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Access to Medicines in Low- and Middle-Income Countries – Is the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to blame?

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Key Messages

1. The TRIPS Agreement is not the sole cause of ATM in LMICs. It's a complex issue influenced by various factors.
2. The TRIPS Agreement offers flexibilities to address ATM. However, their effective implementation is challenging due to various factors.
3. Addressing ATM requires a multifaceted approach. This includes domestic policy reforms, international cooperation, and investment in domestic manufacturing.
4. LMICs need to prioritize access to medicines. Governments should demonstrate political will and commitment to achieving medicine self-sufficiency.

Abstract

This paper argues that the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement is not solely responsible for the lack of access to medicines (ATM) in Low and Middle-Income Countries (LMICs). ATM is a complex global health governance issue influenced by various factors, including intellectual property laws, trade agreements, domestic policies, and manufacturing capacity.

While the TRIPS Agreement provides flexibilities to address public health concerns, such as compulsory licensing and parallel imports, their effective implementation is hindered by several challenges. This paper emphasizes the need for a multifaceted approach to address ATM, involving domestic policy reforms, international cooperation, and investment in domestic manufacturing capacity. By leveraging these strategies, LMICs can enhance access to essential medicines and improve health outcomes for their populations.

Introduction

Lack of access to medicines (ATM), vaccines, medical products, and technologies is a health challenge confronting the world, particularly people living in Low and Middle-Income countries (LMICs). The perennial scarcity of medicines has prompted critics to point accusing fingers at the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (Fisher and Rigamonti, 2005).

In this paper, I argue that blaming the TRIPS Agreement for the shortage of medicines in LMICs is a misdiagnosis of the problem and rather too simplistic. ATM is a global health governance issue and must be seen as a product of a complex web of activities, processes, rules, and procedures involving individuals, groups, philanthropists, states, and nonstate actors outside and within mainstream health (Fidler, 2010).

Medicines play a central role in health delivery due to their horizontal and cross-cutting nature. They are used to treat health conditions in both public health and clinical settings, and across the entire population spectrum, from neonates to geriatrics. ATM has attracted so much attention that international and regional human rights institutions recognize it as fundamental to realizing the highest attainable standard of health (Elliot, 2006).

The term "access to medicines" is a term of art used to illustrate medicines that are physically available, geographically accessible, affordable, acceptable (culturally and used rationally), and of good quality. In other words, people who need medicines should have them in the right quantities and dosage formulations, quality, at the right place and time, and affordable prices (Wirtz et al, 2016).

Attainment of global medicine sufficiency has eluded global leaders since the founding of the World Health Organization in 1948 (WHO, 1948). The inability to acquire prescribed medications results in pain, suffering, prolonged illness, and preventable deaths (Ozawa et al, 2019). Currently, the global median medicines availability is 61.5%, leaving nearly 2 billion of the global population with no access to prescribed medications. In Africa, almost 70% of people who go to private and public health facilities do not receive the necessary medicines. The resultant effect of medicine shortages is price hikes, further worsening the ability of poor countries to obtain drugs for common ailments like malaria, tuberculosis, and HIV/AIDS (Ozawa et al, 2019). ATM is the biggest threat to the global achievement of universal health coverage (UHC) and the realization of the Sustainable Development Goals (UN, SDG 3).

Due to the complexity and heterogeneity of medicines, it becomes daunting for health authorities to decide which medicines to stock, and which to leave out. To guide countries, the WHO classifies certain medicines as "essential" and recommends a minimum of 80% essential medicine availability in healthcare settings and dispensaries at all times (Zuma et al, 2019).

The classification is based on disease prevalence, clinical efficacy, safety, cost-effectiveness, and public health relevance. Essential medicines are those that are necessarily required to manage priority health conditions of the global or a country's population (WHO, 2023). Adopting the concept of essential medicines is an efficient management strategy that leads to better healthcare delivery, drug management, and use of financial resources (Yenet et al, 2023).

