



# COVID-19 vaccine inequity and Big Pharma: time to rethink our love affair?

Shehzad Ali<sup>1,2,3,4,5</sup>  • Ayesha Jacob<sup>6</sup> • Saverio Stranges<sup>1,7,8</sup>

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Dear Editor:

Two years into the pandemic, 67.7% of the world has received at least one dose of vaccine; however, the percentage in developing countries is only 21% (Ritchie et al., 2022). This massive vaccine inequity is, quite frankly, an embarrassment. Companies have prioritized sales to governments willing and able to pay the highest price. As a result, 70% of the doses produced by Moderna, Pfizer, and BioNTech are going to wealthy nations, creating massive vaccine inequities (Yamey et al., 2022). Here we discuss two areas where the global community can play an important role in addressing this gap.

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✉ Shehzad Ali  
shehzad.ali@uwo.ca

- <sup>1</sup> Department of Epidemiology and Biostatistics, Schulich School of Medicine, Western University, London, Ontario, Canada
- <sup>2</sup> Interfaculty Program in Public Health, Western University, London, Ontario, Canada
- <sup>3</sup> The World Health Organization Collaborating Centre for Knowledge Translation and Health Technology Assessment in Health Equity, Bruyère Research Institute, Ottawa, Ontario, Canada
- <sup>4</sup> Department of Health Sciences, University of York, Heslington, UK
- <sup>5</sup> Department of Psychology, Macquarie University, Sydney, Australia
- <sup>6</sup> Wits Medical School, University of the Witwatersrand, Johannesburg, Johannesburg, South Africa
- <sup>7</sup> Department of Family Medicine, Schulich School of Medicine & Dentistry, Western University, London, Ontario, Canada
- <sup>8</sup> Department of Precision Health, Luxembourg Institute of Health, Strassen, Luxembourg

## Intellectual Property (IP) rights for COVID-19 vaccines

IP rights for COVID-19 vaccines are protected under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

### Arguments to waive IP rights

First, much of the vaccine technology was funded through public money. Pfizer received \$1.95 billion from the United States government while Moderna's vaccine was almost entirely funded by taxpayers (\$2.5B). These vaccines brought in revenues of \$37B and \$13B for the two companies in 2021, with projected revenues of \$54B and \$21B in 2022, respectively (Hopkins & Grossman, 2022). This 'double dipping' of funds is unacceptable and has been widely criticized by public policy leaders. Second, the current capacity of patent holders and ingredient producers is not sufficient to vaccinate the world. There are, however, many companies in developing countries that can fulfill this shortfall if IP rights are waived.

### Failure of the global community at WTO

While some countries have argued that existing TRIPS flexibilities are sufficient, these flexibilities operate on a country-by-country and product-by-product basis and involve time-consuming bureaucratic hurdles and legal concerns (Zaman, 2022).

In October 2020, India and South Africa put forward a comprehensive IP waiver proposal to WTO to ease all restrictions during the pandemic. The proposal was supported by >100 countries, but some WTO members, home to large pharmaceutical companies, pushed back. After 20 months of negotiation, a significantly modified form of the original waiver text was adopted on June 17, 2022. Many opinion leaders called it a major disappointment and not even close to the original proposal (Frontieres, 2022). The watered-

down text has several issues: (a) it does not include sharing of trade secrets, copyright, industrial design, and technical know-how, without which a waiver may be useless; (b) the waiver has added new and prohibitively onerous requirements for producers to identify and report all patents covered by the waiver application, including overlapping patents ('patent thickets') that can be extremely burdensome to establish for a complex network of vaccine IPs; and (c) the waiver does not include therapeutics and diagnostics, which have been a major line of defence during the pandemic.

### The onus is on individual governments

With WTO's failure to support an all-inclusive waiver, individual governments must do more to facilitate local manufacturers and exporters by issuing compulsory licenses. While the option to use TRIPS flexibilities exists, the process is cumbersome and non-functional (Labonté et al., 2021). For example, Biolyse Pharma has been trying to export 20 million doses of a COVID-19 vaccine to Bolivia but its efforts have been stymied since March 2021 by the first step of the process (Crombie, 2021). This is an area where individual governments can take decisive action to remove roadblocks to vaccine production and export (Clarke et al., 2022).

### Supporting non-big pharma initiatives

IP waivers would be a major step forward but are not a panacea. Another major hurdle is the limited infrastructure, technical know-how, and production capacity outside the mainstream pharmaceutical industry. To counter this challenge, the WHO 'mRNA Vaccine Technology Transfer Hub' was established in 2021 in South Africa to facilitate the manufacturing of vaccines in developing countries by transferring technology and technical know-how to local producers of vaccines, including data, formulae, IP, training, and the fully validated manufacturing process (WHO, 2021).

This initiative uses a hub and spoke model, with individual spokes distributed across developing countries. The hub can fast-track vaccine development and has produced its first batch of a COVID-19 vaccine based on publicly available information (WHO, 2021). However, many steps remain before the vaccine can be distributed, including the challenge of being undermined by the pharmaceutical industry (Davies, 2022).

### Conclusion

The COVID-19 pandemic has raised several ethical and economic questions for high-income countries, including the

trade-off between working with (and not antagonizing) the pharmaceutical industry and lobbyists at home, and trying to meet vaccine equity goals globally. Unfortunately, this balancing act has not produced favourable and timely outcomes for developing countries. We recommend that individual governments should expedite current IP flexibilities and remove roadblocks to locally producing and exporting vaccines. We also recommend that countries should strongly support the WHO mRNA Hub through financial investments and technical knowledge, so the Global South does not need to rely on vaccine charity.

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