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The Forgotten Provisions of Trips: A Comparative Study of Articles 7 And 8 In Shaping Pharmaceutical Patent Policy in South Asia

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Abstract- ***The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is often analysed in terms of its fundamental criteria for intellectual property safeguarding, especially Article 31 concerning compulsory licensing. Articles 7 and 8 have received very little academic scrutiny, since they outline the aims and purposes of the Agreement while establishing the normative structure for patent protection. These regulations acknowledge that intellectual property rights are not unconditional but should facilitate technical advancement, societal benefit, technology dissemination, and public health. The importance of their role has been more evident since the Doha Declaration on the TRIPS Agreement and Public Health, which reiterated the entitlement of Member States to interpret and apply TRIPS in a way that promotes public health and access to medications. This study rigorously examines the influence of Articles 7 and 8 on the formulation of pharmaceutical patent regulations in South Asia. It contends that these rules are not only aspirational declarations but serve as essential interpretive principles that shape the formulation and execution of compulsory licensing frameworks in national law systems. The research conducts a comparative analysis of India, Bangladesh, Pakistan, Nepal, Sri Lanka, Bhutan, and the Maldives to assess how national patent systems integrate the developmental goals outlined in Articles 7 and 8. It moreover examines judicial advancements, legislative strategies, and policy obstacles that persistently influence access to inexpensive pharmaceuticals in the area. The paper asserts that whereas South Asian nations have progressively used the adaptability inherent in the TRIPS framework, significant inequalities persist in legislative execution and institutional capability. Enhancing the domestic implementation of Articles 7 and 8 may foster a more equitable intellectual property framework that safeguards innovation while also serving the wider public good, especially in public health.***

Keywords: TRIPS Agreement; Articles 7 and 8; Pharmaceutical Patent Policy; Compulsory Licensing; South Asia.

I. INTRODUCTION

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) significantly altered the international intellectual property framework by instituting consistent minimum criteria for the safeguarding and enforcement of intellectual property rights among World Trade Organization (WTO) members. Since its implementation in 1995, the Agreement has profoundly impacted national patent systems, especially in the pharmaceutical industry, where the conflict between patent safeguarding and drug accessibility is most apparent. Enhanced patent protections aim to foster innovation and promote investment in research and development; nevertheless, they may also postpone the accessibility of cost-effective medications, presenting challenging policy dilemmas for developing nations.

To alleviate this conflict, the TRIPS Agreement includes certain flexibilities enabling Member States to safeguard public interests while adhering to their international commitments. Compulsory licensure as specified in Article 31 has garnered significant scholarly and legal scrutiny. Nonetheless, the overarching aims and tenets outlined in Articles 7 and 8 have often been relegated to the periphery, even though they provide the conceptual underpinning of the Agreement. These regulations acknowledge that safeguarding intellectual property is not a goal in itself, but rather a mechanism to foster technical advancement, enable technology dissemination, improve social and economic well-being, and protect public health. They consequently establish the normative foundation for the interpretation and execution of all substantive duties under the Agreement.

The importance of Articles 7 and 8 has grown more evident in the post-Doha period. The Doha Declaration on the TRIPS Agreement and Public Health reiterated the entitlement of WTO Members to construe the Agreement in a way that promotes public health and access to pharmaceuticals. The Declaration, although focusing on the mechanics of compulsory licensing, subtly bolstered the developmental aims outlined in Articles 7 and 8. As a result, these clauses have transformed from preliminary declarations into significant interpretive doctrines that influence modern discussions on pharmaceutical patent governance.

The significance of this discussion is especially evident in South Asia. The area, housing almost a quarter of the global populace, persists in facing considerable public health obstacles while concurrently establishing itself as a prominent hub for generic drug production. Nations like India and Bangladesh have heavily used TRIPS flexibilities to enhance access to cost-effective medications, whereas Pakistan, Sri Lanka, Nepal, Bhutan, and the Maldives have implemented very varied legal and institutional strategies. The varied experiences provide a significant chance to analyse the impact of the goals and tenets outlined in Articles 7 and 8 on pharmaceutical patent regulations across the area.