The existing international legal regime that affects ATM are mainly international trade and investment-related laws, especially intellectual property (IP) laws, and bilateral or multilateral trade agreements. It is so because medicines, in addition to being articles of trade, are products of the ingenuity of the human brain. In this paper, I focus on the trade-related aspects of intellectual property, which has dominated the ATM debate for the last thirty years. Intellectual property is a creation or invention of the human mind. IP rights are rights granted by law to inventors to protect new inventions and processes, encourage innovation, and commercially reward creators for their creativity (Saha et al, 2011).

In the run-up to the establishment of the World Trade Organization (WTO) on 15th April 1994 under the Marrakesh Agreement, a cluster of other agreements were concluded by member states of the WTO. The cluster comprises General Agreements on Tariffs and Trade (GATT 1994), Trade in Services (GATS Agreement), Technical Barriers to Trade (TBT Agreement), Sanitary and Phytosanitary Measures (SPS Agreement), and Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). The Agreements were annexed to the WTO Agreement and entered into force on 1st January 1995. Among these, it is the TRIPS Agreement that has had the most impact on ATM and technologies.

The TRIPS Agreement is an international legally binding comprehensive multilateral instrument that grants rights and protection to intellectual property owners. It sets global standards of rights protection and provides rules of administration and enforcement of IP rights (WTO, 1994). The Agreement has generated considerable worldwide controversy and diversity of opinions.

Proponents contend that the Agreement or intellectual property (IP) rights protection provides incentives for innovation and discovery of new drug molecules (Subhan, 2006). They maintain, for instance, that it is the protection intellectual property law grants that provided the needed incentives for multinational pharmaceutical giants, in partnership with governments and research institutions, to invest millions of dollars in developing COVID-19 vaccines and countermeasures in a relatively short time following the pandemic (United Nation, 2022). In addition to providing incentives, the advocates often cite advantages such as the generation of indirect revenues, promotion of culture, dissemination of technical information, facilitation of technology transfer, provision of collateral to secure financing, and guaranteeing the safety and quality of products (The European Commission, 2023). I explain these advantages below.

Firstly, intellectual property rights holders, in addition to getting revenues from direct sales of products, may generate indirect revenue by licensing the rights to third parties to manufacture and sell the products in return for payment of royalties. Secondly, in the creative arts, such as musicians and performers, inventors get economic returns for their creations, enriching culture and benefiting society. Thirdly, technical information about any invention is often published and available to the general public. The public can use the information to make products that benefit society. Fourthly, licensing intellectual property rights, such as patents, to third parties involves a detailed description of the technology involved in the invention. This practice facilitates technology transfer, which benefits the larger public. Fifthly, intellectual property rights are valuable assets. Businesses often leverage the value of IP rights to secure funds from financial institutions. Lastly, enforcing IP rights prevents counterfeit and fake products from entering the market. For example, regulators can eliminate counterfeit pharmaceuticals from the market by enforcing rules related to trademarks and industrial designs of genuine products (The European Commission, 2023), (Dhaval Chudasama, 2021).

These benefits notwithstanding, opponents of IP rights contend that stringent protection of IP rights keeps prices of medicines high beyond the reach of those who need them (Subhan, 2006).

The scope of IP rights covered under the TRIPS Agreement includes patents, trademarks, trade secrets, copyrights, and industrial designs. Of the rights, it is those conferred by patents, data (market) exclusivity, and to some extent trade secrets that have ignited worldwide public discourse. Beyond TRIPS countries negotiate and conclude bilateral and

multilateral investment treaties or free trade agreements (FTAs) that are inimical to ATM (Gostin, 2014).

Examining the TRIPS Agreement at first sight, especially those relating to patents, data exclusivity, and trade secrets may lead one to erroneously conclude that the Agreement is a restraint on ATM. But that is not the case upon deeper analysis.

In their search for new drug molecules, innovators undertake risks and incur a lot of expense, so patents are granted to motivate and provide financial incentives for them to recoup their investments (Frederick et al, 2015). A patent is effective in a specified jurisdiction for a limited period of time and confers exclusive rights on the right holder to prevent third parties from exploiting his invention or process without authorization (Taubman and Watal, 2020).

