

## The COVID-19 Pandemic: R&D and Intellectual Property Management for Access to Diagnostics, Medicines and Vaccines

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### Abstract

The ongoing rapid spread of COVID-19 is challenging the capacity of governments and of the World Health Organization (WHO) to timely put in place a global coordinated response to the pandemic. Developing countries and Least Developed Countries (LDCs) in particular in Africa are especially vulnerable to the unfolding effects of the public health crisis. A priority area for global collaboration is to advance research and development (R&D) for vaccines and medicines that are made available, affordable and accessible worldwide.

There is currently no vaccine and no proven safe and effective direct therapy for COVID-19. There is also the need to accelerate testing capacity and tools in developing countries and LDCs with increased access to low-cost diagnostics. The approach to the management of intellectual property rights by research institutions, pharmaceutical and biotech companies and R&D funders will decisively affect availability and access, as well as the transfer of technology and know-how. Governments must ensure that they have legislative and procedural frameworks in place to enable them to overcome any patent, data exclusivity and trade secret barriers to procure and produce COVID-19 diagnostics, vaccines, medicines and other therapeutics.

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*La rápida difusión actual de COVID-19 está poniendo a prueba la capacidad de los gobiernos y de la Organización Mundial de la Salud (OMS) para poner en marcha una respuesta mundial coordinada a la pandemia. Los países en desarrollo y los países menos adelantados (PMA), en particular los de África, son particularmente vulnerables a los efectos de la crisis de salud pública. Una esfera prioritaria para la colaboración mundial es el fomento de la investigación y el desarrollo de vacunas y medicamentos que estén disponibles, sean asequibles y accesibles en todo el mundo. En la actualidad no existe una vacuna ni una terapia directa segura y eficaz probada para COVID-19. También es necesario acelerar la capacidad y los instrumentos de ensayo en los países en desarrollo y los países menos adelantados con un mayor acceso a diagnósticos de bajo costo. El enfoque de la gestión de los derechos de propiedad intelectual por parte de las instituciones de investigación, las empresas farmacéuticas y biotecnológicas y las entidades de financiación de la investigación y el desarrollo afectará de manera decisiva a la disponibilidad y el acceso, así como a la transferencia de tecnología y conocimientos técnicos. Los gobiernos deben asegurarse de que disponen de marcos legislativos y de procedimiento que les permitan superar cualquier barrera de patentes, de exclusividad de datos y de secretos comerciales para adquirir y producir diagnósticos, vacunas, medicamentos y otros productos terapéuticos de COVID-19.*

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*La propagation rapide actuelle du COVID-19 met à l'épreuve la capacité des gouvernements et celle de l'Organisation mondiale de la santé (OMS) à apporter une réponse mondiale coordonnée à la pandémie. Les pays en développement et les pays les moins avancés (PMA), en particulier en Afrique, sont particulièrement vulnérables aux effets de la crise de santé publique. Un domaine prioritaire de collaboration mondiale consiste à faire progresser la recherche et le développement (R&D) de vaccins et de médicaments qui soient disponibles, abordables et accessibles dans le monde entier. Il n'existe actuellement aucun vaccin et aucune thérapie directe pour COVID-19 dont l'innocuité et l'efficacité ont été prouvées. Il est également nécessaire d'accélérer les capacités et les outils d'essai dans les pays en développement et les PMA en leur donnant un accès accru à des diagnostics peu coûteux. L'approche de la gestion des droits de propriété intellectuelle par les institutions de recherche, les entreprises pharmaceutiques et biotechnologiques et les organismes de financement de la R&D aura une incidence décisive sur la disponibilité et l'accès, ainsi que sur le transfert de technologie et de savoir-faire. Les gouvernements doivent s'assurer qu'ils disposent de cadres législatifs et procéduraux leur permettant de surmonter les obstacles liés aux brevets, à l'exclusivité des données et aux secrets commerciaux afin de se procurer et de produire des diagnostics, des vaccins, des médicaments et d'autres produits thérapeutiques pour le COVID-19.*

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## **I. The COVID-19 Pandemic**

The novel coronavirus (COVID-19) was first detected in Wuhan, China in December 2019 and then quickly spread worldwide.<sup>1</sup> COVID-19 as other infectious diseases does not stop at country borders. The outbreak of COVID-19 was declared a Public Health Emergency of International Concern on 30 January 2020 by the World Health Organization (WHO), requiring a coordinated, international public health response.<sup>2</sup> On 11 March 2020, the WHO declared COVID-19 a pandemic, the first for a coronavirus, given the growing spread and increasing percent of global population affected, in order to trigger more urgent action and resource deployment. Tedros Adhanom Ghebreyesus, the Director-General of WHO noted “alarming levels of inaction”, even as many countries were in lockdown. As of 30 March 2020, it is estimated that there are more than 1,252,265 million people affected (number of declared cases), including approximately 258,495 people that have recovered and 68,148 deaths.<sup>4</sup> The growing toll of the disease points that national health systems and international health agencies were not prepared to handle the new coronavirus outbreak.