Notwithstanding the expanding corpus of research on compulsory licensing and pharmaceutical patents, very less academic inquiry has focused on Articles 7 and 8 as standalone normative clauses that might influence domestic patent policy. Current research mostly emphasises Article 31 or examines compulsory licensing as a procedural tool, resulting in the interpretive significance of Articles 7 and 8 being largely overlooked. This essay aims to fill that void by rigorously analysing the impact of these rules on pharmaceutical patent regulation in South Asia. It contends that Articles 7 and 8 need not to be seen just as aspirational clauses but as fundamental tenets that persist in shaping equitable patent policies that harmonise innovation with public health and socio-economic well-being.

II. WHY ARTICLES 7 AND 8 MATTER: THE NORMATIVE FOUNDATION OF PHARMACEUTICAL PATENT GOVERNANCE

The TRIPS Agreement is often seen as a tool mostly focused on enhancing the protection of intellectual property. This interpretation, however, neglects the wider policy aims inherent in the Agreement. Articles 7 and 8 stipulate that intellectual property rights should serve to enhance innovation, facilitate technological transfer, and promote societal well-being instead than acting as unqualified ownership rights. These stipulations thus provide the normative structure through which all substantive duties under TRIPS, including pharmaceutical patent protection, need to be construed.

Article 7 acknowledges that safeguarding and upholding intellectual property rights ought to foster technical innovation and promote the exchange and distribution of technology for the reciprocal benefit of both producers and consumers. This clause embodies the notion that patent protection is warranted just when it promotes overarching developmental goals. Innovation is consequently not merely a standalone business concern but rather an integral component of a broader system aimed at fostering economic development, technological advancement, and societal benefit.

Article 8 further this goal by explicitly acknowledging the regulatory independence of Member States. It allows governments to implement actions essential for safeguarding public health, fostering socio-economic advancement, and curbing the misuse of intellectual property rights, as long as these actions align with the Agreement. Thus, the TRIPS Agreement does not exclude governmental participation; rather, it recognises that public interest factors may warrant restrictions on exclusive patent rights under suitable conditions.

The practical importance of these regulations became more evident after the ratification of the Doha Declaration on the TRIPS Agreement and Public Health in 2001. The Declaration reiterated that TRIPS ought to be construed in a way that bolsters

public health and enhances access to pharmaceuticals. The Declaration primarily emphasised mandatory licensing and parallel imports, while also underscoring the interpretive significance of Articles 7 and 8 by acknowledging that the Agreement inherently included enough flexibility to address public health issues.

When considered collectively, Articles 7, 8, and the Doha Declaration indicate that pharmaceutical patents should not be understood exclusively as private commercial entitlements. They necessitate that governments, judicial systems, and legislators reconcile innovative incentives with conflicting public goals, including accessible healthcare, technological advancement, and fair access to pharmaceuticals. This equilibrium has gained significant importance during worldwide health crises, because rigorous adherence to patent exclusivity may clash with pressing public health requirements.

The impact of Articles 7 and 8 is not limited to mandatory licensing. These stipulations also validate legislative actions concerning rigorous patentability criteria, governmental use, research exemptions, antitrust law engagement, and technology transfer regulations. These methods together enable States to meet their international commitments while preserving enough policy autonomy to tackle national healthcare concerns.

This normative paradigm has significant relevance for South Asian nations. The area concurrently accommodates one of the major generic pharmaceutical sectors globally and a considerable segment of the worldwide populace in need of cost-effective medications. As a result, national patent regulations are progressively influenced by the need to harmonise international intellectual property responsibilities with constitutional pledges to health, social equity, and economic advancement. The degree to which nations have implemented Articles 7 and 8, however, differs significantly, illustrating variations in legislative frameworks, institutional capabilities, and public health objectives.

This discrepancy illustrates that the efficacy of Articles 7 and 8 relies not on its linguistic acknowledgement but on their integration into national legal frameworks. A comparative analysis of South Asian nations therefore offers significant understanding of how these fundamental regulations have impacted the administration of pharmaceutical patents in reality.

III. COMPARATIVE TRENDS IN SOUTH ASIAN PHARMACEUTICAL PATENT POLICIES

a. Countries with Proactive Utilisation of TRIPS Flexibilities: India and Bangladesh

Among South Asian nations, India and Bangladesh have most adeptly used the policy opportunities afforded by Articles 7 and 8 of the TRIPS Agreement. Despite variations in their legal systems, both nations have implemented pharmaceutical policies that emphasise public health and generally align with international intellectual property commitments.

