PATENTS, POWER, AND PUBLIC HEALTH: TRIPS-PLUS RULES AND PHARMACEUTICAL INDUSTRIALISATION IN THE GLOBAL SOUTH

Sargam Sharma, O.P. Jindal Global University

ABSTRACT

By imposing minimum requirements on World Trade Organization (WTO) members, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) fundamentally changed the global pharmaceutical patenting scene. Although the Doha Declaration of 2001 aimed to preserve WTO members' autonomy to implement TRIPS provisions in ways that safeguard public health and advance access to medications, the introduction of "TRIPS-Plus" regulations has progressively reduced this flexibility. TRIPS Plus measures, which are typically enforced by bilateral and regional free trade agreements (FTAs), require stricter data exclusivity, patent linkage, and other intellectual property protection standards than those mandated by TRIPS. This paper argues that TRIPS Plus regulations restrict the effective use of TRIPS flexibilities, strengthen monopolistic control for originator companies, and impede access to reasonably priced pharmaceuticals in the Global South. COVID-19 pandemic further illuminated these structural inequalities by demonstrating how the lack of access to vaccines and medical technologies can accelerate the outbreak of the public health crisis and how formal legal flexibilities are limited in practice due to political influence, technological reliance, and low manufacturing capacities. It also shows the need for health impact assessments and greater transparency before accepting TRIPS Plus commitments in FTAs. These evaluations are necessary since trade pacts that touch on the health of people cannot be carried out as mere business undertakings, especially when the impacts of the suggested provisions could spill to the prices of medicine, entry of generics and the local production. Furthermore, these stringent regulations jeopardize the vital role that countries like Brazil and India play as the "pharmacy of the developing world" by limiting the expansion and sustainability of strong local generic pharmaceutical industries and weakening the industrial foundations needed for long-term access to medicines. The Global South governments should thus collaborate to resist the incorporation of TRIPS Plus provisions, but maximize the benefits of the existing multilateral trade law on public health to maintain policy space, promote public health, and equitable access to vital medicines in developing countries in the long-run.

I. Introduction

The intersection of international trade along with intellectual property (IP) and public health is a site of constant conflict where competing interests and values collide. High income countries generally support strict patent protection to encourage innovation spearheaded by global pharmaceutical corporation, whereas low and middle incomed nations seek flexible patent laws to progress in public health motives by ensuring availability to affordable treatment. The adoption of the TRIPS Agreement was done in the year 1995 which established minimum standards for IP protection within WTO signatories which fundamentally transformed patent structures worldwide.[1] Prior to TRIPS, many developing nations intentionally excluded pharmaceuticals from product patent protection in order to foster the growth of local generic industries. The TRIPS framework, however, mandated product patents, leading critics to argue that the agreement ignored the specific public health conditions of low- and middle-income nations and favoured high-income countries.[2]

In response to mounting worries about how strict IP laws could affect health crises, especially the HIV/AIDS pandemic, the WTO passed the Doha Declaration on the TRIPS Agreement and Public Health in November 2001. The Doha Declaration made it clear that TRIPS should be interpreted and implemented in a way that supports WTO members' right to protect public health, particularly by making medicines available to everyone. This declaration gave countries seeking to use TRIPS flexibilities important political legitimacy.[3]

In the years that followed, however, industrialised countries, especially the United States and the European Union, remained dissatisfied with the level of IP protection offered by TRIPS. They began promoting bilateral and regional free trade agreements that contained stricter IP rules. These measures, commonly referred to as TRIPS Plus, require stronger patent protection than TRIPS itself and reduce the policy space preserved under the Doha Declaration. During the COVID-19 pandemic, these tensions became even more visible, as unequal access to vaccines and essential medical technologies exposed the practical limits of existing flexibilities

[1] Hoen E't, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha' (2003) 3 Chi J Int L 27.
[2] Watal J, 'Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?' (2001) http://www.iie.com/publications/papers/watal0104.pdf.
[3] Abbott FM and J Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 J Int Econ L 921.

and the need for broader international cooperation.[4] [5] This paper examines the power dynamics associated with the expansion of TRIPS Plus regulations, their detrimental impact on public health outcomes, and their effect on the potential for pharmaceutical industrialisation in the Global South. It also argues that governments should undertake health impact assessments and ensure greater transparency before accepting such commitments in trade agreements.[6] [7]