As the pandemic reaches countries with weaker national health systems, the need for international collaboration and solidarity is even greater. The main recommendation for governments for urgent actions are to detect early, isolate and treat COVID-19 cases. The best scenario is for early screening, quarantine and care to patients to be effective in preventing community transmission, otherwise the number of infected people will spread quickly. Yet national health capacities for pandemic preparedness and response are highly uneven. Assistance for increasing testing capacity, healthcare infrastructure and workforce is direly needed to support least developed countries (LDCs) and many developing countries in Africa, Central and Latin America, and Asia. The scale of the public health emergency that may unfold in poorer countries is unpredictable. Currently there is a chronic global shortage of personal masks and other protective equipment for health workers affecting even in rich countries such as France, shortages of beds and ventilators in hospitals, the shortfall of diagnostic testing kits, and concerns of insufficient supply of essential medical supplies and products leading some governments to ration or ban exports.<sup>4</sup>

## **II. Increasing Testing Capacity and Diagnostics**

A key intervention for all countries is to increase capacity to identify and isolate persons infected with -19 to slow down its spread. This requires deploying testing kits that can rapidly test for infection. There is also need to increase serological testing to identify people who were infected and were recovered, which could help thousands of people whose livelihoods depend on daily wages to get back to work.

Global collaboration is needed to enable rapid and accessible, low-cost testing around the world. Prompt collaboration by China for sequencing and releasing the full genome of the SARS-Cov2 virus by mid-January enabled research labs around the world to develop test kits to begin detecting infections of COVID-19. Advances have been made to develop new diagnostics and testing is increasing, though there is lack of tests to ensure wide testing.<sup>5</sup>

Countries are struggling with diagnostic deployment and adopting different strategies. Most diagnostics are mainly being developed commercially and with proprietary technology, meaning that the manufacture and sale, including for export, may be restricted unless a license is granted under agreed terms. In these conditions, prices may be set high. This advances the profit and revenue maximizing strategy of commercial vendors, but not public health. Moreover, exports are currently insufficient to meet the high and growing global demand. Government research institutes and laboratories that have developed diagnostics could share the technology and know-how more broadly to facilitate their transfer. It is essential to rapidly increase the domestic production capacity in developing countries. Non-profit initiatives to bring low-cost diagnostics to developing countries and LDCs such as FIND<sup>6</sup> are few and need increased funding. No government so far has made a concerted effort to address patent, trade secret and contractual barriers that are obstacles to the broad deployment of diagnostics.

## **III. Research and Development for a Vaccine and Therapeutics**

There is currently no vaccine to prevent COVID-19 infection and no proven safe and effective direct therapy to treat patients. There is an on-going race to advance research and development in this field. Several vaccine candidates have entered human trials, though it is estimated that a vaccine is at least 12 to 18 months away.<sup>7</sup> In a matter of weeks, it is expected that first evidence will be available on the safety and efficacy of potential medicines to treat COVID-19.

There are a number of efforts from public and private research institutions, non-profit development initiatives, and from large pharmaceutical and biotech firms to develop a vaccine. The WHO created a R&D blueprint for COVID-19<sup>8</sup> in coordination with various international research funding organizations<sup>9</sup> to support alignment and coordination of vaccine research efforts, but it has missed the opportunity to call for more openness in research; sharing data, research tools and avoiding intellectual property barriers. Governments and philanthropic institutions have also provided substantial funding for accelerating research.<sup>10</sup> The advances are good news, but the lack of global coordination and collaboration among these efforts casts a cloud on the future deployment of vaccines for COVID-19.<sup>11</sup>

Governments, funders and public and private actors involved in research and development have not collabo-

rated sufficiently with the WHO to provide early guidance for equitable and affordable access worldwide to medicines and other therapeutics for COVID-19 and for a vaccine once it is developed. There is no roadmap for any of these initiatives and institutions to support equitable and affordable access.<sup>12</sup> Pricing and other access considerations should not come after product development, especially when public financing has supported development.

The Coalition for Epidemic Preparedness Innovations (CEPI) initiative is an exception in that it has a formal policy aimed to safeguard equitable access to the vaccines it assists to develop. However, the CEPI access policy was relaxed due to concerns of large vaccine companies that it could conflict with a competitive business model and in particular that they could lose access to intellectual property that may have been developed, or planned to be used, for another commercial purpose.<sup>13</sup> The move drew strong criticism that the new policy does not provide guarantees that the vaccines that CEPI funds will be made available at an affordable price.<sup>14</sup> CEPI is providing funding to seven programs for COVID-19 vaccine development.<sup>15</sup>

Governments must ensure that they have legislative and procedural frameworks in place to enable them to overcome any patent, data exclusivity and trade secret barriers.