India has established one of the most equitable patent systems among emerging nations. India has implemented measures including Section 3(d) of the Patents Act, compulsory licensing under Section 84, opposition processes before and after grants, and the Bolar exemption to curb patent misuse while fostering genuine innovation. Judicial rulings, especially Novartis AG v. Union of India (2013), have emphasised that patent protection should align with public health goals rather than function independently. The mandatory license issued for Bayer's cancer medication Nexavar further illustrated that the need for inexpensive pharmaceuticals might justifiably impose restrictions on exclusive patent privileges.

Bangladesh offers a another, although comparably important, paradigm. As a Least Developed Country (LDC), it has availed itself of transitional exemptions under the TRIPS Agreement, allowing it to defer the enforcement of pharmaceutical product patents. This adaptability has enabled the expansion of a competitive generic pharmaceutical sector, permitting local producers to manufacture cost-effective

medications for both internal use and exportation. Instead of depending on mandatory licensing, Bangladesh has mostly used the regulatory latitude afforded by its LDC designation. Its experience demonstrates that Articles 7 and 8 can be actualised not solely via legislative protections but also through differentiated treatment that acknowledges diverse levels of economic advancement.

Despite the divergent legislative frameworks used by India and Bangladesh, both nations illustrate that the aims of technical advancement, public health, and pharmaceutical accessibility may harmoniously align with global intellectual property commitments. Their experiences exemplify the most efficient implementation of the principles outlined in Articles 7 and 8 in South Asia.

b. Countries with Moderate Legislative Implementation: Pakistan and Sri Lanka

Pakistan and Sri Lanka have integrated TRIPS commitments into their national patent legislation, acknowledging the significance of safeguarding public health. In contrast to India and Bangladesh, both states have used the flexibilities permitted by the Agreement to a somewhat lesser extent.

Pakistan's patent laws allow for compulsory licensing and governmental use in situations pertaining to public welfare, national crises, or anti-competitive behaviour. Nonetheless, these stipulations have hardly been used in reality. Administrative constraints, restricted domestic pharmaceutical research capabilities, and prudent regulatory enforcement have curtailed the effective use of TRIPS flexibilities.

Sri Lanka also acknowledges compulsory licensing in its intellectual property system; nonetheless, its pharmaceutical industry is significantly reliant on foreign medications. The lack of substantial domestic pharmaceutical production has diminished the prospects for using compulsory licensing or similar protections as tools for public health policy. As a result, both nations increasingly depend on adherence to TRIPS legislation rather than actively leveraging its developmental goals.

c. Countries with Emerging Pharmaceutical Patent Frameworks: Nepal, Bhutan and the Maldives

Nepal, Bhutan and the Maldives represent jurisdictions where the implementation of pharmaceutical patent policy remains at an evolving stage. While each country has undertaken legislative reforms to meet international obligations, institutional capacity, limited pharmaceutical manufacturing, and dependence on imported medicines continue to influence the practical operation of their patent regimes.

Nepal has incorporated compulsory licensing provisions within its patent legislation, particularly to address public interest and public health concerns. However, limited administrative infrastructure and technological capacity have constrained their practical application. Bhutan's intellectual property framework reflects its commitments under the WTO, yet pharmaceutical patent regulation remains comparatively underdeveloped, with little evidence of active reliance on TRIPS flexibilities. The Maldives, owing to its relatively small pharmaceutical market and dependence on imported medicines, has similarly adopted a compliance-oriented approach rather than developing an independent pharmaceutical patent strategy.

Although these countries differ in their institutional and economic capacities, they share common challenges relating to healthcare infrastructure, technology transfer, and access to affordable medicines. Their experience demonstrates that the effectiveness of Articles 7 and 8 depends not merely upon legislative recognition but upon the institutional ability to translate these principles into practical public health measures.

Collectively, the South Asian experience reveals that the implementation of Articles 7 and 8 is shaped less by the text of the TRIPS Agreement than by domestic political commitment, industrial capability, and regulatory capacity. While India and Bangladesh have actively utilised available policy space, the remaining jurisdictions continue to adopt comparatively cautious approaches. These contrasting experiences reaffirm that Articles 7 and 8 are capable of supporting diverse national strategies

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while preserving the central objective of balancing patent protection with public welfare.