Patent provisions in the TRIPS Agreement are thought to undermine the quest for global medicines sufficiency. Firstly, the authority given to inventors to exclude third parties from exploiting their inventions results in the emergence of "patent monopolies." (Fidler, 2010). Patent monopolies have the disadvantage of putting prices of medicines beyond the reach of poor people (Khachigian, 2020).

Secondly, patent term protection under the TRIPS Agreement lasts for at least twenty years from the filing date (WTO, 1995). However, the duration is often significantly reduced, as a considerable portion of that time expires before receiving marketing authorization from public health regulatory bodies. Innovators often request countries to grant them patent term extensions in their domestic legislation as compensation to mitigate the loss of time. The effect of extending patent terms for pharmaceuticals impedes access to medicines by delaying early market entry for generics, which are usually cheaper (Bing, 2021).

Besides patents, IP rights on data exclusivity are thought to be detrimental to ATM. Data exclusivity refers to the data that the originator company submits to regulatory authorities to prove the safety and efficacy of its product while seeking marketing approval (Shaikh, 2016). Before granting marketing approval for medicines, countries typically require pharmaceutical manufacturers to submit tests and other data, especially when introducing new chemical entities. Article 39.3 of the TRIPS Agreement requires members to protect such undisclosed tests data. Protection is required against unfair commercial use and disclosure. The effect of implementing data exclusivity is that it gives the originator temporary exclusive user rights to the data and prevents generic competitors from relying on the originator's data in applications for marketing approval for identical or similar products (Shaikh, 2016).

Generic manufacturers or competitors usually rely on the clinical trial data already provided by the originator to demonstrate that their drugs are bio-equivalent to the original medicine, safe, and effective. In effect, data exclusivity periods delay the entry of lower-cost treatments or generics onto the market as long as the data exclusivity period holds (Hoen et al, 2022).

Related to data exclusivity are provisions on trade secrets or undisclosed information. Trade secrets comprise information that the owner intends and takes reasonable steps to keep secret and which has commercial value. WTO members have an obligation not to unfairly appropriate the trade secrets of other members in a manner contrary to honest commercial dealings. Protection of trade secrets, unlike patents, is forever. There are arguments that protection of trade secrets delays the early market entry of generics, sustaining high prices of branded medicines.

The hurdles I have enumerated supra seem insurmountable, but the TRIPS Agreement itself offers a solution by providing policy options or flexibilities that allow member states to implement the Agreement in a manner that prioritizes national public health challenges (Yenet et al, 2023). The available flexibilities are concessions granted to least developed countries, the exercise of discretion on grant of patents, issuance of compulsory licenses, and parallel imports. The flexibilities were fortified in 2001 when trade ministers of WTO member states issued a declaration on TRIPS at Doha, Qatar (the Doha declaration) (WTO, 2001).

The Doha declaration reaffirmed the right of WTO members to fully utilize provisions in the TRIPS Agreement to protect public health and recognizes the right of members (i) to grant compulsory licenses and the freedom to determine the grounds of those grants; (ii) to determine what constitutes a national emergency and circumstances of extreme urgency; and (iii) the freedom for members to establish their regime of exhaustion of IP rights. The declaration affirmed "that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." (WTO, 2021).

The declaration clarified that states could implement the TRIPS Agreement and still pursue their access to medicines objectives. Firstly, the TRIPS Agreement grants a period of reprieve to least-developed countries (LDCs) during which they are absolved from implementing certain provisions of the Agreement. About pharmaceuticals, the transition period was for eleven years; until January 2006, with an option for extensions upon request from members of the least-developed countries. Subsequently, the period was extended to 2016 and recently, until January 1st, 2033, or until a country is no longer classified as least developed, whichever occurs earlier.

Secondly, under the Agreement, states have the discretion to determine whether a new medicine meets the patentability criteria of novelty, inventiveness, and capability of industrial application (WTO, 1994).

States have the autonomy to prevent the issuance of patents that offer no substantive technological advancements and impede fair market competition. They can reject issuance of patents for new uses, formulations, dosages, or combinations of previously patented medicines (Carlos, 2022). In addition, the Agreement does not include provisions on extensions of patent terms, which means member states may restrict or prohibit the extension of patent terms for pharmaceuticals in their national laws and expedite introduction of generic alternatives into the market.