Various large pharmaceutical companies are involved in vaccine projects, particularly for downstream manufacturing and distribution. As they seek profitability, protection for patent and other intellectual property rights will likely be central to their strategic engagement. These interests may come into conflict with the broader public health interest in ensuring wide availability and affordable access to tackle a global pandemic. Even so, high-income countries will likely put in large orders for vaccine doses to meet the needs of their populations and may be willing to pay high prices. Meanwhile, there is no global entity to ensure sufficient vaccine supply worldwide and procurement at affordable prices for developing countries and LDCs. The GAVI Alliance has pledged to help in the deployment of a vaccine once one becomes available. The G20 too. However, the capacity to respond to the global demand, pricing, intellectual property management and other terms on which current vaccine developers will be prepared to make the vaccine available are not known. Governments and global health agencies should be urgently putting on the table options for ensuring that once a vaccine is developed there can be sufficient vaccine manufacturing capacity. This will require free access to all relevant technologies and rapid transfer of know-how and technology for scaling up production and delivery of the new vaccines as public goods so as to ensure equitable access to all. If the poorest populations cannot get access to preventative tools, an unprecedented humanitarian crisis will arise. In addition to creating manufacturing capacity, governments should ensure

that there will be no patent or other intellectual property barriers that may impede equitable and affordable access to vaccines.

### Treatments

While a vaccine is developed, numerous therapeutics are being considered to treat COVID-19. There is concern that individuals may be using treatments that have not been demonstrated to be effective against COVID-19 and that use of drugs approved for other therapeutic indications may create shortage of those drugs for people who need them. The US Government has allowed emergency use of unapproved anti-malarial medicines to treat very ill COVID-19 patients<sup>16</sup> while the WHO warns that the ingestion of high doses of these medicines may be associated with adverse or seriously adverse health outcomes.<sup>17</sup>

There are various existing treatments approved for other diseases that are being tested for safety and efficacy for COVID-19 mainly for severely or critically ill patients.<sup>18</sup> An important collaboration is taking place among governments under WHO auspices for a large-scale multi-country open clinical trial which started on March 26, 2020.<sup>19</sup> The

“Solidarity” trial is comparing four treatments considered to be promising,<sup>20</sup> in order to test their safety and efficacy against COVID-19.

Remdesivir is one of the more promising treatments for COVID-19 selected for the WHO Solidarity trial. It is an experimental antiviral medicine developed by Gilead Sciences<sup>21</sup> with substantial public funding<sup>22</sup> that has not been approved for any indication. Various clinical trials are ongoing to test for safety and efficacy for COVID-19. Clinical trial results from China are expected in mid April and from the United States in May. Gilead holds various patents for Remdesivir in multiple countries.<sup>23</sup> This means that no other party would be able to develop or produce the medicine unless authorized through a license by Gilead. In addition, Gilead obtained for remdesivir seven years of exclusive marketing rights among other benefits by the United States Food and Drug Administration (FDA) under the Orphan Drug Act. That status is meant to incentivize treatments for rare diseases. Following the immediate uproar of public interest groups,<sup>24</sup> Gilead announced that it was rescinding the orphan drug designation for remdesivir. Pressure from civil society is also mounting on Gilead to commit to not enforce its existing patents or claim new patents and other exclusivities on remdesivir in any country, and to enable the production and supply of remdesivir by generic manufacturers.<sup>25</sup> Various companies are reportedly already developing and preparing to scale up production of generic remdesivir if proven safe and effective to treat COVID-19.<sup>26</sup>

Other treatments in addition to those selected for the WHO Solidarity trial under clinical trials for COVID-19 include the biologics tocilizumab and sarilumab approved for treatment of rheumatoid arthritis. Tocilizumab, commercially known as Actemra®, was developed by Roche and Genentech and has received FDA approval of a clinical trial to evaluate its efficacy and safety for the treatment of patients with COVID-19 pneumonia.<sup>27</sup> Clinical trials have started for sarilumab, commercially known as Kevzara® and developed by Sanofi and Regeneron.<sup>28</sup> The portfolio of protected patents and other exclusive rights in various countries for these treatments also needs to be carefully watched, as evidence for COVID-19 becomes available. A particular concern for this and other treatments based on the repurposing of existing medicines, is the acquisition of patents on the use of such medicines for COVID-19 (even if they are not new). This is a possibility allowed in many countries but not required under international law, as discussed below.

