



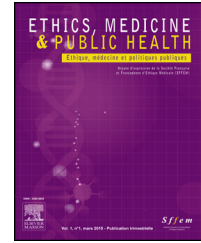
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LETTER TO THE EDITOR

Time to boost COVID-19 vaccine manufacturing: The need for intellectual property waiver by big pharma



Keywords Big Pharma; COVID-19; Intellectual property rights; Pandemic; Vaccine

Dear Editor,

Vaccines are the major means of evading the pandemic. This, however, will only occur if vaccines are widely available and affordable around the world. Given the severe vaccine shortages in low- and middle-income countries (LMICs) [1], the issue of intellectual property (IP) rights has come to light. As the pandemic plagues economically disadvantaged countries, rich countries stockpiling has stressed the need for pharmaceutical industries to waive IP rights.

This waiver, proposed in October 2020 by South Africa and India [2], would allow poor countries to manufacture COVID-19 vaccines without having to reimburse pharmaceutical industries for patent rights, at least until the pandemic comes to an end [3]. This will boost the global supply of COVID-19 vaccines at a reduced cost while accelerating efforts to vaccinate the whole world before the end of the year. Many countries, particularly LMICs, supported the proposal, which was to be negotiated through the World Trade Organization, but it was met with significant resistance by Big Pharma, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and rich countries, including the EU, the United Kingdom, Canada, Switzerland, Australia [4], and, initially, the United States [5]. However, the United States withdrew its resistance in early May to boost vaccines 'access and supply to put the pandemic to an end sooner [6]. The approval of the proposal is much more likely now that the US government has thrown its weight behind it. The IFPMA, on the other hand, has expressed displeasure and disappointment at the stance of the United States, claiming that waiving IP rights would not address the lack of manufacturing capacity in developing countries or help them to manufacture additional doses of the COVID-19 vaccines [7]. Alternatively, they propose lowering trade barriers, which would make it easier for Big Pharma to sell vaccines to poor countries [7]. However, the reality is that not waiving IP rights is a step backward in the fight against global vaccine equities [8,9]. Waiving IP rights while simultaneously allowing the exchange of manufacturing expertise is critical to increasing the global production of vaccines and ending the pandemic [10–12]. The waiver is much more

necessary now than when the proposal was first submitted in October 2020.

The world is currently witnessing a two-way pandemic, with affluent countries returning to normalcy while poorer countries are struggling with fresh outbreaks and an acute shortage of vaccines and therapeutics [1]. This is a condition that the World Health Organization (WHO) has labelled "vaccine apartheid" [13]. Another cause for concern is that there is a potential that vaccine-resistant variants may continue to arise as long as new COVID-19 outbreaks emerge [14].

The point of questioning the safety of products manufactured by industries in the global south, particularly in LMICs, is not new and is gradually becoming a norm [15]. One of the most remarkable precedents in history was the dispute involving big pharma and poor countries over the production of antiretroviral medications for AIDS, which cost around \$10,000 per person annually until the development of generics, which reduced the price to \$300 per person annually [16]. In 1998, a similar episode of that dispute played out when an alliance of multinational drug manufacturers and the South African Pharmaceutical Manufacturers Association filed a lawsuit against the Nelson Mandela-led South African government for attempting to encourage local, patent-free manufacturing of more cost-effective AIDS medications, though the charges were eventually dropped [17]. At that time, western pharmaceutical industries asserted that drugs manufactured in LMICs did not satisfy quality requirements, despite data repeatedly showing no basis for this assertion [7,17]. Today, we would not have achieved significant success in antiretroviral therapies in LMICs if it had not been for generic manufacturers, and we have seen that generics are safe and of high quality [18].

Granted, vaccines are much more difficult to manufacture than oral medications, but UNICEF and other global agencies have long relied on big vaccine manufacturers in developing countries, including India – the world's biggest vaccine manufacturer – to produce their vaccines, with constant quality scrutiny [19]. Developing countries have developed and manufactured their own vaccines in times past, such as the hepatitis B vaccine developed by Shanta Biotechnics in India [20]. This resulted in a mass vaccination against the virus, with over 120 million doses delivered to poor countries around the world [20]. As such, the present COVID-19 vaccine is no exception.

