

Lessons from the pandemic for LDCs: Implementing intellectual property flexibilities

Sangeeta Shashikant

The global crisis of COVID-19 has underscored the vital importance of utilizing, to the fullest extent, policy space in the area of intellectual property. Since the onset of the pandemic, many countries around the world have had to confront various challenges of access including to tools protected by intellectual property (IP). These include copyrighted materials as learning shifted to online platforms, and affordable health products and technologies to prevent and treat the infection. The pandemic has also accentuated the significance of local production as limited supplies of critical commodities are rapidly snapped up by developed countries.

Since March 2020, the least developed countries (LDCs) have perhaps struggled the most with limited financial resources, facilities and technological capacity to contain the pandemic and deal with its socio-economic impacts. In October 2020, the United Nations Conference on Trade and Development (UNCTAD) reported that middle- and low-income countries have been largely priced out from access to COVID-19-related products.¹ On average, each resident of high-income countries benefited from US\$10 of imports of COVID-19 products, while this number is much lower for middle-income countries at about US\$1, and lower still for low-income countries at a mere US\$0.10.

This points to the staggering inequity witnessed in this pandemic and which continues till today and threatens to deepen. For instance, although testing is crucial to identify the nature and scale of infection, as of February 2022, testing in LDCs constituted a mere 1% of tests reported globally.² It is no different for vaccines, as by February 2022 just 28% of the LDC population had received at least one dose of a COVID-19 vaccine.³ Only 13% in the Africa region,⁴ which has the most LDCs, have been fully vaccinated. This vast disparity has shone a spotlight on flexibilities within the IP system to address national needs.

¹ <https://unctad.org/webflyer/global-trade-update-october-2020>

² <https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/LDC-testing-28-Feb-22.pdf>

³ Ibid.

⁴ <https://africacdc.org/covid-19-vaccination/>

Third World Network (TWN) is an independent non-profit international research and advocacy organisation involved in bringing about a greater articulation of the needs, aspirations and rights of the peoples in the South and in promoting just, equitable and ecological development.

Published by Third World Network Berhad (198701004592 (163262-P))

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IP protection standards were globalized with the entry into force of the World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights. This instrument, commonly known as the TRIPS Agreement, set minimum requirements to be followed by the WTO Member states. These standards generally confer exclusive rights to the right holder across the different categories of IP covered by the Agreement. But the Agreement also contains flexibilities allowing Members to take measures to prevent abuse by the IP holders as well as to protect public health, nutrition and to promote the public interest in sectors of vital importance.⁵

The LDC WTO Members enjoy a greater set of flexibilities. In view of their special needs and requirements, their economic, financial and administrative constraints and their need for flexibility to create a viable technological base, the LDCs are generally exempt from implementing the TRIPS Agreement pursuant to Article 66.1.⁶ In addition to this general exemption which presently continues till 1 July 2034,⁷ LDCs also have a specific exemption from TRIPS requirements on patents and protection of undisclosed information applicable to pharmaceutical products until 1 January 2033.⁸ The LDCs also have a right to seek an extension of this exemption known as “transition period”.

In 2020, when requesting for extension of the general exemption, then set to expire on 1 July 2021, the LDCs argued, among others, that to “overcome the difficulties confronting LDCs, magnified manifold by the COVID-19 crisis, LDCs need maximum policy space *inter alia* to access various technologies, educational resources, and other tools necessary for development and to curb the spread of COVID-19 pandemic. Most intellectual property (IP)-protected commodities are simply priced beyond the purchasing power of least developed countries”.⁹

A concrete example of the significance of this policy space in the ongoing pandemic is the case of Bangladesh. In mid-2020, a therapeutic known as remdesivir was considered to be important for the treatment of COVID-19 (although it was later found to be lacking in efficacy for treating COVID-19 patients¹⁰). Gilead Sciences, which holds patents on remdesivir in more than 70 countries, engaged a few manufacturers as licensees to produce and supply to a group of low- and middle-income countries. The terms of the licence agreement are shrouded in secrecy but what is known is that the agreement excludes nearly half of the world's population from benefiting from price-lowering generic competition on the drug.¹¹ Gilead's own supply was itself rapidly bought up by the rich countries.¹² However, with robust manufacturing capacity and no IP barriers in Bangladesh – which is an LDC – other generic producers (not licensed by Gilead) were able to supply to satisfy domestic and foreign demand for affordable remdesivir, even to India as it battled against a second wave of the pandemic.¹³ The generic alternative from Bangladesh is also significantly cheaper, being sold in the domestic market at one-tenth of the price for a five-day treatment.¹⁴