### **Intellectual property measures**

With the concern that patent and other exclusivities granted for diagnostic, vaccine and medicines may limit access for COVID-19 response, Costa Rica advanced a proposal for the WHO to undertake an effort to pool rights to clinical and other data, know how, patents, trade secrets and other proprietary information on a voluntary basis, to provide free access or licensing on reasonable and affordable terms, in every member country.<sup>29</sup> Wide support for this proposal is important for WHO members and funders to rapidly find agreement on measures to promote openness and avoid intellectual property barriers.<sup>30</sup> Voluntary licensing models have proven they can promote access,<sup>31</sup> however it requires agreement by the right holders, which may cause delay and may not be possible to obtain on the terms demanded.

### **Patent measures**

To respond to the COVID crisis, governments should be aware that, consistently with the World Trade Organization (WTO) Agreement on Intellectual Property Rights (TRIPS), they can take measures to rapidly overcome potential patent barriers in order to increase access to patented diagnostics, medicines including biologics, and vaccines.<sup>32</sup>

A patent is a government-granted title that gives the title holder the rights to exclude others from making, using and selling the “invention.”<sup>33</sup> During the patent term,<sup>34</sup> the inventor may choose to make, use, and sell the patented invention, or to license others to do so on an exclusive or non-exclusive basis.

Countries can adopt strict criteria of patentability for the examination of pharmaceutical patent applications. Such an approach rewards significant inventions. It does not allow for claims that do not merit a patent grant, thus discouraging patent applications for trivial inventions.<sup>35</sup> In the current crisis it is of particular im-

portance to apply policies that prevent the grant of patents around the SARS-Cov2 virus itself, and in relation to the *new medical use* of existing medicines. Claims on the second medical use of medicines are allowed in many countries that interpret patentability criteria expansively. However, these claims protect methods of treatment and fail to comply with the requirements of novelty and industrial applicability. There is no requirement under the TRIPS Agreement or other international treaties to grant such claims.<sup>36</sup>

Least developed countries are not required to provide patents for pharmaceutical products or processes.<sup>37</sup> If they grant pharmaceutical patents, these may be obstacles for access. Lacking local manufacturing capacity, Least developed countries are not able to use non-voluntary licensing mechanisms to produce patented medicines. A mechanism has been set up under the TRIPS Agreement to facilitate access for countries in this situation, but to date the mechanism has not proved to be an effective solution.<sup>38</sup>

To facilitate collaborative early stage research, it is also important that patent laws do not extend protection to essential research tools and include broad exceptions to patent rights for research purposes. Such exceptions should allow to develop and commercialize any product obtained on the basis of such research. Similarly, a “Bolar exception” to patent infringement should be incorporated into the national laws, if not yet provided for, in order to allow for the early market entry of generic products.<sup>39</sup>

By incorporating legislation to allow for parallel imports, countries can procure lower-priced medical products.<sup>40</sup> Countries can incorporate into their national laws the principle of international exhaustion of rights, allowing for parallel imports on an international scale. In this case, a patent holder does not have the right to prevent importation of a product covered by a patent that has been put on the market in any country by the patent holder, or by an authorized party. This can also include parallel importation of a patented product produced under compulsory license in a third country, up to certain quantities.

Importantly, governments should include and operationalize in their laws and regulations provisions to allow the effective use of compulsory licenses and government non-commercial use to address patent barriers to access. To facilitate their implementation, the requirements under national laws and procedures for the grant of these licenses should be simplified to the extent possible, in accordance with international legal obligations. Most countries include in their national patent laws provisions for compulsory licensing and government non-commercial use.<sup>41</sup> Although there are many examples of instances when compulsory licensing and government non-commercial use have been used, procedures for the speedy grant of such licenses may need to be implemented.<sup>42</sup> These licenses do not preclude the patent holder from continuing to exploit the invention.

A compulsory license is an authorization given by a national authority to a private party or government agency to exploit the patented invention, without the consent of the patent holder. A voluntary license should previously be sought from the patent holder, and adequate remuneration should nonetheless be provided to the patent holder, taking into account the particular circumstances of the case and the economic value of the compulsory license. The grant of compulsory licenses is expressly allowed by the TRIPS Agreement. WTO Members have freedom to determine the grounds for their grant.

Government non-commercial use (“government use”) is a form of compulsory license that does not require prior negotiation with the patent holder, which is an exception also made in situations of public health emergency. The rationale is generally to promote the public interest in access to the patented invention, as in the case of a public health emergency. Compulsory licenses and government use can be utilized to import or produce a patent-protected diagnostic, vaccine or medicine, for instance, in the case that they are not made available in sufficient quantities by the right holder or it is priced excessively high.