While there is much talk going on vaccine equity in light of the current circumstances, the prioritization of vaccine equity has not been in the first place. The discussion of whether to waive the intellectual property rights has been

raised involving Big Pharma and LMICs. One can imagine that despite the tremendous profits that Big Pharma makes from vaccine manufacturing, waiving IP rights is still a topic of debate. Needless to say, vaccine distribution has created an enormous disparity between high, and low and middle-income countries. In the aftermath of such disparity, the pandemic has particularly caused more concerns for LMICs. An evident example is the precipitating cases of the virus in some LMICs, with the third wave in sight. At this critical juncture, Big Pharma has an immense role to play, and they should take a unanimous stance to help LMICs fight the pandemic and put more value on human lives than profits. Life will return to normalcy in LMICs if immediate actions are taken. At this moment, an urgent agreement is needed between Big Pharma and LMICs to accelerate the production of the vaccines. Such agreement can help with; the creation of vaccine hubs in different regions which can help with the rapid production of the vaccine, especially for countries that have been hit hard with the third wave of the pandemic; and the follow-up creation of surveillance hubs close to the vaccine hubs which can be used for constant monitoring to ensure good manufacturing practices and quality control of the vaccines. These hubs can be also used for prospective pandemics or disease outbreaks. The COVID-19 pandemic has taught humankind to be prepared for any unexpected or unprecedented disease outbreaks as fast production and delivery of the vaccines can help ensure effective disease containment in the affected regions. There has been unequal and delayed delivery of the vaccines, particularly to highly affected countries, resulting in an upsurge in the number of reported cases with a more pronounced impact on the governments and the economy. These pinpoint the need for vaccine hubs in regions with a relatively higher disease burden. Lastly, the issue of profit that has provoked Big Pharma can be solved through negotiation. Big Pharma can deploy adequate manpower and technical expertise to run the vaccine hubs together with local manpower in the affected regions. A minimum profit from LMICs where these vaccine hubs are run throughout the course of production should be convincing enough for Big Pharma, as human lives are at stake.

Waiving or relaxing intellectual property rights over COVID-19 vaccines would not solve the global pandemic alone. However, it has the potential to clear several road-blocks as efforts to ease IP rights can see the balance shifted towards COVID-19 containment. Drawing on lessons learned from the AIDS story on the dispute between Big Pharma and LMICs over waiving IP rights for antiretrovirals, it can be argued that waiving IP rights for COVID-19 vaccines is a reasonable decision if we are to achieve significant success in the fight against COVID-19. With such actions, ending the pandemic totally will become achievable.

Human and animal rights

The authors declare that the work described has not involved experimentation on humans or animals.

Informed consent and patient details

The authors declare that the work described does not involve patients or volunteers.

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Author contributions

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Disclosure of interest

The authors declare that they have no competing interest.