II. The TRIPS Framework and Public Health Flexibilities

Despite requiring patent protection, the TRIPS Agreement stipulates an array of safeguards or flexibilities which allow member states the policy flexibility to address issues of public interest, specifically public health. Clarifying and confirming the legitimacy of these tools was made achievable in large part by the Doha Declaration.[8]

The most notable of these flexibilities include:

A. Compulsory Licensing and Government Use

Government utilization exceptions and compulsory licensing (CL) authorize a state or an authorized third party to manufacture or use a patented invention without the patent holder's approval, usually in exchange for fair compensation. Since this tool eliminates the patent holder's exclusive right to use the patent, it may be the most effective mechanism available under TRIPS to further public health goals.[9] By creating generic competition or bolstering a government's negotiating position, the use and availability of CLs, or even the credible threat of issuing them which helps to reduce the cost of patented medications. In response to the HIV/AIDS crisis, nations like Brazil, Thailand, and Zimbabwe have clearly implemented CLs, or government use authorizations, especially with regard to antiretrovirals (ARVs), proving

[4] WTO, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19' (Communication from India and South Africa, 2 October 2020) IP/C/W/669.
[5] Amos S Y Wong, Cole B Cole and Jillian C Kohler, 'TRIPS Flexibilities and Access to Medicines' (2022) 96 *Bulletin of the World Health Organization* 225.
[6] Carlos M Correa, 'Implications of Bilateral Free Trade Agreements on Access to Medicines' (2006) 84 *Bulletin of the World Health Organization* 399.
[7] David Vivas-Eugui, *Regional and Bilateral Agreements and a TRIPS Plus World* (Quaker United Nations Office 2003).
[8] Hoen E't and others, 'The Poorly Understood Power of TRIPS Flexibilities: A Comprehensive Overview of Their Use in the Procurement and Supply of Medicines 2001–2016' (2018) 96 Bull World Health Org 225.
[9] Reichman J, 'Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) 37 J L Med & Ethics 241.

their usefulness in gaining access to less expensive generic medications.[10]

The importance of TRIPS flexibilities was reintroduced to the centre stage during the COVID-19 pandemic, which highlighted the profound disparities in the access to vaccines and other basic medical technologies in the world.[11] When developed nations were able to have advance purchase deals and large proportions of the supply of vaccines, the developing nations experienced acute shortages, even though the demand of the population health was urgent. In this regard, India and South Africa have co-proposed a temporary lift of some of the TRIPS commitments at the World Trade Organization in 2020, to make it easier to produce vaccines and technologies to that end.[12] Though the waiver debate pointed to the constraints of the current TRIPS flexibilities, it also revealed the political and procedural obstacles which make them challenging to employ effectively in the crisis times on a global scale. Compulsory licensing was not easy to execute quickly, although legally practicable, because of the technological complexity, absence of manufacturing capacity, and external political pressure.[13] [14] The pandemic thereby highlighted the importance of legal flexibilities being formal and backed by international cooperation, technology transfer and minimized TRIPS Plus constraints, especially in times of emergencies when the prompt and fair access to life-saving innovations are needed.

B. Exceptions to Exclusive Rights

The TRIPS Agreement allows exceptions to patent rights such as the "Bolar exemption". This crucial exception aids the production and introduction of generic medicine before patent expiration by permitting generic manufacturers to utilize the patented invention to get regulatory approval.[15] Ensuring that generic versions can be released to market as soon as the

[10] Hoen E't and others, 'The Poorly Understood Power of TRIPS Flexibilities: A Comprehensive Overview of Their Use in the Procurement and Supply of Medicines 2001–2016' (2018) 96 Bull World Health Org 225.
[11] Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* (Health Action International 2016); Carlos M Correa, 'Implications of Bilateral Free Trade Agreements on Access to Medicines' (2006) 84 *Bulletin of the World Health Organization* 399.
[12] WTO, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19' (Communication from India and South Africa, 2 October 2020) IP/C/W/669.
[13] Jerome H Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) 37 *Journal of Law, Medicine & Ethics* 241.
[14] Yousuf A Vawda, 'Compulsory Licensing and Government Use for Access to Medicines: An Analysis of the Context and Challenges' in Carlos M Correa and Reto M Hilty (eds), *Access to Medicines and Vaccines* (Springer 2022).
[15] Hoen E't, 'Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines' (Health Action International 2016).

patent expires prevents patent holders from attempting to prolong their monopoly through legal action or regulatory delays.

