The unprecedented global pandemic caused by the novel coronavirus known as COVID-19 has challenged the health systems in both developed and developing countries. All countries have the necessity to rapidly scale up the production and procurement of products such as pharmaceuticals, personal protective equipment (PPE), testing kits, CT scanners, and ventilators. Accelerating innovation of medicines for the treatment of COVID-19 as well as vaccines for worldwide immunization against COVID-19 is also a critical need that has been recognized by the international community. Strengthening local production of medicines and vaccines for COVID-19 is also urgently required in developing countries. Though no medicine or therapy has been

Abstract

The rising incidence of COVID-19 will require all countries, particularly developing and least developed countries, to be able to procure and manufacture the products required for the diagnosis, prevention and treatment of COVID-19. Intellectual property (IP) rights over such products can constrain the ability of countries to rapidly procure and produce and supply the products required at a mass scale. This Policy Brief describes the measures and actions taken by different countries to address potential IP barriers to access to the products required for COVID-19. A number of countries, both developed and developing, have adopted measures to enable governments to take action to overcome IP barriers in case they constrain access to the products required for COVID-19. In addition to these measures, the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) also allows considerable flexibility to adopt a number of other possible measures which can be considered by developing countries where necessary.

En raison de l’incidence croissante de la COVID-19 tous les pays, en particulier les pays en développement et les pays les moins avancés, doivent pouvoir se procurer et fabriquer les produits nécessaires au diagnostic, à la prévention et au traitement de la maladie. Les droits de propriété intellectuelle sur ces produits peuvent limiter la capacité de ces pays à se les procurer, à les produire et à les fournir rapidement et à grande échelle. La présente note de synthèse décrit les mesures et les actions prises par différents pays pour lever les obstacles potentiels liés aux règles relatives à la propriété intellectuelle qui entravaient l’accès aux produits nécessaires pour lutter contre la COVID-19. Un certain nombre de gouvernements des pays développés et des pays en développement ont adopté diverses mesures afin de faciliter la mise en œuvre des actions nécessaires pour surmonter les obstacles liés à la propriété intellectuelle dans le cas où ils auraient pour effet de limiter l’accès aux produits essentiels au traitement des patients atteints de la COVID-19. En plus de ces mesures, l’Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC) de l’Organisation mondiale du commerce (OMC) offre également une grande souplesse dans l’adoption d’un certain nombre d’autres mesures qui peuvent être envisagées par les pays en développement en cas de besoin.

El aumento de la incidencia del COVID-19 requerirá que todos los países, en particular los países en desarrollo y los países menos desarrollados, puedan adquirir y fabricar los productos necesarios para el diagnóstico, la prevención y el tratamiento del COVID-19. Los derechos de Propiedad Intelectual (P.I.) sobre tales productos pueden limitar la capacidad de los países de adquirir, producir y suministrar rápidamente los productos necesarios a gran escala. En este Informe de Políticas se describen las acciones y medidas adoptadas por los distintos países para hacer frente a los posibles obstáculos de P.I. para acceder a los productos necesarios para el COVID-19. Varios países, tanto desarrollados como en desarrollo, han adoptado medidas para permitir a los gobiernos tomar acciones para superar los obstáculos que se presenten en relación con la P.I. en caso de que ésta limite el acceso a los productos necesarios para el COVID-19. Además de estas medidas, el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC) de la Organización Mundial del Comercio (OMC) también permite una flexibilidad considerable para adoptar una serie de otras medidas posibles que pueden ser consideradas por los países en desarrollo cuando sea necesario.

