International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

Patents and Public Health: Balancing Innovation and Access to Medicines

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Abstract:
The world has widely recognized the right to health as a fundamental right in various international instruments, yet it has been observed that the same constantly collides with the global patent regime governing pharmaceutical products. This paper aims to critically examine the complex relationship between intellectual property rights, particularly as stated under the WTO's TRIPS Agreement, and the need for equitable access to patented medicines. Through an analysis of international legal instruments like the UDHR and ICESCR, as well as some pivotal case law, policy frameworks, and the Doha Declaration on TRIPS and Public Health, this study explores the far-reaching implications of patent laws on the affordability and availability of essential drugs, particularly in low- and middle-income countries. The paper highlights the landmark decisions made by the judiciary, the growing need for generic medicines, and the constant challenges including high pricing, limited local production, and the political economy of global health governance. It also explains how bilateral trade agreements and TRIPS-plus provisions further exacerbate access barriers, and to reduce the same, it also suggests the role of generic drugs, which lays ways for the world through which one can achieve equitable medical access, which stands as one of the important goals of human rights law. The study also preaches for a human rights-based approach for medical access that is grounded in legal obligations and moral imperatives, emphasizing structural reforms in global patent governance, corporate accountability, and pandemic preparedness, also highlighting the need for structural reforms in global patent governance, stronger corporate accountability, transparent pricing mechanisms, and strict pandemic preparedness strategies. Despite the constant challenges faced, it tries to conclude with actionable recommendations aimed at balancing innovation with equity and ensuring that life-saving medicines are treated not as luxuries, but as universal entitlements and thereby promoting human life growth.

Keywords: Right to Health, Patented Medicine, TRIPS Agreement, Generic Drugs, Human Rights Approach.

1 |Introduction

Today, access to essential medicines has become both a need and a right, as acknowledged in the various international instruments such as the Universal Declaration of Human Rights (article 25) and the International Covenant on Economic, social and Cultural Rights (Article 12). But it has been often observed the global pharmaceutical landscape is quite often impacted by the regimes of intellectual property, particularly the Patent laws, putting a barrier in the equitable access of the patented medicine. A patented medicine is referred to those pharmaceutical products that are protected under a national or international patent system, which grants the patent holder exclusive rights to manufacture, market, and

sell the product for a limited period (typically twenty years). The intention behind such protection is to promote innovation by allowing the companies to recover cost of the research and development.

Yet, there arises a situation where the monopoly that has been granted to the patent holder can lead to high drug prices thereby limiting access in low- and middle-income countries and creating a tension intellectual property right and the fundamental human right to health. This conflict has constantly sparked significant tussle and debates within the ambit of international law, especially under the frameworks of the World Trade Organization's TRIPS Agreement[1]and the Doha Declaration on Public Health.[2]

2 | The Right to Health in International Human Rights Laws

The right to health is a fundamental concept in the perspective of international human rights law and serves as both legal and a moral framework for the states to ensure the well-being of the individuals. The rights have been enshrined in multiple international instruments, enforced by various such authoritative bodies to ensure access to essential medicines, preventive care and equitablehealthcare systems. A comprehensive part of this must be understood by the Universal Declaration of human rights (UDHR),[3] as adopted in the United General Assembly in 1948. Although not legally binding, the UDHR forms a major pillar to international human rights which has led to becoming a basis to following binding treaties and customary international law. Within this foundational document, Article 25(1) explicitly affirms the right of every individual to enjoy a standard of living adequate for health and well-being, encompassing access to food, clothing, housing, medical care, and necessary social service.

The very language of article 25 has a very broad perspective and interpretation to it adding an inclusive approach to its interpretation. By framing health within the wider context of an "adequate standard of living," it reflects an early recognition of the interdependence of social and economic determinants of health. This in the aspect of health law is referred to as 'social determinants of health framework' emphasizing the importance of other factors and not just access to healthcare systems. Factors that involve shelter, sanitation, nutrition, and income security. As the right to health is based on such an important aspect the UDHR establishes a connection between the importance of well-being of an individual with the realization of other socio-economic rights of the person as well.