C. Defining Patentability Standards

WTO members can define the "novelty, inventive step and industrial applicability" criteria for patentability under TRIPS. By strictly enforcing strict patentability standards countries can prevent "secondary patents" which is also known as "evergreening" on minor or insignificant advancements of medications that have already received approval such as new uses, forms or formulations.[16] [17] India's specific exclusionary clause, Section 3(d) of the Patents Act, 1970 prohibits patents for novel applications of common compounds unless they demonstrate a significant improvement in therapeutic efficacy. This is an important safeguard against unwarranted monopoly expansion.

D. Transitional Arrangements and Parallel Imports

The least Developed Countries are exempt from many TRIPS obligations which includes the protection of clinical trial data and pharmaceutical patents thanks to extended transitional periods which will last until 2033 for pharmaceutical products. This provides crucial flexibility for LDCs like Bangladesh. Furthermore, the TRIPS Agreement allows parallel importation, which permits countries to buy protected pharmaceuticals from any country where they are available at a reduced cost, as the Doha Declaration attests.

III. The Ascendancy of TRIPS Plus Rules

The Influential trading partners especially the USA and the EU continued to advocate for increased IP protection through bilateral and regional channels despite the Doha agreement.[18] Free trade agreements (FTAs) and bilateral investment treaties (BITs) mostly contain TRIPS Plus clauses that are made to reduce the policy space created by the Doha Declaration.[19]

[16] Sampat BN and KC Shadlen, 'Secondary Pharmaceutical Patenting: A Global Perspective' (NBER Working Paper No 23114, 2017).
[17] Amin T and A Kesselheim, 'Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades' (2012) 31 Health Aff 2286.
[18] El Said M, 'The Impact of TRIPS Plus Rules on the Use of TRIPS Flexibilities: Dealing with the Implementation Challenges' in CM Correa and RM Hilty (eds), Access to Medicines and Vaccines (Springer 2022) 297.
[19] Xiong P, 'Patents in TRIPS Plus Provisions and the Approaches to Interpretation of Free Trade Agreements and TRIPS: Do They Affect Public Health?' (2012) 46 J World Trade 155.

The pharmaceutical industry aggressively pursues these enhanced protections, a tactic commonly referred to as "life cycle management" or in a derogatory sense "evergreening," motivated by the business need to maintain market exclusivity. This strategy guarantees that patent holders can continue to control drug prices and maintain exclusive rights for as long as possible.

A. Data Exclusivity

One important TRIPS Plus clause data exclusivity delays the regulatory approval of generic equivalents even after patent expiration by limiting the use of clinical test data submitted by the originator company for a predetermined amount of time usually five to fifteen years.[20] TRIPS Article 39.3 does not require market exclusivity or grant exclusive rights over the data but it does require protection against unfair commercial use of undisclosed data. FTAs effectively get around the patent system and hinder generic competition by granting such exclusivity which reduces impoverished populations' access to medications. TRIPS Plus data exclusivity provisions have been linked to significant increases in pharmaceutical expenditures and delayed generic entry according to studies conducted in nations such as Jordan, Colombia and the Dominican Republic.

B. Patent Linkage

According to patent linkage provisions, national regulatory bodies must associate the patent status of the original drug with the marketing approval of generic medications. Unless the patent holder agrees, this linkage frequently requires that marketing approval for a generic be refused before the originator patent expires.[21] By effectively giving the drug regulatory body control over the enforcement of patent rights, linkage systems postpone the release of reasonably priced generic medications and may even completely prevent generic competition. Generally speaking, developing nations are exempt from these TRIPS Plus linkage requirements.