* Nirmalya Syam is Senior Programme Officer of the Health, Intellectual Property and Biodiversity (HIPB) Programme of the South Centre.
Intellectual Property, Innovation and Access to Health Products for COVID-19: A Review of Measures Taken by Different Countries

invented or discovered yet as a definitive cure for COVID-19, some existing medicines that have been beneficial in some cases are being repurposed for the treatment of COVID-19. Several are part of a Solidarity Trial by the World Health Organization (WHO).\(^5\)

Intellectual Property (IP) rights can potentially impede the mass production of existing health products such as PPEs, testing kits, ventilators, etc. that are necessary for the treatment of the massive numbers of patients infected by COVID-19, as well as innovation and research and development. IP rights can be exercised by their owners to decide on whether to grant a license or withhold from licensing the technology, designs and knowhow required for manufacturing or for further developing the products required for COVID-19. In case the IP owner declines to grant a license, the technology will not be available for other firms to manufacture or supply unless specific legal measures are taken by governments to overcome such constraints. Moreover, usually several IP rights, like a bundle of primary and secondary patents, exist around a particular technology, which makes it difficult for follow on innovators to invent around the thicket of IP rights without risking the possibility of encountering IP infringement litigations from right holders, thus discouraging follow on innovation by third parties.\(^6\)

Thus, though representatives of the multinational pharmaceutical industry such as the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) have expressed skepticism about IP acting as a barrier to innovation and access,\(^7\) the member States of the WHO have recognized the possible need for countries to adopt measures to ensure that IP rights do not constrain global equitable access to health technologies for COVID-19 through the full use of the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)\(^8\) as well as voluntary pooling of patented technologies, data and knowhow.\(^9\) In spite of the call for global solidarity as well as voluntary pledges of cooperation by IP rights holders, the possibility of exploiting IP rights to profit from the crisis remains.\(^10\)

Indeed, there have been instances where patent infringement proceedings have been initiated or transfer of technical designs have been denied to third parties manufacturing IP protected products to meet the demand in the context of COVID-19.\(^11\) Italian volunteers who sought to manufacture ventilator valves through 3D printing technology were denied access to the designs of some ventilators’ components, forcing them to engage in reverse-engineering.\(^12\) In the United States (US), the Governor of the State of Kentucky admitted to difficulties in procurement and manufacturing N-95 masks owing to several patents related to the same.\(^13\) Patents on critical enzymes may also restrict development of testing kits.\(^14\) Trade secrets may also restrict access to health technologies required to respond to COVID-19 as experienced in the Netherlands with regard to access to critical components required to perform diagnostic tests.\(^15\)

**Flexibilities Available under the TRIPS Agreement**

A number of flexibilities are available under the TRIPS Agreement which can be applied by governments to ensure that IP rights do not constrain innovation and availability of health technologies required for responding to COVID-19. These measures include application of rigorous patentability requirements, use of exceptions and limitations including the research and security exceptions, grant of compulsory licenses or government use authorization, use of the transitional waivers for least developed countries (LDCs), parallel importation, and ensuring fair procedures for the enforcement of IP rights.\(^16\)

**National Measures Taken by Countries**

A number of varied measures\(^17\) can be taken to ensure that IP rights do not create barriers to access to technology and products for COVID-19. To date, the national measures that have been adopted by different countries largely focus on measures enabling ministries of health to grant compulsory licenses or government use autorizations,\(^18\) with some countries also offering indemnity against IP infringement proceedings, and use of competition law.

**Compulsory Licensing and Government Use Authorization**

A number of countries have enacted specific laws or issued parliamentary resolutions that authorize or call upon the government to issue compulsory licenses or government use authorization for health products related to COVID-19. However, apart from Israel, no other country has so far issued a compulsory license or government use authorization to secure access to a health product for COVID-19.

**Canada:** On 25 March 2020, Canada enacted the COVID-19 Emergency Response Act,\(^19\) which allows the government to issue a compulsory license without first negotiating with the rights holder, or establishing its own ability to supply a product, and the patent holder is only entitled to receive an amount as remuneration instead of a compensation. While the Commissioner of Patents has the discretion generally under the Canadian patent law to grant a government use authorization on the application of the government, the Emergency Response Act has removed this discretion and mandates the Commissioner of Patents to grant such authorization upon the application of the Ministry of Health.

This law will be in force till 30 September 2020. However, any government use authorization granted during this period by the Commissioner of Patents upon the application of the Ministry of Health will remain in force for one year or for a lesser term if the Minister of Health notifies that the authorization is no longer necessary.