The threat of a compulsory license or government use authorization may lead the patent holder to reassess their strategy, for example to offer a substantial price reduction. Recently, the Attorney General of Israel authorized the issuance of a compulsory license to allow the importation of generic versions of the combination HIV treatment lopinavir and ritonavir (Kaletra®) that is patent protected in Israel to treat COVID-19. Apparently, in response to this move, the developer AbbVie, reportedly gave notice to Medicines Patent Pool (MPP) that it would not to enforce its patents in respect to Kaletra® in any territory.<sup>43</sup> The patents for Kaletra® have expired in many developing countries where they were filed and granted, and in some such as India, the patent applications were rejected for not meeting the patentability criteria.

Israel is not alone in taking prompt action on compulsory licensing to secure access to COVID-19 treatments, vaccines or diagnostics. Canada has also recently amended its Patent Act to provide for compulsory licensing in the event of a public health emergency.<sup>44</sup> Germany is also preparing the ground to make use of its compulsory licensing provisions under its patent law.<sup>45</sup> Chile and Ecuador have also taken important steps to move forward the procedures required for the issuance of compulsory licenses for patented products as part of the COVID-19 response, if needed.

#### **Trade secrets**

In some countries, techniques, methods, compilations, processes and software applied in medical devices such as ventilators and diagnostic tests or in vaccine or medicine production, may be protected through trade secrets. Hence, trade secrets may also become a barrier for access to these essential tools during the COVID-19

pandemic. Firms are increasingly opting for protection of trade secrets for subject matter that they are able to keep secret<sup>46</sup> and for which patent protection may not be afforded.<sup>47</sup> Compulsory licensing and government use authorizations can only be granted with respect to patents. However, governments could put in place mechanisms to require trade secrets to be disclosed for necessity in the case of a public health emergency.

#### **Protection of test data**

The protection of test data, as mandated by the TRIPS Agreement, should not erect an obstacle to the production and distribution of needed medicines, as it does not require the grant of exclusive rights.<sup>48</sup> In addition, such protection only applies to new chemical entities and does not extend to vaccines and other biological medicines. Governments can also provide exceptions and waivers, in case that data exclusivity regulations, such as those established under free trade agreements, would prevent the marketing approval of generics and biosimilars.<sup>49</sup>

Finally, the TRIPS Agreement allows countries to introduce “security exceptions”, allowing a WTO Member to take “any action which it considers necessary for the protection of its essential security interests”. This exception can be used to suspend the enforcement of any intellectual property right (including patents and trade secrets) that may pose an obstacle to the procurement or local manufacturing of the products and devices necessary to protect their populations.<sup>50</sup>

#### **IV. Conclusion**

A global mechanism is needed to drive open and collaborative R&D and sustain production and supply for essential diagnostics, vaccines and therapeutics.<sup>51</sup> In order to address the COVID-19 challenges, global collaboration is needed to support developing and least developed countries to scale up testing capacity and to enable equitable and affordable access to approved treatments and vaccines.

The international health community, with WHO lead, should reassert the right of governments to use TRIPS flexibilities to protect public health. Governments can act swiftly to take policy and legislative measures to ensure that patents and other intellectual property rights do not erect barriers to access to medicines, diagnostics, vaccines and medical supplies and devices.

There is a need to review national and regional regulations to assess the extent to which they provide for the above described TRIPS flexibilities. In particular, whether they permit the effective compulsory licensing or government use of products that are protected by patents. If not, the necessary reforms should be promptly introduced in order to streamline procedures and facilitate the implementation of such measures.

The South Centre offers technical assistance to developing and least developed countries in this area.<sup>52</sup>

## Endnotes:

<sup>1</sup> COVID-19 is the name associated to the disease caused by a new strain of coronavirus that previously had not been identified in humans, called the severe acute respiratory syndrome coronavirus 2 (SARS-Cov2). Previous coronavirus outbreaks include Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS). See [https://www.who.int/health-topics/coronavirus#tab=tab\\_1](https://www.who.int/health-topics/coronavirus#tab=tab_1).

<sup>2</sup> A Public Health Emergency of International Concern is defined in the International Health Regulations 2015 that bind all WHO member States, as “an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response”. See <http://www10.who.int/features/qa/emergency-committees/en/>.

<sup>3</sup> Data from the Center for Systems Science and Engineering (CSSE) at John Hopkins University, as of 5 April 2020, <https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>.

<sup>4</sup> For example, the European Union has imposed a temporary export licensing requirement on certain personal protective equipment for a period of six weeks. See <https://www.globaltradealert.org/state-act/43486/eu-temporary-export-licensing-requirement-imposed-on-certain-personal-protective-equipment-including-protective-masks-gloves-and-garments-in-response-to-covid-19>.

<sup>5</sup> An interactive map of testing across countries is available at <https://www.finddx.org/covid-19/test-tracker/>.