⁵ Article 8 of the TRIPS Agreement

⁶ Article 66.1 of the TRIPS Agreement granted a 10-year transition period to LDCs, which can be renewed on request by the LDCs. This initial general transition period for LDCs ended in 2005. In 2005, the Council for TRIPS at the WTO renewed the general transition period until 1 July 2013 through decision IP/C/40; in 2013, the Council renewed the general transition period until 1 July 2021 through decision IP/C/64; and on 29 June 2021, it renewed the general transition period until 1 July 2034 through decision IP/C/88.

⁷ WTO document IP/C/88

⁸ WTO document IP/C/73

⁹ WTO document IP/C/W/668

¹⁰ <https://www.who.int/news-room/feature-stories/detail/who-recommends-against-the-use-of-remdesivir-in-covid-19-patients>

¹¹ <https://www.msf.org/msf-supports-india-and-south-africa-ask-waive-coronavirus-drug-patent-rights>

¹² <https://www.theguardian.com/us-news/2020/jun/30/us-buys-up-world-stock-of-key-covid-19-drug>

¹³ <https://www.livemint.com/news/india/bangladesh-hands-over-10-000-vials-of-remdesivir-to-india-11620308084836.html>

¹⁴ <https://www.moneycontrol.com/news/business/companies/a-bangladesh-pharma-company-causes-heartburn-in-indias-drugmakers-5375801.html>

The rise of Bangladesh's generic industry can be attributed to several policies adopted by the government. Upon the country's independence, it inherited the British Patents and Designs Act, 1911, which allowed the patenting of new pharmaceutical products. With a liberal approach towards multinational corporations (MNCs), in the early 1980s, foreign companies dominated the pharmaceutical sector.¹⁵ In 1982, however, through the Drugs (Control) Ordinance, the government banned the manufacture, import and sales of drugs identified by an Expert Committee as harmful, unnecessary and otherwise undesirable; and the marketing by MNCs of drugs manufactured on contract basis for the MNCs was banned if the MNCs did not have any manufacturing plant in the country and if these drugs or their substitutes were produced locally.¹⁶

Notably, in 2008, utilising the LDC exemption allowed under the TRIPS Agreement, the Bangladesh government issued an executive order that removed pharmaceutical product patents. This step is significant for it has enabled the production of generic alternatives of therapeutics patented in other jurisdictions, such as remdesivir. There are similar examples beyond COVID-19 products. Domestic company Incepta was the first to launch a \$10-per-tablet generic version of Gilead's blockbuster drug sofosbuvir sold in the US for \$1,000 per tablet.¹⁷ Sofosbuvir is the backbone for the treatment of hepatitis C, an infectious disease afflicting an estimated 58 million persons around the world.

These national policies have supported the significant growth of the pharmaceutical industry in Bangladesh, with a compound annual growth rate of about 13.5% between 2012 and 2017. The country is largely self-reliant in pharmaceuticals, with local production accounting for 97% of the market for formulation products. Manufacturers have indicated that they have the capacity to also manufacture COVID-19 vaccines.

IP policy space is important even beyond access to medicines. As the pandemic forced school closures in more than 190 countries, learning shifted online. But a significant number of copyright laws in all regions lack adequate flexibilities to permit education to be conducted through digital and online means. Access to and use of essential materials for remote education and research, text and data mining of scientific publications, reverse engineering of software, repairs of medical equipment that imbed software and other copyright-protected elements – these are all relevant to the containment of COVID-19 but may be hampered by restrictive copyright laws. As highlighted by Tel Amiel, UNESCO Chair in Distance Education, “*Scientific information and educational resources related to the COVID-19 pandemic need to circulate in a timely and effective manner, and this can only be achieved if they are to be done openly without legal barriers and limitations.*”¹⁸

Recognizing the central role of “freedom to operate” to scale up and diversify global manufacturing to address the global inequity in access, in October 2020, India and South Africa submitted to the WTO a proposal to temporarily waive certain TRIPS obligations with respect to patents, copyright, protection of undisclosed information and industrial designs for the prevention, treatment and containment of COVID-19.¹⁹ This proposal, which is now co-sponsored by 65 WTO Members and supported by many other Members, has received tremendous global support from various international organizations such as the World Health Organization and UNITAID, civil society, IP experts, parliamentarians, Nobel laureates and world leaders. While supported by a large majority of the WTO membership, it is opposed by a handful of developed countries such as the EU, Switzerland, United Kingdom, Norway etc. The US has indicated support for an IP waiver for vaccines.

