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EDITORIAL

Global Health Equity – An Unfulfilled Promise

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We are nearing the end of two years into the COVID-19 pandemic.

It was the best of times. And it was most certainly the worst of times!

There have been spectacular advances in scientific collaboration with the identification of the SARS-CoV-2 pathogen and the development of vaccines, hope in the intent of global leaders to marshal the financial resources to provide equitable access to health products, and the record-time development and marketing approval of several vaccines. Yet today we witness vaccine hoarding and excess in developed countries, and scarcity in developing and least developed countries – with devastating consequences.

In all this, the role of intellectual property (IP) looms large. Shortages of essential health products have been artificially created through the refusal of IP rights holders to share their technology and know-how in the midst of the worst pandemic in the past century.

The IP landscape has, for the past few decades, been a highly contested arena. Since the advent of the World Trade Organization's TRIPS Agreement (WTO, TRIPS), we have witnessed the increasing stranglehold of intellectual property rights (IPRs) on the accessibility and affordability of medicines and other health technologies. As all inventions, including medicines and medical devices, are protected by patents and other forms of IP, the exclusive rights granted to holders invariably create monopolies, enabling a single supplier of a product to set any price that the market will bear. This often results in excessively high pricing of newer medicines, and those still under patent protection.

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Nowhere has this been more evident in the past two years than during the COVID-19 pandemic. From the outset, IP rights holders maintained tight control over their technology and know-how on the manufacture of key testing kits, ventilators and certain medicines, refusing to share their knowledge to enable a larger pool of suppliers to produce these items and meet global needs. In the absence of competition, this "artificial scarcity" resulted in life-threatening shortages and inflated pricing of essential supplies.

The production and supply of vaccines to immunise the world's population against the COVID-19 virus have been beset by the same constraints. As of 18 October 2021, across 184 countries, more than 6.67 billion doses of vaccines have been administered – enough to fully vaccinate 43.4% of the global population. But the distribution has been uneven and inequitable – the least wealthy countries which comprise 20.5% of the global population have administered a mere 4.1% of vaccinations.[1] In contrast, wealthy countries have had ample supplies and indeed surpluses, and consequently high rates of vaccination – with the UK at 66%, the EU at 62% and the US at 55%, compared to the paltry 4.4% vaccination rate in Africa.[2] Early predictions with regard to promising new treatments like *molnupirivir* now coming into the market indicate similar constraints of excessive pricing and supply shortages. Under such circumstances, how will access and equitable distribution be guaranteed?[3]

Such constraints are hardwired into the global IP system and portend continuing production and supply challenges. The current system reflects a fundamental imbalance in the IP system and betrays the *raison d'etre* of IP protection – the essential *quid pro quo* or bargain involving the grant of exclusive rights in exchange for public disclosure and knowledge dissemination.

Contrary to the avowed intention of Art. 7 of the TRIPS Agreement to promote knowledge sharing and technology transfer "in a manner conducive to social and economic welfare", the lack of willingness on the part of developed countries and their IP-holding industries to engage in meaningful exchange has resulted in an unbalanced and inefficient IP system[4] that impedes neglected populations' access to essential medicines. It precludes countries in the global south from using the very IP frameworks and practices that were essential to securing economic development in the global north, thus perpetuating a historical injustice.[5] It prioritises private property protection over improving the baseline level of welfare of vulnerable populations, with research and development (R&D) being directed towards profitable medicines rather than those benefiting vulnerable populations.

[1] Bloomberg "More Than 6.67 Billion Shots Given: Covid-19 Tracker" (18 October 2021) https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/.

[2] BBC News "Covid-19 vaccinations: More than 50 nation have missed a target set by the WHO" (1 October 2021) https://www.bbc.com/news/56100076.

[3] DND*i* "COVID-19 Policy Report: Another Triumph of Science, But Defeat for Access?" (6 October 2021) https://dndi.org/wp-content/uploads/2021/08/DNDi-COVID-19-Policy-Report-2021.pdf.

[4] Stiglitz JE (2007) "Economic foundations of intellectual property rights" Duke LJ. 57:1693-724. URL: https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1362&context=dlj.

[5] Chang HJ "Intellectual property rights and economic development – historical lessons and emerging issues" Third World Network Intellectual Property Rights Series, No. 3. Undated https://www.twn.my/title2/IPR/pdf/ipr03.pdf.

The current model regulating IP has failed to achieve any semblance of balance and has in effect disserved the majority of the world's population. There is significant scholarly work pointing to alternative funding and incentive mechanisms for the IP system to better balance the rights of inventors to just rewards with the human rights to health and to share in the benefits of scientific progress. They include public rather than private ownership of knowledge; awarding prizes rather than patents for medical innovations;[6] and implementing flexible compulsory licensing systems.[7]

Advocates for a balanced IP system have also favoured a legally binding R&D convention that addresses the adverse public health impacts of the TRIPS framework more systematically. One set of recommendations, the UN Secretary General's High-Level Panel on Access to Medicines,[8] specifies the kind of IP reforms such a covenant should contain. However, these recommendations have been ignored in high-level policy discussions, including a recent World Health Assembly (WHA) Resolution on local production.[9] The issue of a global instrument to counteract future pandemics will be addressed in the November–December 2021 special session of the WHA which will debate the case for a pandemic preparedness treaty.[10]