Table 1: Comparative Position of South Asian Countries in Implementing the Objectives of Articles 7 and 8 of the TRIPS Agreement

Country	Patent Framework	Use of TRIPS Flexibilities	Pharmaceutical Manufacturing Capacity	Overall Alignment with Articles 7 & 8
India	Strong and well-developed	Extensive (Compulsory licensing, Section 3(d), Bolar exception, patent opposition)	Very High	High
Bangladesh	LDC transitional framework	Extensive through TRIPS transition period	High (Generic medicines)	High
Pakistan	TRIPS-compliant legislation	Moderate; limited practical utilisation	Moderate	Moderate
Sri Lanka	TRIPS-compliant legislation	Limited use of compulsory licensing	Low to Moderate	Moderate
Nepal	Developing patent framework	Limited utilisation	Low	Moderate to Low
Bhutan	Emerging legal framework	Minimal practical implementation	Very Low	Low
Maldives	Compliance-oriented framework	Minimal reliance on TRIPS flexibilities	Very Low	Low

Source: Compiled by the author based on an analysis of national patent legislation, WTO obligations, and pharmaceutical policy frameworks.

The comparative analysis demonstrates that although all South Asian countries are bound by the same international framework under the TRIPS Agreement, their implementation of Articles 7 and 8 varies considerably. These differences are shaped less by the wording of the Agreement than by domestic legislative choices, institutional capacity, pharmaceutical manufacturing capability, and public health priorities. India and Bangladesh have utilised the available policy space more proactively, whereas the remaining jurisdictions continue to adopt relatively cautious approaches. The South Asian experience therefore illustrates that the effectiveness of Articles 7 and 8 depends not merely upon legal recognition but upon their meaningful incorporation into national pharmaceutical policy and regulatory practice.

IV. REASSESSING THE ROLE OF ARTICLES 7 AND 8: LESSONS FROM SOUTH ASIA

The prevailing discourse on the TRIPS Agreement has largely centred on Article 31 and the procedural dimensions of compulsory licensing. Such an approach, although important, overlooks the broader objectives and principles that shape the Agreement's philosophy. This study demonstrates that Articles 7 and 8 are not merely introductory or aspirational provisions; rather, they constitute the normative foundation upon which a balanced international intellectual property regime is built. By recognising innovation, technology transfer, public welfare, and public health as complementary rather than competing objectives, these provisions provide the legal justification for adopting measures that reconcile private patent rights with broader societal interests.

The comparative experience of South Asian countries illustrates that the practical significance of Articles 7 and 8 extends far beyond treaty interpretation. India's utilisation of compulsory licensing, stringent patentability standards, and public-interest safeguards demonstrates how TRIPS flexibilities can be effectively operationalised without undermining innovation. Bangladesh has similarly leveraged the transitional arrangements available to least-developed countries to establish a competitive generic pharmaceutical industry. In contrast, Pakistan, Sri Lanka, Nepal, Bhutan, and the Maldives have adopted comparatively cautious approaches, reflecting differences in institutional capacity, industrial development, and domestic healthcare priorities. These variations indicate that the effectiveness of TRIPS flexibilities depends less upon the wording of the Agreement and more upon the willingness and ability of States to incorporate its underlying objectives into national policy.

The COVID-19 pandemic further reinforced the continuing relevance of Articles 7 and 8. The unprecedented demand for equitable access to vaccines, medicines, and medical technologies revived international debates concerning compulsory licensing, technology transfer, and the balance between patent exclusivity and public health. These developments demonstrated that the objectives of technological innovation cannot be pursued in isolation from the broader imperatives of global health, particularly in developing regions where access to affordable medicines remains a persistent challenge.

Future discussions on pharmaceutical patent governance should therefore move beyond viewing Articles 7 and 8 as interpretative aids and instead recognise them as substantive guiding principles for legislative and judicial decision-making. National governments should actively incorporate these provisions into patent policy, strengthen institutional mechanisms for implementing TRIPS flexibilities, and encourage greater regional cooperation in pharmaceutical production and technology sharing. Such an approach would not only promote legal certainty but also enhance the resilience of healthcare systems across South Asia.

Ultimately, the enduring relevance of the TRIPS Agreement lies not in the strength of patent protection alone but in its capacity to accommodate both innovation and public welfare within a coherent legal framework. Reaffirming the centrality of Articles 7 and 8 is therefore essential for ensuring that the international patent system continues to serve its broader developmental purpose. As the South Asian experience demonstrates, these provisions are not the forgotten clauses of the TRIPS Agreement; they are its guiding principles, shaping a more balanced, equitable, and socially responsive approach to pharmaceutical patent governance.

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