<sup>6</sup> See <https://www.finddx.org>.

<sup>7</sup> A WHO draft landscape of vaccine candidates for COVID-19 is available at [https://www.who.int/blueprint/priority-diseases/key-action/Novel Coronavirus Landscape nCoV Mar26.PDF?ua=1](https://www.who.int/blueprint/priority-diseases/key-action/Novel%20Coronavirus%20Landscape%20nCoV%20Mar26.PDF?ua=1).

<sup>8</sup> See <https://www.who.int/blueprint/priority-diseases/key-action/novel-coronavirus/en/>.

<sup>9</sup> The Global Research Collaboration for Infectious Disease Preparedness (GloPID-R).

<sup>10</sup> These include the Bill and Melinda Gates Foundation, see <https://www.gatesfoundation.org/Media-Center/Press-Releases/2020/02/Bill-and-Melinda-Gates-Foundation-Dedicates-Additional-Funding-to-the-Novel-Coronavirus-Response> and the Wellcome Trust <https://wellcome.ac.uk/press-release/wellcome-statements-novel-coronavirus-covid-19>.

<sup>11</sup> See Seth Berkley, COVID-19 needs a Manhattan Project, *Science*, 27 Mar 2020: Vol. 367, Issue 6485, pp. 1407. Available at <https://science.sciencemag.org/content/367/6485/1407>.

<sup>12</sup> A WHO draft landscape of COVID vaccines in development as of 20 March 2020, is available at <https://www.who.int/blueprint/priority-diseases/key-action/novel-coronavirus-landscape-ncov.pdf?ua=1>.

<sup>13</sup> B. Huneycutt et al. Finding equipoise: CEPI revises its equitable access policy, *Vaccine*, Volume 38, Issue 9, 2020. Available at <http://www.sciencedirect.com/science/article/pii/S0264410X19317190>.

<sup>14</sup> See Médecins Sans Frontières Access Campaign Policy Brief, August 2019, The Wrong Prescription for Vaccine Access. Available from: <https://msfaccess.org/wrong-prescription-vaccine-access>, and Open Letter <https://msfaccess.org/open-letter-cepi-board-members-revise-cepis-access-policy>.

<sup>15</sup> These include programs involving Inovio, University of Queensland, Moderna, Curevac, University of Oxford, University of Hong Kong, a consortium led by Institut Pasteur and including Themis Bioscience and University of Pittsburgh, and Novavax. GlaxoSmithKline (GSK) agreed to provide access to its pandemic vaccine adjuvant platform technology. See <https://cepi.net/>.

<sup>16</sup> See for example <https://nypost.com/2020/03/30/fda-approves-limited-use-of-malaria-drugs-for-coronavirus/>.

<sup>17</sup> See WHO Q&A on Malaria and the COVID-19 pandemic <https://www.who.int/news-room/q-a-detail/malaria-and-the-covid-19-pandemic>.

<sup>18</sup> See <https://www.statnews.com/2020/03/24/when-might-experimental-drugs-to-treat-covid-19-be-ready-a-forecast/>.

<sup>19</sup> See Tedros A. Ghebreyesus and Soumya Swaminathan, Scientists are sprinting to outpace the novel coronavirus, *The Lancet*, Volume 295, Issue 10226, Available at [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30420-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30420-7/fulltext). [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30420-7/fulltext#.XoOBzMOjCMs](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30420-7/fulltext#.XoOBzMOjCMs) and WHO Director General speech at Press Conference 27 March 2020, <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---27-march-2020>.

<sup>20</sup> The therapies being tested are Remdesivir (an experimental antiviral); lopinavir and ritonavir (approved for HIV, brand name Kaletra®); lopinavir and ritonavir ((approved for HIV) plus interferon beta; chloroquine and hydroxychloroquine (anti-malarial agents).

<sup>21</sup> Gilead Sciences is a biopharmaceutical from the United States. In 2019 its total revenues were US\$ 22.4 billion. See <https://www.gilead.com/news-and-press/press-room/press-releases/2020/2/gilead-sciences-announces-fourth-quarter-and-full-year-2019-financial-results>.

<sup>22</sup> See KEI Briefing Note on the Role of the U.S. Federal Government in the Development of GS-5734/Remdesivir. [https://www.keionline.org/wp-content/uploads/KEI-Briefing-Note-2020\\_1GS-5734-Remdesivir.pdf](https://www.keionline.org/wp-content/uploads/KEI-Briefing-Note-2020_1GS-5734-Remdesivir.pdf).

<sup>23</sup> The MedsPal database by the Medicines Patent Pool (MPP) provides information on Remdesivir patents by country, see [medspal.org](https://www.inquartik.com/inq-china-coronavirus-patents-gilead-portfolio/). Information on the Gilead patent portfolio for Remdesivir is also available from: <https://www.inquartik.com/inq-china-coronavirus-patents-gilead-portfolio/>.

