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Editorial

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Open Access to Scientific Innovation as a Means to Combat COVID-19

On 11 March 2020 the World Health Organization (WHO) declared the occurrence of the pandemic COVID-19 (Coronavirus Disease – 19), a disease caused by a completely new virus, which spreads rapidly, is significantly lethal and whose progression and immune response is still quite unknown. This has caused a major impact on public health worldwide. The geopolitical reality of greater globalization and demographic density has facilitated the spread of the coronavirus, demanding the need for quick responses by science to face it. It turns out that many of the current technologies that are necessary for actions against the pandemic have some form of intellectual property protection.

Important steps were taken early on at the outbreak of the pandemic by the international scientific community, which obtained the sequencing of SARs-CoV2 (the virus that causes the disease) by sharing information and data in record time. This action allowed for a global understanding of the virus, enabling researchers from different countries to act in a joint effort to seek a more rapid development of diagnosis, medicinal uses and also future vaccines.

On 18 and 19 May 2020 the WHO held wide-ranging debates during the 73rd World Health Assembly, which brought together 194 Member States, culminating in unanimous approval of a resolution supporting the possibility of broad access and open licensing of patents for future vaccines or treatments to combat the COVID-19 pandemic.

The role of the WHO Resolution is to make an assessment of the strategies developed so far in the fight against the coronavirus, as well as to point out future policies and open access to scientific innovation that should be adopted by countries.

In his opening speech the WHO's Director-General, Tedros Adhanom Ghebreyesus, reported on the dizzying rate of scientific research to face the health crisis brought on by the new virus, both to understand its molecular structure, as well as to develop possible vaccines, medicines and other technologies.[1] Ghebreyesus highlighted that the condition of obtaining scientific information by researchers of different nationalities guarantees that we can produce vaccines and therapies that are safe, effective and accessible in the shortest possible time. Undoubtedly, access to information is fundamental to overcoming COVID-19, but he also stressed the need to guarantee equitable permission for the entire world population. In this sense, he stated that 'we need to unleash all the power of science, and offer scalable, usable innovations that benefit everyone, anywhere, at the same time'.

The concern regarding expanding efforts and initiatives to accelerate and encourage innovation by the WHO is even more justified if we consider the traditional market models in the production and commercialization of medicines. The same can be said about the rules established by the international system for the protection of intellectual property, regarding access to scientific information by researchers.

A new policy of global scale is needed and it should prioritize licensing and open support, technology transfer, and new partnerships for technical access. As to the market, there is need for a commitment not to increase drug prices during the pandemic.

The concern of the lack of production capacity is real, so much so that the pharmaceutical company which holds the patent for the drug Remdesivir (a new chemical entity being tested for the treatment of COVID-19) claims to have a production capacity, until December 2020, of 1.5 million treatments,[2] which is well below the global need. A closer look at Remdesivir reveals the existence of eight patent applications related to the product used to fight the coronavirus. Access to medicines is a complex issue, with numerous regulations and issues to be tackled in order to ensure that drug developments reach the people who need them – intellectual property being one such issue.

The challenge is not whether intellectual property exists, but how it will be exercised. In this area there is a great opportunity to practice intellectual property management, focusing on public interest, particularly during a pandemic. Thus, in the case of COVID-19, thinking about open licensing aims to eliminate a barrier to the production capacity of the input needed to face the pandemic.

The 73rd WHO Assembly featured the motion proposed by the European Union to create a pool of

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1 <who.int/travel-advice> accessed 10 May 2020.

2 <https://www.gilead.com/purpose/advancing-global-health/covid-19/working-to-supply-remdesivir-for-covid-19> accessed 15 May 2020.

voluntary patents for vaccines, whereby pharmaceutical companies and producers would forgo the monopoly on the exclusive use of their patents so that other countries with fewer resources could acquire or produce locally. This would aim at ending the pandemic.

The position taken by the WHO is clear with regard to implementing a global strategy that ensures a balanced distribution and guarantees equity in access to resources for all, regardless of the economic capacity of each country to purchase medicines used to combat the pandemic. The central discussion is the democratic access to drugs for combating COVID-19, that is to say: (i) access with equality, without any type of discrimination; (ii) access with equity in the face of the need of each human being, without distinction; and (iii) access regardless of one's country or region, as it is a global pandemic.