C. Restrictions on Compulsory Licensing

The legitimate use of compulsory licensing is frequently severely restricted by TRIPS Plus

[20] Correa CM, 'Protection of Data Submitted for the Registration of Pharmaceutical Products: TRIPS Requirements and TRIPS Plus Provisions' (2013) Intellectual Property and Access to Medicines 16.
[21] Raju KD, 'Patent Linkages and Its Impact on Access to Medicines: Challenges, Opportunities for Developing Countries' in CM Correa and RM Hilty (eds), Access to Medicines and Vaccines (Springer 2022) 329.

agreements, which essentially limit its application to public noncommercial use, emergency situations, and antitrust remedies. Additionally, some FTAs substitute the more onerous standard of "reasonable and entire" remuneration for the TRIPS requirement of "adequate remuneration" for the patent holder. These clauses make it more difficult for governments to step in and safeguard public health both legally and procedurally by limiting the acceptable grounds for issuing a CL and raising the cost of doing so.[22] [23]

IV. TRIPS Plus and Pharmaceutical Industrialisation in the Global South

Public health as well as the industrial sovereignty and technological advancement of the Global South are at risk from the unification of stricter IP protection standards through TRIPS Plus provisions. Using TRIPS flexibilities is essential for nations with strong domestic generic pharmaceutical industries, such as Brazil and India, to preserve their industrial base and function as international suppliers of reasonably priced medications.

A. Impact on Manufacturing Hubs

Known as the "pharmacy of the developing world," India is well-known throughout the world for its enormous generic pharmaceutical market, which provides the majority of the generic ARVs used worldwide. TRIPS Plus clauses, particularly those that the UK and EU are currently negotiating with India (like data exclusivity and patent term extensions), are specifically made to prevent Indian generic producers from providing reasonably priced medications to other countries.[24] As a result, local generic production capacity is suppressed and developing nations' ability to rely on South-South cooperation for their medical needs is compromised due to the strengthening of patent monopolies.

In order to balance its local industrial capacity and access concerns during the transition to TRIPS compliance, Brazil also relied on policy mechanisms, such as requiring health authority intervention (prior consent by ANVISA). Increased IP standards, however, pose a threat to

[22] Vawda Y, 'Compulsory Licensing and Government Use for Access to Medicines: An Analysis of the Context and Challenges' in CM Correa and RM Hilty (eds), Access to Medicines and Vaccines (Springer 2022) 73.
[23] Wong ASY, CB Cole and JC Kohler, 'TRIPS Flexibilities and Access to Medicines: An Evaluation of Barriers to Employing Compulsory Licenses for Patented Pharmaceuticals at the WTO' (South Centre Research Paper No 168, 2022).
[24] Duggan M, C Garthwaite and A Goyal, 'The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India' (NBER Working Paper No 21360, 2015).

these important public health and industrial policies.[25] Maintaining the local generic industry's viability while enforcing TRIPS-compliant legislation is a challenge.

B. The Barrier of Enforcement and Political Pressure

Political pressure from developed nations supports the application and enforcement of TRIPS Plus standards beyond the express language of free trade agreements. Governments that wish to take public health related actions are severely stifled by the United States' frequent use of its Special 301 Report to publicly discourage countries from utilizing legal TRIPS flexibilities such as mandatory licensing. Regardless of whether a country complies with the requirements of Article 31 or 31bis this pressure is commonly applied.

Legal, procedural and technical anti-diversion requirements complicate the use of Article 31bis, the mechanism that allows the compulsory export of licensed medicines, for countries with limited domestic manufacturing capacity.[26] [27] Because of the burdensome nature of Article 31bis and political pressure on potential exporting countries, the LDCs and LMICs, who most urgently need imported generic drugs, bear a disproportionate amount of the burden of A2M. This fact suggests that the current system is ill-equipped to meet the demands of global health in a timely manner.

C. Health Impact Assessments and Transparency in FTA Negotiations

Prior to the countries in the Global South committing to the TRIPS Plus provisions in free trade agreements, they ought to conduct proper health impact analysis to know how the proposed intellectual property provisions can impact medicine prices, generic competition, and local pharmaceutical production.[28] [29] This is particularly significant inasmuch as the provisions of TRIPS Plus are normally agreed upon under the carpet despite the fact that its impact on access to vital medicines and industrialization may be felt far beyond. In places where states embrace