<sup>24</sup> A letter by over 50 civil society groups was sent to Gilead requesting the company to renounce its claim to Orphan Drug Legislation, on 25 March 2020. See <https://www.citizen.org/news/gilead-must-relinquish-monopoly-on-potential-coronavirus-treatment>.

<sup>25</sup> See Open Letter from MSF and 150 civil society organizations to Gilead, 27 March 2020, [https://msfaccess.org/sites/default/files/2020-03/REPORT\\_COVID\\_Open%20Letter\\_To%20Gilead\\_30.3.2020\\_1.pdf](https://msfaccess.org/sites/default/files/2020-03/REPORT_COVID_Open%20Letter_To%20Gilead_30.3.2020_1.pdf).



- <sup>26</sup> Including CIPLA from India, see <https://www.biospectrumindia.com/news/73/15991/cipla-links-agreement-with-iict-to-develop-covid-19-drug.html>, and BrightGene from China, see [http://www.pmlive.com/pharma\\_news/chinas\\_brightgene\\_successfuly\\_copies\\_gileads\\_coronavirus\\_hopeful\\_remedesivir\\_1325639](http://www.pmlive.com/pharma_news/chinas_brightgene_successfuly_copies_gileads_coronavirus_hopeful_remedesivir_1325639).
- <sup>27</sup> See Genentech Press Release, 23 March 2020, <https://www.gene.com/media/press-releases/14843/2020-03-23/genentech-announces-fda-approval-of-clin>.
- <sup>28</sup> See Sanofi Press Release, 30 March 2020, <https://www.sanofi.com/en/media-room/press-releases/2020/2020-03-30-07-00-00>.
- <sup>29</sup> The proposal by the president of Costa Rica is available from <https://www.presidencia.go.cr/comunicados/2020/03/costa-rica-submits-proposal-for-who-to-facilitate-access-to-technologies-to-combat-covid-19/>. It has received support from various public interest groups and academics. See for example <https://healthgap.org/rationale-for-supporting-costa-ricas-proposal-for-emergency-covid-19-technology-ip-pool-for-all-countries/> and <https://www.keionline.org/32649>.
- <sup>30</sup> On 6 April 2020, the WHO Director General expressed support for the Costa Rican pool proposal, and the expansion of the UNITAID-funded Medicines Patent Pool to include COVID-19 related health technology, see <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19--6-april-2020>.
- <sup>31</sup> The Medicines Patent Pool, for example, has successfully negotiated with various patent holders for voluntary licenses to allow generic manufacturing to increase access to medicines for HIV, hepatitis C and tuberculosis.
- <sup>32</sup> See Velasquez, G et al, Intellectual Property, Human Rights and Access to Medicines, A Selected and Annotated Bibliography Third Edition (forthcoming); Carlos M. Correa (2016) Public Health Perspective on Intellectual Property and Access to Medicines. A compilation of studies prepared for WHO, South Centre; Carlos M. Correa (2013), Intellectual Property and Access to Medicines, South Centre.
- <sup>33</sup> The TRIPS Agreement does not define the term invention. The Agreement allows discretion to governments to define the scope of patent protection in how the patentability criteria are applied, and to introduce exclusions and limitations to patent rights. National patent laws define more precisely these elements.
- <sup>34</sup> A minimum term of protection of 20 years is defined in the TRIPS Agreement.
- <sup>35</sup> See Correa, C. M. (2014), Patent Examination and Legal Fictions: How Rights are Created on Feet of Clay, Research Paper 58, South Centre, [https://www.southcentre.int/wp-content/uploads/2014/12/RP58\\_Patent-Examination-Legal-Fictions-rev2\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2014/12/RP58_Patent-Examination-Legal-Fictions-rev2_EN.pdf), see Gurgula O. [The 'obvious to try' method of addressing strategic patenting: How developing countries can utilise patent law to facilitate access to medicines](https://www.southcentre.int/research-paper-101-december-2019/), Policy Brief 59, April 2019, South Centre.
- <sup>36</sup> See Ducimetière C., Second Medical Use Patents – Legal Treatment and Public Health Issues, Research Paper 101, December 2019, <https://www.southcentre.int/research-paper-101-december-2019/>, and Carlos M. Correa, ed. (2012). A Guide to Pharmaceutical Patents, South Centre, <https://www.southcentre.int/product/a-guide-to-pharmaceutical-patents/>.
- <sup>37</sup> Until 1 January 2033, or until the date on which they cease to be a Least developed country Member. Least developed country WTO Members have the right to seek other extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement. See TRIPS Council decision, 6 November 2015, IP/C/73F for the rationale for seeking extension, see LDCs Request For An Extension of their Transition Period under TRIPS, South Bulletin 72, 12 May 2013, <https://www.southcentre.int/question/lcds-request-for-an-extension-of-their-transition-period-under-trips/> and Transition Period for Providing Patent Protection for Pharmaceutical Products by LDCs: The Need for Extension, Analytical Note December 2014, South Centre. <https://www.southcentre.int/analytical-note-december-2014/>.
- <sup>38</sup> See Correa C., Will the Amendment to the TRIPS Agreement Enhance Access to Medicines? Policy Brief 57, South Centre, and presentations at <https://www.southcentre.int/sc-side-event-paragraph-6-of-the-doha-declaration-on-trips-and-public-health-an-effective-solution-8-november-2016/>.
- <sup>39</sup> See Correa, The Bolar Exception: Legislative Models and Drafting Options Research Paper 66, March 2016, <https://www.southcentre.int/research-paper-66-march-2016/>.
- <sup>40</sup> See Matthews D., Munoz Tellez V., Parallel Trade: A User's Guide, in A. Krattiger et al (eds), Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices, 2007, 1429. <http://www.iphandbook.org/handbook/chPDFs/ch15/ipHandbook-Ch%2015%2004%20Matthews-Munoz-Tellez%20Parallel%20Trade.pdf>.
- <sup>41</sup> Correa C., Guide for the issuance of compulsory licenses and government use of patented pharmaceuticals, South Centre (Forthcoming 2020). See WIPO compilation of provisions on compulsory licenses and government use by country [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_30/scp\\_30\\_3-appendix1.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-appendix1.pdf).
- <sup>42</sup> See Table on Compulsory Licenses and Government Use, available at [www.southcentre.int](http://www.southcentre.int).
- <sup>43</sup> See report in the Financial Times, AbbVie drops patent rights for Kaletra antiviral treatment, 23 March 2020 <https://www.ft.com/content/5a7a9658-6d1f-11ea-89df-41bea055720b>.
- <sup>44</sup> Statutes of Canada 2020, Chapter 5, Bill C-13, Assented to 25 March, 2020, Part 12: Patent Act, [https://www.parl.ca/Content/Bills/431/Government/C-13/C-13\\_4/C-13\\_4.PDF](https://www.parl.ca/Content/Bills/431/Government/C-13/C-13_4/C-13_4.PDF).
- <sup>45</sup> See <http://patentblog.kluweriplaw.com/2020/03/24/german-government-plans-possibilities-to-limit-patents-in-view-of-corona-pandemic/> and German Patent Act, Section 13 [https://www.gesetze-im-internet.de/englisch\\_patg/englisch\\_patg.html](https://www.gesetze-im-internet.de/englisch_patg/englisch_patg.html).
- <sup>46</sup> For example, if these are not made evident in manufacturing, don't require disclosure in relation to obtaining regulatory approvals. Efforts made to keep the information secret include non-disclosure clauses in employee contracts or when sharing in business ventures.
- <sup>47</sup> For some discussion with respect to US patent law and trade secret protection, see