Although there is no legally direct obligation towards the UDHR it has gained normative weight over the decades, Many of its provisions, including Article 25, have been incorporated into national constitutions, interpreted by international courts, and codified in binding treaties such as the International Covenant on Economic, Social and Cultural Rights (ICESCR). Consequently, the UDHR serves not only as a symbolic affirmation of fundamental values but also as a guiding standard for evaluating state conduct in health-related matters, including pharmaceutical regulation and public health interventions. While the UDHR laid the groundwork, the International Covenant on Economic, Social and Cultural Rights (ICESCR)[4] adopted in 1966 and ratified by over 170 countries provided the first legally binding articulation of the right to health.

Moreover, the recognition of essential medicine access as a human right calls for reconceptualizing the pharmaceutical industry's role. While private corporations are not direct parties to human rights treaties,

[1] World trade organization's TRIPS agreement, 1989
[2] The Doha Declaration on Public Health, 2001
[3] Universal Declaration of human rights, art.25
[4] International covenant on Economic, Social and cultural rights, 1966

international guidelines such as the UN Guiding Principles on Business and Human Rights impose a responsibility on pharmaceutical companies to respect human rights, including refraining from obstructing access to life-saving medications.

Together, the UDHR and ICESCR establish a broad normative and legal framework for the right to health that unequivocally extends into the field of access to patented medicine. By proclaiming that all individuals have a right to attain the state of highest feasible health, these resources place clear responsibilities on states and ethical obligations on enterprise to ensure that drugs are not consumed as luxuries, but as public goods which are useful for attaining human dignity. As such, they lay a solid foundation for critiquing the current global pharmaceutical regime and advocating for an approach to healthcare governance grounded in human rights.

3 | Patent Laws and Their Implications for Medicine Access

One of the biggest challenges in respect to global health is balancing patent protection with the need for affordable access to medicine. In 1995 there marked a significant and important shift in the regulation of the pharmaceutical patents, under the Agreement on Trade Related Aspects of Intellectual property Rights (TRIPS), which was adopted by the WTO. It required to provide a patent protection for a minimum of 20 years to all the member states of WTO and thereby it shaped and standardized the intellectual property rights globally. Though the primary goal behind this agreement was to promote innovation and strengthen pharmaceutical research, its implementation excessively impactedthe low- and middle-income countries, where due to high costs and limited availability of generic alternatives the access to life-saving drugs became uncontrolled. The monopoly rights granted to patent holders allowed them to set high prices without competition, creating a systemic barrier to essential medicines for vulnerable populations, resulting in the failure of such nations in ensuring access to affordable treatment, thus raising concerns for the citizens right to health under international law. Furthermore, TRIPS faced massive criticism for prioritizing the commercial needs over the public health. Although the agreement contained few flexibilities in compulsory licensing and parallel importation, but countries feared due its procedural complexities and the political pressures. Therefore, although TRIPS agreement promoted commercial activity by ensuring rigid intellectual property rights, it increased the structural inequality among the nations.

In a response for the rapidly growing criticism over the impact of the TRIPS agreement on public health, the member states of WTO adopted the Doha Declaration on2001. The countries gathered to recognize the constant challenges faced by the developing countries in ensuring access to affordable medicines, it laid a landmark development in balancing the trade law and human rights as for the first time the WTO member states prioritized public health over commercial protection. The agreement emphasized that the nations, for the protection of public health can take measures and would not be prevented by WTO. Most importantly this agreement removed ambiguity of the TRIPS flexibilities by acknowledging the nations right in issuing compulsory license and the grounds upon which they would be granted was to be determined by the nations. It also introduced measures for medicine export under compulsory license for the nations insufficient in manufacturing, thereby providing the moral and legal clarity. But the practical implementation still lacked, pharmaceutical companies along with the developed nations resisted in following the guidelines, as a response they are often citied their concerns over intellectual property infringement.

4 | Conflict Between IP Rights & Human Rights

There are times when the patent protection granted under the IP rights prohibits the equitable access of essential medicines, especially when there is public health crisis. One such incident happened in the 1990s and early 2000s in South Africa, where the nation confronted with a high alarming rate of HIV/AIDS cases. The South African government for the urgent need looked for the import and manufacturing of the generic versions of antiretroviral drugs (ARVs) to combat with the epidemic. However, the same faced a massive challenge as the pharmaceutical companies, protected under the TRIPS-based patent protections, blocked the export of the same under a legal action and argued that the same protection is granted to them under TRIPS agreement. This invited the global criticism and the same forced the companies to withdraw the suit, but it showed how rigid patent protection can block the nation's ability to protect their public health, which is one of the obligations under the right to health and life.