**Chile:** On 17 March 2020, the parliament of Chile adopted Resolution No. 896 declaring that the global coronavirus...
outbreak justifies the use of compulsory licensing to facilitate access to vaccines, drugs, diagnostics, devices, supplies, and other technologies useful for the surveillance, prevention, detection, diagnosis and treatment of the coronavirus in Chile.20

**Germany:** On 25 March 2020, Germany adopted the Prevention and Control of Infectious Diseases in Humans Act,21 which authorized the ministry of health to issue government use authorization under the patent law, upon the declaration of a national epidemic by the lower chamber of the German federal legislature (Bundestag). Such authorization by the ministry of health was made applicable to medical products including active ingredients, starting materials and excipients for medicines, medical devices, laboratory diagnostics, aids, items of personal protective equipment and products for disinfection. The law will expire on 31 March 2021.22

**Israel:** On 20 March 2020, Israel issued a government use authorization under the Israeli patent law for the importation of generic lopinavir/ritonavir combination for the treatment of COVID-19 patients from an Indian generic company by a local company acting on behalf of the ministry of health.23

It is noteworthy from the above instances that only two developed countries (Canada and Germany) very rapidly adopted legal measures to enable the government to issue compulsory licenses for government use for COVID-19, by making use of the provisions relating to the grant of compulsory licenses under their existing patent laws. For instance, the Emergency Response Act in Canada has made it binding on the Commissioner of Patents (and not a discretionary decision) to grant a government use authorization if the Ministry of Health applies for the same on the ground of the COVID-19 public health emergency. In this context, it would be pertinent for developing countries to review the provisions relating to the grant of compulsory licenses in their patent laws and assess whether similar enabling legislation would be required to explicitly guarantee the freedom of the government to grant compulsory licenses for COVID-19 related technologies.

**Indentify against Infringement Claims**

Another approach that countries can take to ensure that IP rights do not impede the use of IP protected technologies for COVID-19 by third parties is to suspend the enforcement of the IP rights and grant indemnity against enforcement actions, including IP infringement lawsuits. It has been argued by some that the recent notice of declaration published by the US Department of Health and Human Services under the Public Readiness & Emergency Preparedness (PREP) Act, conferring immunity from tort litigation for those engaging in acts related to COVID-19 countermeasures, also grants indemnity against patent infringement liability for third parties that use health technologies in relation to COVID-19.24 Though this interpretation has not been tested out in a court of law in an IP infringement litigation involving the use of a technology for COVID-19, this suggests that countries can adopt specific legislation suspending the enforcement of IP rights in respect of use of IP protected products or knowledge for COVID-19. Article 73(b) of the TRIPS Agreement allows World Trade Organization (WTO) members to take any measure for the protection of its essential security interests in times of an emergency situation (see below).

**Use of Competition Law**

It is also possible for countries to use measures for anti-competitive use of IP protected technologies in relation to COVID-19. For instance, as noted above, recently the European Commission (EC) launched a preliminary investigation on the abuse of the dominant position in the Dutch market by the multinational pharmaceutical company Roche, on account of its reported refusal to share the secret formula for producing a buffer solution that is necessary for use in testing kits for COVID-19. The EC has also stated that during the pandemic it will also continue to closely and actively monitor relevant market developments to detect instances of undertakings taking advantage of the current situation to breach European Union (EU) competition law, either by engaging in anti-competitive agreements or abusing their dominant position.25 It is possible for developing countries to also use competition law to prevent anti-competitive behaviour by IP right holders over technologies that are critical for COVID-19, both for the development of industries necessary to produce and supply the products required to respond to COVID-19 as well as to protect the interests of consumers.26

**Exercise of Absolute Sovereign Powers**

On 23 March 2020, France enacted a new law No. 2020-290 which introduced a new article - L.3131-15 - to the country’s public health code, allowing the Prime Minister to order the seizure of all goods and services necessary to: fight against sanitary disaster; to temporarily control the prices of products; and to take any measures necessary to make relevant medicines available to patients.27 IP related measures, including revocation and grant of compulsory licenses could also fall within the scope of measures that can be adopted by the government under this law.

