

A person wearing a full white protective suit, including a hood and a face shield, is walking on a balcony. The person is carrying a piece of medical equipment, possibly a ventilator, in a bag. The background shows a building with a window and a metal railing.

POLICY PAPER

THE **TRIPS** AGREEMENT LAID BARE

Learning the lessons of COVID-19 to improve access
to health technologies

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Learning the lessons of COVID-19 to improve access to health technologies

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Intellectual property (IP) enforcement tools, chiefly patents, negatively impact access to health technologies in a number of ways. Pricing is a major area often discussed, but availability as a result of the disproportionate role that IP-based monopolies and market returns play as incentives in the current biomedical research and development (R&D) model should not be overlooked.

Governments can and should harness an IP protection and enforcement framework (essentially a domestic competency) to fulfil a pro-health-oriented agenda, both at national and international levels. This should guarantee not only equitable and sustainable access to health technologies, but also effective technology transfer and a more health needs-aligned research agenda. Academia and public-interest civil society have a role and responsibility to contribute to this conversation.

This document intends to provide the historical background, current stakes and future options to achieve a more coherent interaction between IP rights protection and enforcement and access to health technologies, with special attention paid to the agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and its role in discussions around equitable access during the COVID-19 pandemic.

The Birth of WTO

Pharmaceutical products are not like other tradable goods and up until the last round of negotiations on the General Agreement on Trade and Tariffs (GATT), had been excluded from IP in a number of countries. These talks culminated in the creation of the World Trade Organization (WTO) in 1995.¹ This milestone in international relations has had major consequences for how governments are bound to regulate the manufacturing and trade of pharmaceutical products.

Built on a number of international treaties encompassing different areas of trade, the WTO constitutes the first attempt at regulating international trade through a permanent multilateral institutional body. The liberalisation of trade and financial flows sought to integrate countries in the Global South into a globalised structure characterised by open markets and the free flow of goods. In practice, it meant that, in order to become WTO members, many countries² had to enact new, often far-reaching, IP protection and enforcement laws on pharmaceutical products, which had been largely exempt from patent protection as established in Article 70 (Protection of Existing Subject Matter) of the TRIPS agreement:

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

- (a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;*
- (b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and*
- (c) provide patent protection in accordance with this Agreement as from the grant of the patent*

and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.³

Consequences of the TRIPS Agreement

The necessary amendments to domestic legal and regulatory frameworks, adopted rapidly by a number of countries failed, on many occasions, to take full account of the impact of the new norms on access to medicines. This was especially the case when considering price and availability, as well as competition and overall policy space for public authorities to respond to health needs, including emergencies. The AIDS pandemic, with many African countries facing a catastrophically high number of cases, contrasted dramatically with the poor availability of anti-retroviral drugs (ARVs) which, being under patent, were out of financial reach. This was the new the new reality of IP enforcement and access to medicines.

While the TRIPS agreement contemplated exceptions, known as flexibilities, such as compulsory licensing, parallel imports and other mechanisms to smooth its implementation, they were vaguely worded in such a way that governments, following advice from some stakeholders, were reluctant (or unsure) to use

them.⁴ The case of South Africa, taken to court in 1999 by pharmaceutical companies while adopting TRIPS-compliant flexibilities⁵ into its legislation, offered an example of the kind of pressure affecting governments, especially those who had recently modified their legal and regulatory framework to benefit from multilateral trade.

Doha Declaration and Flexibilities

The backlash from low- and middle-income countries (LMICs) not able to respond to urgent health needs and pressure from organised civil society came to a head in November 2001 with the adoption of the Doha Declaration on the TRIPS agreement and public health.⁶ It confirmed the legal validity of flexibilities and clarified their use beyond emergencies and without restriction to any given disease.

The approval of the document was considered a watershed moment in the debate on the deleterious impact of IP protection measures on health, for once validating the principle that health needs may on occasion trump trade rules. It paved the way for the introduction of generic ARVs on the African continent, which precipitated a fall in prices, greatly improving access conditions and saving many lives.

Paragraph 6 Solution

A critical component, located in the sixth paragraph of the declaration, eluded consensus: how could countries with no or insufficient pharmaceutical manufacturing capabilities make effective use of flexibilities like compulsory licensing?