The limits imposed by the world patent system need to be tackled. Some advances have been made in the past, for instance in the fight against HIV. An example can be seen in the 2001 Doha Declaration on TRIPS and Public Health of the World Trade Organization (WTO). Here it was endorsed that 'the TRIPS Agreement does not and should not prevent Members from adopting measures to protect public health', since 'the Agreement can and must be interpreted and implemented in such a way as to imply support for the right of WTO Members to protect public health and, in particular, to promote everyone's access to medicines'.[3]

In the 1990s the world was hit by HIV, and Brazil sought compulsory licensing of drugs to combat the virus. In this respect the DOHA Declaration established that 'each Member has the right to grant compulsory licenses, as well as freedom to determine the bases on which such licenses are granted', thus 'each Member has the right to determine what constitutes a national emergency and other circumstances of extreme urgency, implying that public health crises, including those related to HIV, tuberculosis, malaria and other epidemics, are liable to constitute a national emergency or circumstances of extreme urgency'.

The recent exceptions to intellectual property rights based on the Brazilian experience in the 1990s in the fight against HIV, using the legal instrument of compulsory licensing, had two distinct milestones: one in 2001 and another in 2007.

In 2001 Brazil, with the support of 48 countries, submitted to the WTO a request for compulsory licensing of certain new drugs that were being used to treat HIV. The request aimed to demonstrate economic abuse by the pharmaceutical industry in view of the high price of medicines in developing countries. Compulsory licensing would make it possible to reduce the cost for patients who urgently needed the medicines. Negotiations between the parties dragged on for almost a year, until the industry accepted the reduction of the prices existing in the national market. Thus, the legal instrument of compulsory licensing was not effectively used, as the pharmaceutical industry conceeded to making the medicines (still protected by patents) accessible for patients in poor countries.[4]

For the first time, in 2007, after another six months of discussions and legal obstacles, the Brazilian government was able to implement the legal instrument of compulsory licensing provided for in Law No. 9929 of May 1996. This instrument regulates the rights and obligations related to industrial property. In its Art. 71 the law establishes that in cases of national emergency or public interest, declared in an act by the Federal Government and provided that the patent holder or its licensee does not meet this need, a compulsory license may be granted, always temporarily and non-exclusively, for the exploitation of the patent without damages to the rights of the respective owner. The act of granting the license will establish its validity period and the possibility of extension.[5]

It should be noted that a compulsory license is always limited in time and restricted to the territorial limits of a given country. Now, however, in the face of the COVID-19 pandemic, it is necessary to establish a global strategy and policy across borders.

The wide access and open licensing of patents for future vaccines or treatments to combat COVID-19 can be found in the guidance given by the 73rd WHO Resolution to be adopted by countries, research centers, universities and the international scientific community.

Some countries such as Germany[6] and Canada[7] have recently modified their national legislation allowing the State to freely use technologies in order to confront COVID-19. It must be emphasized that Israel[8] was the first country to issue a compulsory license to allow access to medicines being tested to combat the pandemic. A Colombian Presidential Decree declared the technologies for combating COVID-19 (a preparatory act for compulsory licensing) to be of public interest, and the Congresses of Ecuador, Peru and Chile have requsted that the Ministries of Health of these respective countries issue compulsory licenses similar to that in Israel. It is important to mention that such use requires the payment of royalties to the owner of the intellectual property regarding the use by the State of the technologies and innovations to combat COVID-19.

The matter is clear in a world with COVID-19 or post-pandemic. The intellectual property system must provide a property management practice that takes into account the public interest, with open licensing, also eliminating barriers to industrialization of the necessary input for production, distribution and access to all countries on an equal basis.

3 Carlos M Correa, 'O Acordo TRIPS e o acesso a medicamentos nos países em desenvolvimento' [TRIPS Agreement and access to medicines in developing countries] 2(3) Sur. Revista Internacional de Direitos Humanos 2005 <https://doi.org/10.1590/S1806-64452005000200003> accessed 10 May 2020.

4 <https://www.bbc.com/portuguese/noticias/2001/010620_omc.shtml> accessed 20 May 2020.

5 <http://www.planalto.gov.br/ccivil_03/Leis/L9279.htm> accessed 10 May 2020.

6 <https://www.gesetze-im-internet.de/ifsg/index.html?_sm_au_=iVVvns5WHQ11sMDPvMFckK0232C0F> accessed 21 May 2020.

7 <https://wipolex.wipo.int/en/legislation/details/19382> accessed 22 May 2020.

8 <https://www.keionline.org/32503> accessed 21 May 2020.