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

Aleksandar Dimkovski; Evgenija Mihajloska; Aleksandra Grozdanova; Ljubica Suturkova; Katerina Ancevska Netkovska

Faculty of Pharmacy, Ss. Cyril and Methodius University in Skopje, str. Mother Tereza 47, 1000 Skopje, R.N. Macedonia

#### Introduction

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. This substantial inequalities in vaccination rates were especially apparent in the early months of the COVID-19 immunization campaign. The 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.

However,

- distribution challenges;
- \* lack of qualified healthcare workers;
- \* and mistrust in local authorities and widespread vaccine hesitancy, currently pose the main reasons for the low coverage of COVID-19 vaccination in low-income nations.

# Waiving IPRs for COVID-19 vaccines – different attitudes

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).

The proposal was consecutively supported by over 100 countries (including American shifted position, announced in early May 2021), World Health Organization (WHO), numerous civil society organizations, as well as several world leaders.

However the representatives of other developed countries argued against the proposal, 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.

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.

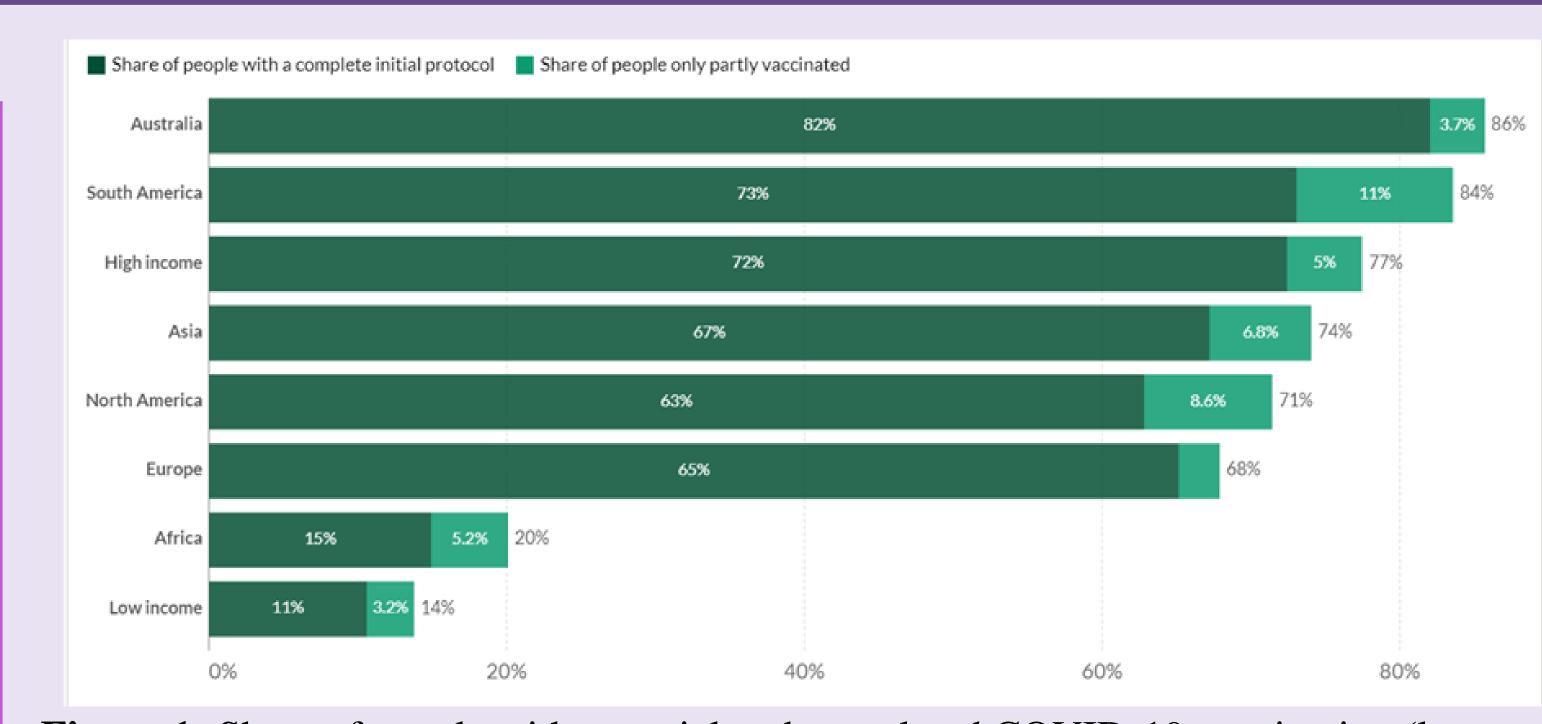
However, injecting public funds into private companies (as seen in COVID-19 vaccine development), can justifie the prevalent conviction that public benefit should be prioritized over IPR of innovators (Zarocostas, 2022).

#### References

**European Commission, 2020.** Questions of Compulsory patent licensing in times of Covid-19. **Mercurio, B., 2021.** WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review. VA. j. int. law online 9-32,

WTO, 2020. World Trade Organization. Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19.

Zarocostas. J., 2022. Mixed response to COVID-19 intellectual property waiver. The Lancet. 399, 10332, 1292-1293.



**Figure 1:** Share of people with a partial and completed COVID-19 vaccination (low income vs high income countries vs continents) as of April 2022 (Data obtained from www.ourworldindata.org)

### Alternatives for IP 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 the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and DOHA Declaration, 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.

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

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.