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Short communication

Impact of intellectual property rights on the access to COVID-19 vaccines

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Introduction

The unprecedented pace in COVID-19 vaccine development triggered initial global elation, which has been tempered with the realization that dealing with the complicated process of vaccine rollout and implementation is a constantly evolving and challenging process. Moreover, the apparent disparity in vaccine access for populations in low vs high-income nations positions as one of the major causes for prolonging the pandemic phase of COVID-19. Despite early policy commitments to ensure that COVID-19 vaccines should become global public goods, the governments of developed countries, which directly or indirectly (via COVAX, for example) funded vaccine research and development (R&D), focused predominantly on their national electorates. As a result, substantial inequalities in vaccination rates emerged, especially apparent in the early months of the COVID-19 immunization campaign. This low fraction of vaccinated inhabitants of low-income countries can be attributed to the inaccessibility of vaccines due to limited supply in their countries. However, despite the fact that more than 11 billion doses were manufactured by the end of 2021, less than 15% of residents of low-income counties have been vaccinated with at least one dose of the COVID-19 vaccine (as of April 2022) (www.ourworldindata.org).

The initial deficiency of vaccine doses in low-income countries is a result of a combination of several factors: limited production capacities and manufacturing facilities capable of transferring novel technologies, legal issues primarily related to intellectual property rights (IPRs) and financial and diplomatic inequity compared to the developed nations. Nevertheless, distribution challenges, lack of qualified healthcare workers, mistrust in local authorities and widespread vaccine hesitancy currently pose the main reasons for the low coverage of COVID-19 vaccination in these nations.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), effective since 1995, establishes the minimum standards for protection and enforcement of IPR as applied to nationals of other World Trade Organization (WTO) members. Combined with the amplified significance of IPRs due to technological and medical advances, TRIPS has a vital role in global access to medical products, therapeutics, and vaccines. As a response to apprehensions expressed by low and middle-income countries, primarily linked to the effect of patents on access to antiretroviral HIV/AIDS drugs, the DOHA Declaration in 2001 elucidated the scope of TRIPS and presented a set of “flexibilities” such that “the TRIPS Agreement does not and should not prevent members from taking measures to protect public health”. The declaration also highpoints that each WTO member country has the right to “grant compulsory licenses and the freedom to determine the grounds” for such licenses (Mercurio, 2021).

In October 2020, India and South Africa submitted a proposal to the World Trade Organization (WTO) for a waiver of IPRs for COVID-19 medical products for the duration of the pandemic. The proposal considers that such a transitory waiver will simplify the cooperation among WTO members on the manufacturing, scale-up and supply of COVID-19-related products, consecutively contributing to more equal access to COVID-19 vaccines in less developed countries (WTO, 2020).

Different attitudes on waiving IPRs for COVID-19 vaccines

The proposal for waiving IPRs for COVID-19 medical products was consecutively supported by over

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100 countries, World Health Organization (WHO), numerous civil society organizations, as well as several world leaders. Regardless of the shifted viewpoint of the Biden administration and American open support for the proposed waiver for COVID-19 vaccines (announced on May 5, 2021), the representatives of other developed countries argued against the proposal. They rationalized their position by assessing that the shortage of production capacities, required technical know-how, and vaccine export curb are the main challenges that need to be overcome in order to establish a fair supply of the essential doses. As expected, pharmaceutical companies also declared against the proposal, addressing that IPR are critical driving force that encourages innovation in the industry and enables the return of invested funds in R&D. However, injecting public funds into private companies (as seen in COVID-19 vaccine development), justifies the prevalent conviction that public benefit should be prioritized over IPR of innovators (Zarocostas, 2022).

Alternatives for IPR waiver

It is evident that despite several international discussions and consultations held between WTO members, misaligned positions of different countries lead to gridlock in deciding on the proposal for waiving IPR for COVID-19 vaccines. Yet, countries have a few other options for enabling vaccine access to their population, which are briefly described below.

According to aforementioned TRIPS flexibilities, governments can issue compulsory licenses in order to protect the health of their citizens in cases of emergencies. When countries issue compulsory licenses, they permit someone else to produce the patented product or process without the authorization of the patent owner. Still, applying for a compulsory license is a complex and time-consuming process, having in mind that a single vaccine might involve numerous different patents (European commission, 2020).

On the other hand, voluntary licenses are agreements between patent holders and other companies, which allow manufacturing of the patented product. With these agreements, the patent holders typically specify the markets where these other companies can sell the product and set desired prices, meaning that patent holders have substantial control over the licensee. A well-known example of voluntary license is the agreement achieved between AstraZeneca and the Serum Institute of India (AstraZeneca, 2020).

Inspired by the Medicines Patent Pool, and its successful role in the accessibility of HIV/AIDS drugs, WHO launched COVID-19 Technology Access Pool (C-TAP), which main purpose is to assemble global knowledge and IPR related to COVID-19 products. Nonetheless, as of June 1, 2022, there are no patents related to COVID-19 vaccines that are available on this platform.

Conclusion

The rapid access to COVID-19 vaccines is noticeably limited by the insufficient production capacities of leading vaccine developers. For low-income countries, the price determined by the innovators may pose a significant obstacle to obtaining an adequate number of doses. Although at first glance IPR can be seen as a major hindrance to fair distribution of the vaccines, they are pharma and biotech companies' most valuable resource, and fundamental feature required for justification of the funds invested in R&D. As a matter of fact, in a state of emergency, the shortage in raw materials, complex manufacturing processes, the necessity of trained employees, substantial investments in building production facilities, as well as strict regulatory requirements applied to biosimilar, it is unlikely that waiving IPR can contribute for rapid and significant increase in the quantity of accessible doses and decrease of their price.

Irrespective of billions of doses produced by the end of 2021 and large donations obtained by richer countries, the percentage of the vaccinated population in low-income countries remains low. It is now apparent that strengthening the existing health infrastructure, increasing the trust in local authorities, investing in education, and combating disinformation are vital steps needed to achieve the goal and defeat the COVID-19 pandemic.

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