<https://patentstrategy.managingip.com/articles/123/alice-five-years-on-trade-secrets-are-still-popular-alternative-to-patents>.

<sup>48</sup> Carlos M. Correa (2002), Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement.

<sup>49</sup> See Carlos Correa, Mitigating the Regulatory Constraints Imposed by Intellectual Property Rules under Free Trade Agreements, Research Paper 74, 2017, available from [https://www.southcentre.int/wp-content/uploads/2017/02/RP74\\_Mitigating-the-Regulatory-Constraints-Imposed-by-Intellectual-Property-Rules-under-Free-Trade-Agreements\\_EN-1.pdf](https://www.southcentre.int/wp-content/uploads/2017/02/RP74_Mitigating-the-Regulatory-Constraints-Imposed-by-Intellectual-Property-Rules-under-Free-Trade-Agreements_EN-1.pdf).

<sup>50</sup> See COVID-19 Pandemic: Access to Prevention and Treatment is a matter of national and international security, Open Letter from Carlos Correa, to the Director Generals of the WHO, WTO and World Intellectual Property Organization (WIPO), 4 April 2020, <https://www.southcentre.int/wp-content/uploads/2020/04/COVID-19-Open-Letter-REV.pdf>.

<sup>51</sup> For a discussion on possible elements of such mechanism, see G. Velasquez, Rethinking R&D for pharmaceutical products after the novel coronavirus COVID-19, South Centre Policy Brief 74, April 2020 (forthcoming).


<sup>52</sup> For a description of the legal expert advisory, trainings and other services provided by the South Centre, see <https://ipaccessmeds.southcentre.int>.



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