Similarly, in the recent times the COVID-19 pandemic also exposed the harsh reality of the world, where a few pharmaceutical companies influenced by the monopolistic control over the vaccines, which restricted the equitable global access to it. Even though there were rapid development in the vaccines various nations were forced to the delays. Initiatives like COVAX and proposals for a TRIPS waiver to temporarily suspend IP protections on COVID-19 technologies reflected an urgent call for prioritizing human rights over commercial interests.

The Pricing barriers also stood as one of the critical aspects of the conflict. The patented medicines are often priced at a very high rate which stands far from the reach of an average patient in the low-income countries. For instance, the cost of 'Hemgenix' approved for the treatment of 'Hemophilia B' (a rare lifelong bleeding disorder) is priced at $3.5 million per dose, thus effectively denying treatment to millions. These pricing strategies, justified under the guise of recouping R&D investments, often fail to consider the public funding and collaborative efforts involved in drug development. As a result, IP rights granted under TRIPS and national regimes have become instruments of exclusion, contradicting the core human rights principle of non-discrimination in access to healthcare.

Thus, eventually it has been observed that while the goal of the IP rights was to promote innovation, their overemphasis on corporate protection and improper enforcement without prioritizing public health led to the fundamental conflict and led to the violation of international laws. There is a need to mediate the gap between the very two legal frameworks and it needs to be dealt with a very balanced approach, which encourages innovation but at the same time respects human dignity too.

5 | Human Rights Based Approach to Medicine Access

Today, a human rights-based approach in the distribution & in the access of the medicine stands as an eminent need, which will ensure that the products are not only developed by also distributed equitably. The AAAQ principle of the human right i.e., Availability, Accessibility, Acceptability& Quality should function in the proper manner. There must be enough medicine and health facility to meet the public need, also the same must be accessible to all without any discrimination, and the same must be culturally and ethically acceptable ensuing assured quality and safety of the same. When one connects the same with the states, three core obligation arises under the human rights law; to respect**,** by not interfering with existing access; to protect, by preventing third parties, including pharmaceutical companies, from impeding access; and to fulfill, by proactively ensuring that health facilities, goods, and services including essential medicines are available and accessible to all.

There are more legal mechanisms affirmed in the Doha Declaration, which are crucial in ensuring a rights-based approach by enabling the state to prioritize public health over intellectual property restrictions, such as Compulsory Licensing and parallel imports. Compulsory licensing is a mechanism where the government grants the manufacturing rights to other entities without the consent of the patent holder, generally in the situation of public need, this will ensure no company having the monopolistic control. The parallel imports enable the nations to purchase patented products at a cheaper rate, various nations follow it because many patented medicine holders do not allow the direct import of their medicine to several nations, this promotes global harmony on the same hand ensures equitable medical access.

6 | The Role of Generic Medicine in Promoting Access

Generic medicine has been considered to be a pivotal in promoting equitable access to healthcare, particularly if we take into the fact of a significant and persistent global challenge in the case of accessing healthcare and essential medicines especially observed in the developing countries where on an average the one-third of the population encounters difficulties in accessing necessary treatment or essential medicines The economic burden is substantial, with a single course of treatment in some regions potentially costing multiple days' wages. In this complex landscape, generic medicines have emerged as a critical and transformative force, fundamentally reshaping how patients can access and afford essential medications.

A generic drug is a pharmaceutical drug that contains the same chemical substance as a drug that was originally protected by chemical patent, pharmaceutical products that are equivalent to brand-name drugs in dosage, strength, route of administration, quality, performance characteristics, and intended use, generic medicines become available after the expiration of patent protection on the original branded product. They are evaluated by regulatory authorities to ensure bioequivalence, meaning they must deliver the same therapeutic effect in terms of safety and efficacy. The role of generic medicines can be analyzed by various dimensions, with consideration to the factors like the cost, affordability, availability, the challenges, the impact.