Thirdly, the doctrine of exhaustion is one of the ways countries may exploit the TRIPS flexibilities to protect public health (WTO, WHO, and WIPO, 2020). When IP rights are exhausted, countries may parallel import. Parallel importation is the importation of genuine products into a country through a channel parallel to the one authorized by the right holder. States are free to determine how they choose to implement exhaustion to achieve domestic policy and public health objectives.

Fourthly, states can improve ATM through the issuance of compulsory licenses. This is a process by which a government grants a third party or itself the authority to manufacture a patented drug without consent from the patent holder. Article 31 of the TRIPS Agreement grants members the right to include provisions in their domestic laws that authorize the

government, or third parties authorized by the government, to use patented subject matter without the patent holder's consent.

Concluding Remarks

LMIC countries face several challenges, other than TRIPS flexibilities, that hinder access to medicines, such as low manufacturing capacity, insufficient health infrastructure, poor health governance, lack of investment in R&D, and insufficient or inappropriate regulatory frameworks (Carlos et al, 2022).

Where LMICs used TRIPS flexibilities to reduce prices of or increase access to medicines, the impact on medicine availability in those countries has been negligible. For instance, in South Africa, the use of flexibilities in intellectual property laws resulted in a more than 20-fold increase in access to antiretrovirals. Similarly, the governments of Zimbabwe, Mozambique, Zambia, and Rwanda, between 2003 and 2007, issued compulsory licenses to import medicines from Canada (Global Commission on HIV and the Law, 2011). The net effect of these few successes is limited, as overall access to life-saving medicines in those countries remains a challenge, emphasizing the need for countries to look beyond the TRIPS Agreement in dealing with the problem of ATMs.

Governments of LMICs must have the political will and commitment to attain medicine self-sufficiency in their countries. The WHO must work with global health initiatives, global health governance institutions, World Bank, the African Regional Intellectual Property Organization (ARIPO), regional bodies such as the Africa Union, pharmaceutical companies, and others to facilitate technology transfer across LMICs to boost domestic manufacturing.

Lack of access to medicines is a huge global health problem. The TRIPS Agreement cannot be blamed for this malady. The Agreement contains enough flexibilities that allow states to prioritize public health while still fulfilling their obligations under TRIPS. This was confirmed by the Doha Declaration. Developing countries find it difficult to exercise the flexibilities due to undue influence from pharmaceutical companies, developed countries, and complexity in understanding the TRIPS Agreement (Gostin, 2014). The WHO and WTO should support LMICs to review their domestic intellectual property laws to facilitate the utilization of available flexibilities (Motari et al, 2021).

There have been calls for a global treaty on pharmaceuticals but considering the difficulty in negotiating treaties by the WHO as evidenced by recent happenings concerning the pandemic treaty, I recommend the use of soft laws in the nature of guidelines to support LMICs implement already existing laws. The United Nations, African Union, ECOWAS, the World Health Organization, and other regional organizations must prioritize access to medicines as a governance issue and give it the attention it deserves at the highest level.

Glossary of terms

1. Agreement: formal arrangement between two or more parties to do, or abstain from doing, something. Terms of an agreement are legally enforceable in court or through arbitration
2. Marrakesh Agreement: agreement among several states to establish the World Trade Organization. It was signed in Marrakesh, Morocco, on 15th April 1994
3. Multilateral: involving three or more states
4. Tariffs: Taxes imposed by one country on goods or services imported from another country
5. Trade: the act of exchanging one thing for another (or buying and selling) for profit such as money for goods, goods for goods, and favors for goods or mone
6. Declaration: an official, authoritative statement on an issue, made by competent persons with sufficient knowledge concerning the issue in contention. A declaration states the rights or obligations of parties in relation to each other
7. License: permission granted by a competent authority permitting a person (licensee) to do something that would otherwise be prohibited. A license may refer to the physical document granting such permission. License and permit are often used interchangeably.

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Article 33 of TRIPS Agreement

Article 66.1 of TRIPS Agreement

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