**Use of LDC Transition Period**

Under article 66 of the TRIPS Agreement, the least developed country (LDC) members of the WTO have a transition period, currently available till 1 July 2021 generally, and till 31 December 2033 for pharmaceutical products, during which the obligations to provide IP protection as required under TRIPS are waived. LDCs can take advantage of this waiver to manufacture IP protected technologies required for responding to COVID-19. Bangladesh has suspended the grant of pharmaceutical patents during this transition period, and recently two local companies in Bangladesh – Beximco and Eskayef – have begun manufacturing of remdesivir for COVID-19.28 However, with the exception of Bangladesh which has some
capacity to manufacture generic antiviral medicines, most LDCs will require transfer of technology to be able to manufacture the necessary health products. This can be facilitated by requiring developed countries to put in place effective incentives for enterprises and institutions in their territories to transfer the technologies to LDCs.29

Other Possible Measures

The above enumeration of legal measures taken by a number of countries to ensure that IP rights do not constrain access to the health products required for responding to COVID-19 is not exhaustive. In accordance with the flexibilities available under the TRIPS Agreement, a number of other IP related measures can be taken by countries. Article 73(b) of the TRIPS Agreement states that nothing in the Agreement will be construed as preventing a member from taking any action which it considers necessary for protection of its essential security interests, taken in the time of war or other emergency in international relations. Thus, in furtherance of its health security interests, the TRIPS Agreement allows a country to take measures such as suspending the grant of patent protection (LDC members of the WTO can do so even without using the security exception as they have transitional waivers under article 66.1), and grant indemnity against enforcement actions. In accordance with article 6 of the TRIPS Agreement, a country can also undertake parallel importation of needed products, including from countries where they are produced under compulsory licenses.

Conclusion

The global response to COVID-19 is critically dependent on the rapid and mass scale innovation and supply of the products and technologies necessary for the prevention, diagnosis and treatment of the disease. With the rising incidence of COVID-19 infections in developing countries, it may be necessary for them to look at the IP rights applicable in their territories in relation to those products and technologies, and consider the legal measures that could be taken, where necessary, to ensure timely and affordable access for the population. The examples in this brief clearly demonstrate that some developed countries have very quickly adopted legal measures to enable the government to take a number of actions, particularly compulsory licensing or government use authorization, to ensure the supply of the products necessary for responding to COVID-19. All of these measures are fully in accordance with the flexibilities available under the TRIPS Agreement, and none of these measures have been challenged. There are other measures that may be adopted by developing countries consistently with the TRIPS Agreement, by effectively implementing existing laws and regulations or amending them, such as temporarily suspending the grant of patent protection, granting third parties indemnity against enforcement action for using the IP protected products or processes, or undertaking parallel importation as generally allowed by the Agreement.

It is time for developing countries to review the extent to which such measures can be adopted, or what changes, if any, need to be introduced into their legal regimes so as to be able to act effectively and timely to address the devastating effects of the COVID-19 pandemic.30

Endnotes:


9 Ibid. On 2 June 2020, the WHO secretariat and the Government of Costa Rica issued a solidarity call to action to realize equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data. The call to action has been acceded to by 38 countries. See Solidarity Call to Action, “Making the response to COVID-19 a public common


14For example, in 1996 a patent infringement suit was initiated in the US by the multinational pharmaceutical company Roche against the unlicensed use of a patented enzyme that was critical for the development of the polymerase chain reaction process that is also used in testing kits for COVID-19. Robert Finn, “Ongoing Enzyme Patent Dispute may Have Ramifications For Academic Researchers”, The Scientist, 13 October 1996. Available from https://www.the-scientist.com/news/ongoing-enzyme-patent-dispute-may-have-ramifications-for-academic-researchers-57806.

15According to reports, the multinational pharmaceutical company Roche initially declined to share the recipe for producing a critical buffer solution required to perform the diagnostic test produced by the company, but subsequently agreed to release the recipe to Dutch companies after the European Commission launched a preliminary investigation for possible anti-competitive conduct by the company. Eleke Van Ark and Jan-Hein Strop, “Roche releases recipe after European Commission considers intervention due to lack of coronavirus tests”, Follow the Money, 27 March 2020. Available from https://www.ftm.nl/artikelen/roche-releases-recipe-after-public-pressure-while-european-commission-consider-intervention-due-to-coronavirus-test.