The most immediate impact of generic medicines is their ability to reduce drug prices substantially. Studies have shown that generics are often priced between 30% and 80% lower than their brand-name equivalents. The role of generic medicines extends beyond cost containment to broader public health gains. In the fight against epidemics such as HIV/AIDS, tuberculosis, and malaria, the availability of low-cost generics has enabled the scale-up of treatment programs globally, increasing the availability but also the affordability increasing standards of treatment in various nations in cases of pandemic and other such outbreaks that come in the view of urgency. With focus on the overall sustainability there have been various enforcements and policies related to generic medicines, generic substitution, streamlined pathways and regulatory pricing have showcased a drastic increase in usage and trust in generic medicines.

From a human rights and public health perspective, it is understood that affordable medicine and its easy accessibility is an essential to realizing the right to health as articulated in various international instruments such as the International Covenant on Economic, Social and Cultural Rights (ICESCR). The UN Committee on Economic, Social and Cultural Rights (2000).

With the increase in trend of the generic medicines it still faces numerous challenges remain especially the public remaining skeptical on the quality of the generic medicines often fueled by misinformation

and unchecked regulatory oversight to it, To address these concerns, robust quality assurance systems and transparent communication strategies are necessary to build trust among healthcare providers and patients alike. Generic medicines represent a cornerstone of strategies aimed at promoting equitable access to healthcare. Their role in lowering drug costs, expanding treatment availability, and supporting public health initiatives underscores their significance in global health policy. However, to maximize their potential, countries must adopt robust regulatory frameworks, promote public awareness, and ensure policy alignment with the principles of the right to health. In doing so, generic medicines can serve not only as economic alternatives but also as enablers of human rights and global health equity

7| Judicial & Policy Responses

In the nations where access to essential medicines is a constitutional or statutory right, the role of Judicial and policy responses becomes quite eminent and important in mediating the clash between IP rights and right to health. In the Indian context, the Supreme court of India in the judgment of Novartis AG v. Union of India (2013)[5] laid a milestone for the global public health. The apex court rejected the petitioner's application which was submitted for its cancer drug “Glievic”,stating that the modified version of the same did not satisfy the requirement of "enhanced therapeutic efficacy" under Section 3(d) of the Indian Patents Act.[6] The very section prevents ‘evergreening’, which is a method used by the pharmaceutical industries to extend patent monopolies after performing minor modifications. The judgment enshrined and ensured the principle that the patent laws must be interpreted in the light of the public health, thereby upholding India’s pro public health patent regime. It has also laid an example for the countries, seeking to resist patent abuses that undermine access to medicine.

In the recent times various nations came up with initiatives to increase the availability of affordable medicines. Taking the reference of India’s National Pharmaceutical Pricing Authority (NPPA)[7] which aims to regulate the drug prices, and schemes like Jan Aushadhi promotes the widespread availability of generic medicine in low costs. These efforts contribute to the efficiency in health sectors and fulfills the state’s obligations to respect, protect, and fulfillthe right to health under international and domestic law. While there are steps taken at the national level, we should not forget that international cooperation also forms a key part of policy interventions aimed at expanding medicine access. Initiatives like the Global Fund to Fight AIDS, Tuberculosis and Malaria**,** Gavi (the Vaccine Alliance)**,** and the Medicines Patent Pool (MPP) represent how global health funding and technology sharing can enable low- and middle-income countries to procure affordable, quality-assured medicines.

In short, the judicial decisions, policy frameworks, and international cooperation must work cooperatively and efficiently to address the structural barriers to medicine access. The duty of the state goes beyond legal compliance with international trade agreements; it involves proactive legislative, judicial, and administrative interventions that prioritize health equity and human dignity. Access to medicines is recognized as a justiciable right and the enforcement of that right through courts and policy are essential for making the right to health a lived reality.

8| Challenges & Recommendation

As already stated earlier, there are several challenges between the IP rights and the right to health, these

[5] *Novartis AG v. Union of India (2013) 6 SCC 1*
[6] The Indian Patents Act, 1970 (Act 39 of 1970), s,3(d)
[7] National Pharmaceutical Pricing Authority

challenges rise particularly during the health emergencies. One of the foremost issues between the two is the constant conflict between incentivizing pharmaceutical innovation and ensuring equitable medical access. The TRIPS agreement of patent regime, which grants exclusive rights to these companies for a long period of time, eventually allows them to set high prices which often place life-saving drugs non-affordable for the low-middle income nations. While companies try to justify this on the grounds of recouping R&D investments, a significant portion of drug development is publicly funded, raising ethical concerns about profit-driven monopolies on essential health technologies. Also, the lack of transparency in drug pricing and R&D expenditures makes it difficult for the governments to ensure fair prices.