“6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”⁷

Despite a six-month deadline, it took WTO members almost two years to reach a consensus to resolve the impasse: the decision of 30 August 2003 set out a complex framework of notifications, information requirements and guidelines for countries with no pharmaceutical industry of their own, willing to make use of compulsory licences.⁸

The mechanism was found impractical and cumbersome and used only once.⁹ However, it was formally endorsed by WTO members after reaching the necessary two-thirds majority, and entered into force as Art. 31bis of the TRIPS agreement in 2017.

COVID-19 Pandemic and Difficulties for Access

The outbreak of the COVID-19 pandemic had a huge impact on global trade relations: borders were closed, and supply chains were severely disrupted. The scramble for personal protective equipment among governments in the early days of the pandemic reinforced patterns of inequality and imbalance between countries, leaving many LMICs unable to access critical health goods.

The scientific and technological breakthrough embodied by the rapid development of vaccines was muted by the realisation that Advance Purchase Commitments with a handful of pharmaceutical companies signed by the European Commission on behalf of the European Union (EU), as well as the United States (US), Canada and United Kingdom (UK), would greatly outpace the limited manufacturing capabilities of patent holders. Monopolies were in fact strangling production and seriously hindering access to life-saving health technologies.

While other issues, such as export controls and health systems performance, also affected the ability of governments to respond to the pandemic, the difficulties endured by developing countries to access pharmaceutical markets were evidence of serious disfunction in global

trade, which WTO had been poised to counter. Twenty years after the introduction of the TRIPS agreement, IP protection and enforcement were actively pursued in most countries while dispositions related to technology transfer and sharing of knowledge remained largely unfulfilled.

Waiver Proposal

A proposal to waive certain aspects of the TRIPS agreement on all COVID-19 related health technologies submitted by India and South Africa in October 2020 (subsequently limited to vaccines, therapeutics and diagnostics) enjoyed the support of over 60 co-sponsoring governments.^{10, 11} The so-called “TRIPS waiver” sought to harness the malaise and distress felt by many LMICs at being left out of the distribution of life-saving health goods. This was exacerbated by novel mechanisms, such as the Covax facility, struggling to gain traction and promises of donations of doses by the EU and others often not being kept.

The IP protection and enforcement threshold that LMICs had been urged to introduce in their domestic legal framework was being used to maintain monopolies that in turn considerably hindered the global scale-up of production in time of dire need.

By addressing IP as a major obstacle for access to health technologies during COVID-19, the proposal highlighted the contradiction of the TRIPS agreement premise: that the IP protection and enforcement threshold that LMICs had been urged to introduce in their domestic legal framework was being used to maintain monopolies that in turn considerably hindered the global scale-up of production in time of dire need.

Even though the proposal rapidly gained support from a wide group of governments, organised civil society, elected representatives, academics and high-profile personalities around the world, it was met with strong resistance by the administrations of EU, UK, Switzerland, and the US.¹² There were several substantive arguments against the waiver: from its indiscriminate nature and broad-brush approach, to a lack of any tangible consensus and support among WTO members.

In their statements and interventions, opponents to the waiver made it clear that they felt the existing flexibilities, chiefly compulsory licenses could, with minor amendments, be used to overcome the negative effect of patent-based monopolies on the manufacture and supply of vaccines.¹³ It is precisely this approach, bearing no resemblance to the original waiver proposal, which was the basis of negotiations that would

end up being approved as a Ministerial decision on TRIPS and COVID-19 at the at the WTO's 12th Ministerial Conference in June 2022.¹⁴

After the Waiver, A Conversation

For nearly two years, the TRIPS waiver discussion brought the issue of the impact of IP protection on access to health technologies to the top of the public agenda. International and domestic public opinion engaged in debates around equity, accountability and, more importantly, what the role of the international community should be to make sure that available technologies be made accessible when needed, beyond market returns and profits.

During this time, several initiatives demonstrated that there is another way of understanding IP that does not rely on patents or exclusive exploitation regimes and explores cooperative schemes, pooling mechanisms and other technology-sharing endeavours. These may shape future responses to pandemics and health emergencies and must be part of the necessary in-depth conversation on IP and access to health technologies to come. This dialogue may be divided into four interwoven components and calls on different actors to step up their actions, fulfil their commitments and improve their coordination.