Although LDCs are generally exempt from TRIPS implementation, the LDC Group in the WTO has also co-sponsored the TRIPS waiver proposal. Its support reinforces the pivotal role of policy space in the realm of IP. LDCs may also benefit from cooperation with other developing countries, for example, in the form of South-South cooperation, if the waiver proposal were to be adopted, allowing non-LDCs the freedom to operate and collaborate, albeit limited to the prevention, treatment and containment of COVID-19.

¹⁵ Sudip Chaudhuri (2020), “Evolution of the Pharmaceutical Industry in Bangladesh 1982-2020”, Centre for Development Studies

¹⁶ Ibid.

¹⁷ <http://www.pharmexec.com/10-sovaldi-sale-bangladesh>

¹⁸ <http://infojustice.org/archives/43020>

¹⁹ WTO document IP/C/W/669

While IP flexibilities provide many opportunities for building productive capacities and responding to national needs including health emergencies, their use in LDCs has been limited. There are many reasons for this. A common misconception is that implementing more IP will lead to investment, innovation and technological development. However, historical evidence suggests otherwise as it reveals that today's developed countries used both legitimate and "illegitimate" means to acquire foreign technologies to support nascent industries in order to become competitive.²⁰ Most advanced countries were still routinely violating the IP of other countries' citizens well into the 20th century.²¹ This situation is aptly captured by Dr. Ha-Joon Chang: "...when they were backward themselves in terms of knowledge, all of today's rich countries blithely violated other people's patents, trademarks and copyrights. The Swiss 'borrowed' German chemical inventions, while the Germans 'borrowed' English trademarks and the Americans 'borrowed' British copyrighted materials – all without paying what would today be considered 'just' compensation."²²

Many industries in the developed countries emerged due to the lack of IP protection. For example, in the 19th century, Switzerland's chemicals and textiles industries strongly opposed the introduction of patents as these would restrict their use of processes developed abroad. In fact, it was recognized that Swiss industrial development was fostered by the absence of patent protection.

The experience of developing countries that have built up technological capacity is also similar.²³ In 1972, India abolished product patent protection in pharmaceuticals, a sector that was then dominated by multinationals. The policy change operated as a pull mechanism that provided Indian companies the space and opportunity to develop and innovate. Supported by public investments in manufacturing and in R&D, Indian pharmaceutical companies made enormous progress. The lack of patents in India during that period has enabled the entry of generic competition including for HIV/AIDS medicines, facilitating access at a fraction of the price being offered by patent-holding multinational pharmaceutical companies. India is thus known as the "pharmacy of the world".

In conclusion, even the TRIPS Agreement has linked "maximum flexibility in the domestic implementation of laws and regulations" to the creation of a sound and viable technological base in the LDCs, and recognizes the LDCs' economic, financial and administrative constraints.²⁴ Hence, under Article 66.1 of the Agreement, LDCs are entitled to renewable exemptions from TRIPS implementation (transition periods).

The lesson for LDCs from the pandemic is that it is time to fully exploit this policy space.

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²⁰ Ha-Joon Chang (2001), "Intellectual Property Rights and Economic Development – Historical Lessons and Emerging Issues", Third World Network Intellectual Property Rights Series No. 3, available at <http://www.twinside.org.sg/title2/IPR/pdf/ipr03.pdf>. Ha-Joon Chang (2003), "Kicking Away the Ladder: the 'Real' History of Free Trade", Foreign Policy in Focus Special Report, available at http://www.fpiif.org/reports/kicking_away_the_ladder_the_real_history_of_free_trade. For a more detailed history, see Ha-Joon Chang (2002), *Kicking Away the Ladder: Development Strategy in Historical Perspective*, Anthem Press.

²¹ Ibid.

²² Ha-Joon Chang (2008), *Bad Samaritans: The Guilty Secrets of Rich Nations & the Threat to Global Prosperity*, Random House

²³ Nagesh Kumar (2003), "Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries", *38 Economic & Political Weekly* 18

²⁴ See Preamble and Article 66.1 of the TRIPS Agreement.