Another challenge that the globe faces today is the limitation in the local production capacity, particularly in the Global South, this creates their overdependence on MNCs for medicine and vaccine access. During the COVID-19 pandemic, this imbalance was clearly visible, where high-income nations accumulated vaccines, the low-income nations were left out without timely access, creating a state of constant fear among them. The unequal distribution of vaccines, known as "vaccine apartheid," served as a stark reminder that public health cannot be left to market forces alone. As a result, many developing nations had to rely on donations or delayed procurement, which in turn affected their economic recovery and trust in international health systems**.** This also exposed how the global health governance remains tilted in the favor of rich nations and wealthier corporate, when the COVAX and other voluntary mechanisms were delayed. Furthermore, public health emergencies often trigger legal and geopolitical barriers, such as export bans, vaccine nationalism, and IP enforcement, which hinder equitable access to critical health products. The lack of binding international obligations on pharmaceutical corporations further increases these challenges, as they are not directly accountable under international human rights law and often resist sharing technology, even in crises.

Several nations lack the political will or institutional infrastructure to implement rigid public health safeguards against IP overreach, exposing their lapse in the legal system. In this context, ensuring a rights-based approach to medicine requires confronting not just technical or legal hurdles, but also the global political economy of health, where commercial interests often prevail over public welfare. Addressing these challenges demands structural reforms in IP law, global health funding, corporate accountability, and equitable distribution mechanisms and also ensuring the participation of the society. Countries must also make full use of TRIPS flexibilities, including compulsory licensing and parallel imports, while resisting pressures to adopt TRIPS-plus provisions in bilateral trade agreements that would restrict access to affordable generics.

There is an urgent need to promote local pharmaceutical manufacturing through public investment, capacity building, and policies that increase domestic production. In addition, regional cooperation through pooled procurement and shared R&D platforms can strengthen the negotiating power of developing countries and reduce dependency on transnational corporations. National governments should also invest in education, research institutions, and public-sector laboratories to enhance innovation that prioritizes public needs rather than market profitability**.** There is also a need for the pandemic preparedness and this must be a clear priority for the world. This involves developing legal and institutional frameworks that automatically authorize compulsory licenses during public health emergencies, create emergency drug and vaccine stockpiles, and support open-source access to pandemic-related innovations.

Last but not the least, the Corporate accountability also needs to be institutionalized. Pharmaceutical companies should be subjected to mandatory human rights due attentiveness laws that require them to assess and mitigate the health and human rights impact of their business practices ensuring the fair implementation of human rights. Voluntary codes are insufficient in the face of systemic inequalities and market-driven barriers to medicine access. In addition,
global solidarity mechanisms such as the Medicines Patent Pool, C-TAP, and COVAX[8] should be strengthened and made permanent, with transparent governance and which is inclusive of participation from low- and middle-income countries.

9| Conclusion

The global health landscape today is defined by an intense and significant contradiction, while medical science and pharmaceutical industry continues to produce groundbreaking innovations, millions still lack access to essential medicines due to rigid intellectual property frameworks. The right to health, recognized under international human rights law, must not be subordinated to the commercial imperatives of pharmaceutical monopolies. As explained in the paper through case laws, international treaties, and national policies, there exists both the moral and legal obligation to prioritize public health over monetary profit.
Although there are certain mechanisms such as compulsory licensing and generic substitution which provide ways to mitigate these tensions, but the same is not utilized to their full potential due to political and economic pressure. Therefore, a holistic and rights-based approach is necessary, one that emphasizes AAAQ principles, promotes local manufacturing capacity, demands corporate accountability, and enhances global cooperation.

[8] https://www.who.int/initiatives/act-accelerator/covax#:~:text=COVAX%20was%20a%20historic%20multilateral,UNICEF%20from%202020%20through%202023.