the public interest. This may be included in domestic laws implementing the TRIPS Agreement.

Finally, companies may hold trade secrets that are important for the use of COVID-19-relevant technologies. WTO members are required to protect undisclosed information as defined in Article 39.1 of the TRIPS Agreement. Consequently, trade secrets are protected by a wide range of legal

³⁶ See references in footnote 4.

³⁷ See Box 1 above.

instruments in WTO members. While these are diverse in character, they typically allow for exceptions to protect the public interest.

5 TRANSPARENCY

Transparency of IPR measures

As part of a longstanding transparency exercise in which the WTO Secretariat compiles regular reports on trade-facilitating and trade-restricting measures introduced by members of the G20 as well as by the WTO membership as a whole, the WTO Secretariat has compiled a list of measures regarding trade-related IPRs taken in the context of COVID-19 which is regularly updated. All the measures listed have been verified by the members concerned. Some members have also notified such measures to the TRIPS Council. The regularly updated, non-exhaustive [list of IP measures](#) is available on the WTO's COVID-19 webpage.³⁸ TRIPS notification requirements and how to access information submitted by members in a searchable database have been set out in the WTO [Information Note on Transparency – Why It Matters in Times of Crisis](#).

Transparency of IPR information

Easy access to patent documents for inventions related to the prevention, detection and treatment of COVID-19 may facilitate R&D and the dissemination of new innovations. For instance, scientists, industry, universities and other stakeholders working on developing technology for combating COVID-19 may use patent documents to determine how to build on existing technology. Additionally, easy access to such information may facilitate the procurement of COVID-19-related health technologies.

Sufficient disclosure of an invention is required in order to grant a patent. Article 29.1 of the TRIPS Agreement sets out the rule that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. The information disclosed in the patent application may form the basis for patent landscapes (i.e. a snapshot of the patent situation at a given point in time, either within a given country or region, or globally) or patent document databases that can facilitate strategic research planning, investments, collaboration, technology transfer, the production of generics and procurement.

The COVID-19 pandemic has given rise to a number of information-sharing initiatives facilitating access to patent information relevant to COVID-19-related technologies (see Box 7).

Box 7: Examples of information-sharing initiatives³⁹

Member countries of the Forum for the Progress and Development of South America (PROSUR) published reports of certain health technologies related to COVID-19. In addition, some PROSUR member countries, such as Argentina, Brazil, Colombia and Ecuador, have published patent landscapes with respect to COVID-19-related technologies, such as diagnostics and ventilators.

In **Chile**, as a way to collaborate in the effort to contain the expansion of COVID-19, the National Institute of Industrial Property (INAPI) prepared special editions of its reports on public domain technologies focused on elements for personal protection (face masks, safety goggles and gloves) designed to mitigate contagion.

In **Ecuador**, the National Service for Intellectual Rights (SENADI) prepared an "Infosite on Technologies" used for the treatment and prevention of COVID-19. The Infosite contains government measures and official information issued by national institutions within the scope of their respective authorities as well as sanitary measures that have been adopted as a result of the emergency declaration in Ecuador. In addition, it provides information generated internationally on COVID-19 contained in dissemination platforms and technological bulletins prepared by international organizations and other national IP offices. The Infosite is constantly updated with information of interest to users.

³⁸ A non-exhaustive list of measures regarding COVID-19 and trade-related IPRs, including measures collected by the WTO Secretariat and provided by members, is available at: https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm.

³⁹ Further details, including links to official sources, are available at: https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm.

In **Greece**, two bulletins were made available to the public via the Hellenic Industrial Property Organisation's website containing published patented medical technology related to vaccines and diagnostic methods and 3D printing patented technology for facial masques and respirators.

In the **Republic of Korea**, the Korean Intellectual Property Office has made available patent information on technology relating to the diagnosis and treatment of COVID-19, including patent analysis and trend reports.

In the **Russian Federation**, a special news section – "Patent of the week" – was created on the official internet site of the Russian Federal Service for Intellectual Property to promote inventions which represent technical solutions related to the fight against COVID-19. Additionally, there is a dedicated section of the website which contains information on patents relevant in the context of a pandemic (patent documents submitted by both domestic and foreign right-holders).

Some members have launched databases specific to COVID-19 patent information. For example, the China Patent Information Center launched a freely accessible database for various coronavirus-related patents.

Other members have undertaken efforts to facilitate the licensing of COVID-19-related technology. For example, the USPTO has launched a website called Patents 4 Partnerships, which lists patents and published applications relating to COVID-19 that the owners have indicated are available for licensing, along with contact information.⁴⁰

In addition, WIPO has established a COVID-19 search facility within its global PATENTSCOPE database, which provides access to international Patent Cooperation Treaty (PCT) applications and to patent documents of participating national and regional patent offices, to identify technological areas relevant to the detection, prevention and treatment of COVID-19.⁴¹ The WIPO Pearl terminology database has added 1,500 COVID-related terms in 10 languages with the aim of fostering international collaboration and promoting access to information in patent documents and other public resources.⁴² The European Patent Office⁴³ and a number of national patent authorities have developed similar search facilities. For example, in Chinese Taipei, the IP office has established a pandemic prevention section in its Global Patent Search System which enables users to find patent information relating to epidemic prevention. In addition, the office has released patent information relating to mask-producing facilities and technologies around the world in order to help prevent patent infringement by producers, and has released drug approval status and patent information of 52 potential medications for combating COVID-19.

MedsPal, the Medicines Patent Pool's publicly available patents and licences database, promotes transparency regarding the patent status and licensing structures of medicines as well as the protection of clinical trial data.⁴⁴ Initially limited to patented medicines needed to treat HIV/AIDS (acquired immune deficiency syndrome), hepatitis C and tuberculosis, and other essential medicines, it now includes patent information for medicines under investigation for possible treatment of COVID-19.

⁴⁰ Further details, including links to official sources, are available at: https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm.

⁴¹ <https://patentscope.wipo.int/search/en/covid19.jsf>.

⁴² https://www.wipo.int/pressroom/en/articles/2020/article_0021.html.

⁴³ See <https://www.epo.org/news-events/in-focus/fighting-coronavirus.html>.

⁴⁴ <https://www.medspal.org/?page=1>.