28See Ed Silverman, “First generic version of Gilead’s remdesivir will be sold by a Bangladesh drug maker”, Pharmalot, 22 May 2020. Available from https://www.statnews.com/pharmalot/2020/05/22/gilead-
Agreement. Please see with the legal obligations and flexibilities under the TRIPS to ensure access to the required health products, in accordance possible measures that could be taken in response to COVID such as the South Centre's Expert Advisory Services to explore 30


development, December 2008). Available from

No.2 (UNCTAD try Submissions to the TRIPS Council (1999

Encourage Technology Transfer to LDCs? An Analysis of Coun-

try members of the WTO to provide incentives to enterprises

and institutions in their territories for the purpose of promoting

and encouraging technology transfer to LDC members in order

to enable them to create a sound and viable technological base.

However, so far this obligation has not been appropriately im-

plemented. See generally, Suerie Moon, “Does TRIPS Art.66.2

Encourage Technology Transfer to LDCs? An Analysis of Country


30 Developing countries can avail technical assistance services such as the South Centre’s Expert Advisory Services to explore possible measures that could be taken in response to COVID-19 to ensure access to the required health products, in accordance with the legal obligations and flexibilities under the TRIPS Agreement. Please see https://ipaccessmeds.southcentre.int/.

---

The South Centre is the intergovernmental organization of developing countries that helps developing countries to combine their efforts and expertise to promote their common interests in the international arena. The South Centre was established by an Intergovernmental Agreement which came into force on 31 July 1995. Its headquarters is in Geneva, Switzerland.

Readers may reproduce the contents of this policy brief for their own use, but are requested to grant due acknowledgement to the South Centre. The views contained in this brief are attributable to the author/s and do not represent the institutional views of the South Centre or its Member States. Any mistake or omission in this study is the sole responsibility of the author/s. For comments on this publication, please contact:

The South Centre
Chemin du Champ d’Anier 17
PO Box 228, 1211 Geneva 19
Switzerland
Telephone: (4122) 791 8050
south@southcentre.int
https://www.southcentre.int

Follow the South Centre’s Twitter: South_Centre

---

Previous South Centre Policy Briefs


No. 66, August 2019 — Impacts of Unilateral Coercive Measures in Developing Countries: the need to end the US embargo on Cuba by Vicente Paolo Yu and Adriano José Timossi

No. 67, October 2019 — Enhancing Access to Remedy through International Cooperation: Considerations from the Legally Binding Instrument on Transnational Corporations and Other Business Enterprises by Danish


No. 69, December 2019 — Crisis at the WTO’s Appellate Body (AB): Why the AB is Important for Developing Members by Danish and Aileen Kwa

No. 70, December 2019 — Lights Go Out at the WTO’s Appellate Body Despite Concessions Offered to US by Danish and Aileen Kwa

No. 71, January 2020 — Major Outcomes of the 2019 World Health Assembly by Mirza Alas and Nirmalya Syam

No. 72, February 2020 — US-China trade deal: preliminary analysis of the text from WTO perspective by Peter Lunenborg

No. 73, April 2020 — The COVID-19 Pandemic: R&D and Intellectual Property Management for Access to Diagnostics, Medicines and Vaccines by Viviana Muñoz Tellez

No. 74, April 2020 — Challenges and Opportunities for Implementing the Declaration of the Right to Development by Yuefen Li, Daniel Uribe and Danish

No. 75, April 2020 — Rethinking R&D for Pharmaceutical Products After the Novel Coronavirus COVID-19 Shock by Germán Velásquez

No. 76, April 2020 — Evolution of Data Exclusivity for Pharmaceuticals in Free Trade Agreements by Wael Armouti

No. 77, May 2020 — COVID-19 and WTO: Debunking Developed Countries’ Narratives on Trade Measures by Aileen Kwa, Fernando Rosales and Peter Lunenborg


No. 79, June 2020 — Articles 7 and 8 as the basis for interpretation of the TRIPS Agreement by Thamara Romero