The option of using the TRIPS public health flexibilities (which countries can adopt in their national laws) has proven to be unworkable. Evidence over three decades confirms how complicated this path is for low- and middle-income countries (LMICs), despite the 2011 Doha Declaration on TRIPS and Public Health. LMICs have been subjected to adverse political and economic pressure when seeking to use compulsory licensing[11] and prevented from doing so by trade agreements that contain stronger patent and other protections (such as data exclusivity) than TRIPS. In addition, LMICs may lack the capacity to institutionalise and enforce these flexibilities speedily, or be subject to competing national, regional and global IP frameworks.

[6] Scherer F (1984) *Innovation and Growth* Cambridge, Massachusetts: The MIT Press.

[7] Moon S, Bermudez J, 't Hoen E (2012) "Innovation and access to medicines for neglected populations: Could a treaty address a broken pharmaceutical R&D system?" PLoSMed. 9(5):e1001218 https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001218.

[8] United Nations (2016) "Report of the United Nations Secretary General's high-level panel on access to medicines. Promoting innovation and access to health technologies" http://www.unsgaccessmeds.org/final-report.

[9] Knowledge Ecology International (2020–2021) "Negotiations on the 74th World Health Assembly (WHA) resolution on local production" https://www.keionline.org/negotiations-on-the-74th-world-health-assembly-wha-resolution-on-local-production.

[10] WHO (31 May 2021) "Special session of the World Health Assembly to consider developing a WHO convention, agreement or other international instrument on pandemic preparedness and response" https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74(16)-en.pdf.

[11] Balasubramaniam T, Goldman AS (2017) "Submission of Knowledge Ecology International to the WIPO SCP: constraints faced by developing countries and least developing countries (LDCs) in making full use of patent flexibilities and their impacts on the access to affordable especially essential medicines for public health purposes in developing countries and LDCs' Knowledge Ecology International" https://www.wipo.int/export/sites/www/scp/en/meetings/session_27/3rdparty_comments/kei.pdf.

Discussions at the WTO have for the past year been dominated by a proposal for a waiver of IP rights. To address the problem of inequitable access of diagnostics, vaccines and therapeutics necessary for an effective response to the COVID-19 pandemic, the delegations of India and South Africa introduced a proposal for a temporary waiver of several IP rights at the WTO in October 2020. Such a waiver is permitted under Art. IX of the Marrakesh Treaty Establishing the WTO.[12] The proposal for the waiver is a relatively modest one. If approved in its revised version, it will be of temporary duration (three years from the date of a decision), and limited in its scope. It will, in effect, suspend members' obligations to enforce IP rights "in relation to health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19."[13]

Despite sponsorship by 63 WTO member countries, the support of over 100 countries and the qualified support for a waiver (on vaccines) by the US, there continues to be opposition to the proposal, in particular, from leading countries in the European Union. The latter have tabled a counter proposal which adopts the view that IP protection is not the issue, and if that were the case, countries could still use the TRIPS flexibilities such as voluntary and compulsory licences to address any access problems.[14] Hence, a waiver would not be necessary. They contend further that even if IP protections were lifted, this would be futile because the manufacturing capacity of especially developing countries is limited. These claims have been thoroughly debunked by access to health and human rights advocates citing, amongst others, evidence that IP is a barrier to rapid scale-up of COVID-19 health products, and the existence of available manufacturing capacity in several countries, both developed and developing.[15] Conflicting views have emerged on the progress achieved so far, with the EU delegation stating that members have found "many points of convergence", a position that has been contradicted by India, one of the leading proponents of the waiver, which contends that the EU proposal merely "reiterates provisions already in the TRIPS Agreement". TRIPS Council chair Dagfin Sorli has acknowledged that the "members' positions have not dramatically changed since previous meetings".[16] Evidently, the negotiations remain deadlocked with no consensus in sight.

[12] WTO (1994) "Marrakesh Treaty Establishing the World Trade Organisation" https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm.

[13] WTO (25 May 2021) "Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19" IP/C/W/669/Rev.1 https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True.

[14] WTO "Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property. Communication from the European Union to the Council for TRIPS" IP/C/W/680 (4 June 2021) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W680.pdf&Open=True.

[15] Human Rights Watch "Seven Reasons the EU is Wrong to Oppose the TRIPS Waiver" (3 June 2021) https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver.

[16] Inside US Trade "EU touts progress on IP waiver talks at he WTO, challenges India's view" (14 October 2021) https://insidetrade.com/daily-news/eu-touts-progress-ip-waiver-talks-wto-challenges-india%E2%80%99s-view.

The world's poorest and most vulnerable cannot be held hostage to narrow vested interests. What is required is an IP design for health technologies that ensures equity in meeting the needs of all. Whether this materialises through a waiver, the reform of existing WTO rules, or the adoption of a pandemic treaty remains to be seen. What is certain, though, is that equity in global health cannot be achieved under the current dispensation.

The world deserves better.

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