[25] Sampat BN and KC Shadlen, 'TRIPS Implementation and Secondary Pharmaceutical Patenting in Brazil and India' (2015) 50 Stud Comp Int Dev 228.
[26] Abbott FM and J Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 J Int Econ L 921.
[27] Wong ASY, CB Cole and JC Kohler, 'TRIPS Flexibilities and Access to Medicines: An Evaluation of Barriers to Employing Compulsory Licenses for Patented Pharmaceuticals at the WTO' (South Centre Research Paper No 168, 2022).
[28] Carlos M Correa, 'Implications of Bilateral Free Trade Agreements on Access to Medicines' (2006) 84 *Bulletin of the World Health Organization* 399.
[29] Bryan Mercurio, 'TRIPS-Plus Provisions in FTAs: Recent Trends' in Lorand Bartels and Federico Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006).

solutions like data exclusivity, patent linkage or stricter restrictions on compulsory licensing without a thorough analysis of their effects, they are likely to lose the policy space that was intended to be preserved by TRIPS and the Doha Declaration.[30]

This must also be very transparent. Trade negotiations which directly relate to the health of people should not be considered as commercial undertakings. The consultation process should include public health authorities, competition regulators, generic manufacturers, and actors in the civil society to ensure the wider ramifications of the proposed agreement are adequately considered.[31] This is particularly important to developing nations, which rely so much on local generic sectors to ensure that affordable medicines can be made available both locally and internationally.

Through this, the health impact assessment can assist governments to create a more tangible boundary between legitimate stimuli to innovate and undue protection of monopolies. Through exposing the true costs of TRIPS Plus actions, they will provide states with a more powerful and evidence-based foundation to oppose damaging provisions and bargain to maintain access to medicines and also maintain national regulatory sovereignty.[32] [33]

V. Conclusion

The expansion of TRIPS Plus regulations through free trade agreements is a significant legal and political setback to the policy space granted to the Global South by the Doha Declaration. Through the introduction of systems such as strict data exclusivity and patent linkage, these agreements permit multinational pharmaceutical companies to grow their monopolistic control over essential medicines. This can result in exorbitant prices and unfavourable effects on public health, particularly in regions that are experiencing high poverty and high rates of illness. The COVID-19 pandemic has further revealed such structural disparities, with access to vaccines and other crucial medical technologies being limited, exacerbating the issues already inflicted by strict intellectual property regulations. It also revealed that formal legal flexibilities cannot

[30] WTO, *Declaration on the TRIPS Agreement and Public Health* (adopted 14 November 2001, WT/MIN(01)/DEC/2); Carlos M Correa, *Protection of Data Submitted for the Registration of Pharmaceutical Products* (2013).
[31] Ellen 't Hoen and others, 'The Poorly Understood Power of TRIPS Flexibilities' (2018) 96 *Bulletin of the World Health Organization* 225.
[32] Frederick M Abbott and Jerome H Reichman, 'The Doha Round's Public Health Legacy' (2007) 10 *Journal of International Economic Law* 921.
[33] Yousuf A Vawda, 'Compulsory Licensing and Government Use for Access to Medicines' in Carlos M Correa and Reto M Hilty (eds), *Access to Medicines and Vaccines* (Springer 2022).

suffice in the face of global crisis unless they are enhanced with effective cooperation across borders, transfer of technology, and true spirit of safeguarding the health of the people rather than overprotecting any monopoly.

The preservation of TRIPS flexibilities is closely linked to the aim of promoting pharmaceutical industrialisation in the Global South. Without worrying about trade reprisals, nations must be allowed to impose strict patentability standards such as India's Section 3(d) and maintain the capability to grant compulsory licences. Concurrently, prior to accepting TRIPS Plus obligations in free trade agreements, governments ought to conduct appropriate health impact assessments and create more transparency in negotiations to ensure that the health authorities of the people, the competition watchdogs, the generic pharmaceutical companies, and the civil society members can be meaningfully involved in evaluating the overall effects of such agreements. This would assist states to counter objectionable terms and maintain the policy space that is needed to safeguard access to medicines and national regulatory independence. Strong political will must be developed to safeguard this space, and thorough health impact assessments should be conducted before entering FTAs in order to curb the aggressive push of TRIPS Plus standards. The promise made at Doha that the right to safeguard the health of the people should prevail over the rigorous enforcement of IP has to be fulfilled eventually through rejection of the requirements of TRIPS Plus and the focus on access to essential medicines as the priority of the trade and intellectual property policy.