References

- [1] Nkengasong JN, Ndemi N, Tshangela A, Raji T. COVID-19 vaccines: how to ensure Africa has access. *Nature* 2020;586:197–9, <http://dx.doi.org/10.1038/d41586-020-02774-8> [PMID: 33024330].
- [2] Usher AD. South Africa and India push for COVID-19 patents ban. *Lancet* 2020;396:1790–1, [http://dx.doi.org/10.1016/s0140-6736\(20\)32581-2](http://dx.doi.org/10.1016/s0140-6736(20)32581-2).
- [3] Gonsalves G, Yamey G. The COVID-19 vaccine patent waiver: a crucial step towards a ‘people’s vaccine’. *BMJ* 2021;373:n1249, <http://dx.doi.org/10.1136/bmj.n1249>.
- [4] World Trade Organization. Members to continue discussion on proposal for temporary IP waiver in response to COVID-19. https://www.wto.org/english/news_e/news20_e/trip_10dec_20_e.htm Accessed 26 June 2021.
- [5] Contreras JL. US Support for a WTO waiver of COVID-19 intellectual property. *Inter Econ* 2021;56:179–80, <http://dx.doi.org/10.1007/s10272-021-0976-7>.
- [6] Reuters. U.S. reverses stance, backs giving poorer countries access to COVID vaccine patents. <https://www.reuters.com/business/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/> Accessed 26 June 2021.
- [7] Quartz. Big Pharma Argues that Poor Nations Can’t Be Trusted to Make Vaccines. <https://qz.com/2013661/big-pharma-argues-poor-nations-cant-be-trusted-to-make-vaccines/> Accessed 26 June 2021.
- [8] Aryeetey E, Engebretsen E, Gornitzka Å, Maassen P, Stølen S. A step backwards in the fight against global vaccine inequities. *Lancet* 2021;397:23–4, [http://dx.doi.org/10.1016/s0140-6736\(20\)32596-4](http://dx.doi.org/10.1016/s0140-6736(20)32596-4).
- [9] Mercurio B. The IP. Waiver for COVID-19: bad policy, bad precedent. *IIC Int Rev Ind Prop Copyr Law* 2021;24:1–6, <http://dx.doi.org/10.1007/s40319-021-01083-5>.
- [10] Bozorgmehr K, Jahn R, Stuckler D, McKee M. Free licensing of vaccines to end the COVID-19 crisis. *Lancet* 2021;397:1261–2, [http://dx.doi.org/10.1016/s0140-6736\(21\)00467-0](http://dx.doi.org/10.1016/s0140-6736(21)00467-0).
- [11] A patent waiver on COVID vaccines is right and fair. *Nature* 2021;593:478, <http://dx.doi.org/10.1038/d41586-021-01242-1>.
- [12] Del Castillo FA. Temporary waiver of intellectual property on Covid-19 vaccines: toward the creation of a better, post-pandemic society. *J Public Health (Oxf)* 2021;fdab184, <http://dx.doi.org/10.1093/pubmed/fdab184>.
- [13] Reuters. World has entered stage of ‘vaccine apartheid’ - WHO head <https://www.reuters.com/business/healthcare-pharmaceuticals/world-has-entered-stage-vaccine-apartheid-who-head-2021-05-17/> Accessed 26 June 2021.

- [14] Duong D. What's important to know about the new COVID-19 variants? *CMAJ* 2021;193:E141–2, <http://dx.doi.org/10.1503/cmaj.1095915>.
- [15] Musungu SF. Benchmarking progress in tackling the challenges of intellectual property, and access to medicines in developing countries. *Bull World Health Organ* 2006;84:366–70, <http://dx.doi.org/10.2471/blt.06.029793>.
- [16] Chirac P, von Schoen-Angerer T, Kasper T, Ford N. AIDS: patent rights versus patient's rights. *Lancet* 2000;356:502, [http://dx.doi.org/10.1016/S0140-6736\(00\)02566-6](http://dx.doi.org/10.1016/S0140-6736(00)02566-6).
- [17] Saslow EL. Compulsory licensing and the AIDS epidemic in South Africa. *AIDS Patient Care STDS* 1999;13:577–84, <http://dx.doi.org/10.1089/apc.1999.13.577>.
- [18] Pagliusi S, Leite LC, Datla M, Makhoana M, Gao Y, Suhardono M, et al. Developing countries vaccine manufacturers network: doing good by making high-quality vaccines affordable for all. *Vaccine* 2013;31(Suppl 2):B176–83, <http://dx.doi.org/10.1016/j.vaccine.2012.11.060>.
- [19] Gupta SS, Nair GB, Arora NK, Ganguly NK. Vaccine development and deployment: opportunities and challenges in India. *Vaccine* 2013;31(Suppl 2):B43–53, <http://dx.doi.org/10.1016/j.vaccine.2012.11.079>.
- [20] Chakma J, Masum H, Perampaladas K, Heys J, Singer PA. Indian vaccine innovation: the case of Shantha Biotechnics. *Global Health* 2011;7:9, <http://dx.doi.org/10.1186/1744-8603-7-9>.

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