Biden calls for intellectual property waivers on COVID vaccines



Levée des brevets sur les vaccins contre le Covid-19 : premier pas vers un compromis

Le Monde

Nations urged to waive vaccine patents while drugmakers say rules are fair

FINANCIAL TIMES

Opinion | Preserving intellectual property barriers to covid-19 vaccines is morally wrong and foolish

The Washington Post
Democracy Dies in Darkness

Drop Covid vaccine patent rules to save lives in poorest countries, UK and Germany told

The Guardian

Time is running out for COVID vaccine patent waivers

nature

Public health experts say vaccine equity a must to end pandemic



Roles and Responsibilities

The pandemic has shaken the global health governance system. While the World Health Organization remains the leading intergovernmental organisation on matters of global health, it will need to not only collaborate but cooperate more closely with other entities, including the Medicines Patent Pool. At the same time, it must seek greater support for the consolidation and expansion initiatives such as the COVID-19 Technologies Access Pool (C-TAP) or the South Africa-based tech-transfer hub. Cooperation with the WTO and the World Intellectual Property Organization should be redefined in order to reflect the primacy of health needs over commercial interests.

As part of its work on the use of TRIPS flexibilities, the WHO should pursue a more focused technical cooperation strategy to advise Member States on how to better accommodate health concerns in domestic legal and regulatory frameworks regarding manufacturing, trade and supply of health technologies. This can be done as part of the implementation of the remaining components of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.¹⁵ WHO Executive Board members should explicitly support a bolder approach to matters of IP matters, drafting, agreeing, considering, and submitting these to the World Health Assembly as a specific resolution on the issue.

Strengths and Opportunities

The COVID-19 pandemic has placed the role (and impact) of IP protection rules on the public agenda. It has also shaped policy discussions around access to health technologies and involving, for example, transfer of technology, manufacturing, and procurement. Equity has been widely acknowledged as the necessary guiding principle and strategic goal in the execution and implementation of plans and initiatives at global, regional, and national levels.

IP protection and its enforcement should be framed as an instrument, not an obstacle, to achieve better and more sustainable access to health technologies by stressing the primary social function of innovation as response to human needs. At the national level, by making patenting rules more stringent in order to reward only genuine innovation while expanding grounds for patent opposition to abusive market practices; at the EU level, by ensuring that public funds and support to health research are linked to non-exclusive licensing agreements for the exploitation of end products; globally, by ensuring that deliberations around an international instrument for the prevention, preparedness, and response to pandemics and international health emergencies include specific clauses to waive IP rules in order to guarantee equitable universal access to health countermeasures.

Weaknesses and Challenges

Fragmentation, duplication, and even contradiction are hindering global efforts to respond to the myriad of challenges that make up global health, and the intersection of IP and health technologies is no exception. A minimal consensus among stakeholders around a common agenda is necessary in order to enhance collaboration; without it, there is the risk of engaging in discussions with no real connection with the problems deemed to address nor possibilities to bring change.

Discussions around the TRIPS waiver proposal highlighted the need for specific goals and the identification of the right stakeholders with a mandate and/or capability to implement. Governments will remain the principal drivers of change, domestic and internationally. High-income countries have the moral responsibility to lead by example in promoting technology transfer, knowledge sharing, and overall harnessing IP protection for public good. LMICs need to push for a transformative agenda that addresses reported imbalances in manufacturing, supply and generation of knowledge related to health technologies.

Timelines and Deadlines

The urgency to improve access conditions to life-saving health technologies and the need to remove obstacles to their fulfilment will not end with the pandemic. The decision on the TRIPS agreement adopted at the 12th Ministerial Conference contemplates a six-month period for WTO members to address the eventual inclusion of therapeutics and diagnostics and there are other policy processes susceptible to provide a basis to address the IP constraints and health concerns.

The Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement

or other international instrument on pandemic prevention, preparedness and response is likely to be discussing, between July 2022 and October 2023, topics relevant to the IP management in relation to access to health technologies. Of particular importance are issues related to technology transfer, licensing, and scale-up of manufacturing capabilities which, as mentioned before, have proven to be problematic during the COVID-19 pandemic. During the second half of 2022, institutions are considering several policy initiatives that may have an impact on the understanding of the role that IP plays in the development, manufacturing and access to health technologies, both domestically and beyond.

Endnotes

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