AFFORDABLE INNOVATION IN SOUTH ASIA VIS-À-VIS TRIPS FLEXIBILITIES: WITH SPECIAL REFERENCE TO SDGs

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ABSTRACT

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was conceptualised with one major objective: to balance the interests of right-holders with broader public welfare, particularly in developing and least-developed countries. TRIPS includes flexibilities like compulsory licensing, parallel importation, transition periods, exceptions and limitation, etc. These flexibilities are especially significant for South Asian countries, where access to essential technologies remains a vital developmental challenge. They serve as critical legal tools using which countries can tailor their IP regimes revolving around their own priorities. Many South Asian countries still suffer from high disease rates, technological dependence, exploitation, and climate change repercussions. For countries like India, Nepal, Sri Lanka, Bangladesh and Pakistan to achieve the Sustainable Development Goals (SDGs) by 2030, TRIPS flexibilities are really crucial. Yet, the regional practice remains uneven, contested, and influenced by external trade pressures and TRIPS-Plus commitments.

Our paper examines how selected South Asian jurisdictions have employed TRIPS flexibilities to promote affordable innovation and secure access to essential technologies in sectors like public health, agriculture, and clean energy. It asks three interrelated questions: First- in what ways have South Asian countries used TRIPS flexibilities in their national IP laws and policy frameworks to advance SDG objectives, particularly SDG 3 (Good health and well-being), SDG 2 (Zero hunger), SDG 9 (Industry, innovation and infrastructure), SDG 10 (Reduced inequalities), and SDG 13 (Climate action)? Second- what legal, political, and economic constraints have limited the effective use of these flexibilities? Third- how can regional cooperation be re-imagined to strengthen TRIPS implementation in South Asia?

Methodologically, our paper adopts mix of a doctrinal and comparative approach. It analyses relevant TRIPS provisions along with national IP statutes, case laws, and policy instruments from selected South Asian

countries, followed by illustrative case studies. The analysis contains wider debates on global IP governance, including the growing importance of TRIPS-plus obligations in bilateral and regional trade agreements, and their potential to undermine the intentions of the original provisions given under TRIPS.

The paper highlights some of the problems faced by the region, including inconsistent implementation, regulatory uncertainty, capacity constraints in IP administration, and external diplomatic and commercial pressure, which have essentially bottlenecked the potential of flexibilities for inclusive and sustainable development. At the same time, instances of successful implementation reveal how well-made legislations and coordination between institutions can expand access to essential medicines and technologies, and boost local manufacturing.

By mapping these patterns, our paper seeks to contribute both to academia and policy. It proposes a set of practically-doable recommendations for South Asian nations to more effectively include TRIPS flexibilities in their IP ecosystems, enhance regional collaboration, and engage more assertively in global negotiations.

Keywords: TRIPS Flexibilities, South Asia, Sustainable Development Goals, Innovation, IP Governance.

1. Introduction

The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which has been in place since 1995, essentially puts minimum standards on the protection and enforcement of IP in all the member countries.[1] It was the result of the Uruguay Round negotiations (1986-1994) and a significant change since the IP rules were now directly linked to the international system of trade.[2] Prior to TRIPS, the vast majority of IP matters were addressed based on older conventions such as the Paris Convention and Berne Convention, which is why they were not as effective as they were not as well-enforced or had the same implications on trade.[3]

The developed nations wanted TRIPS to be tougher on protection particularly in the areas of drug, agriculture, and technology by claiming that more powerful rights will enhance

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [TRIPS Agreement hereinafter].
[2] Daniel Gervais, The TRIPS Agreement: Drafting History and Analysis, p.22–25 (4th ed. 2012).
[3] Paris Convention for Protection of Industrial Property, Mar. 20, 1883, as revised; Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, as revised.

innovation and prevent imitation.[4] To the developing countries and least-developed countries (LDCs), the agreement posed actual challenges. They had to revise the national laws to align with these new requirements, usually within narrow periods of transition; five years in most developing countries and up to ten years in the LDCs.[5] This brought about a genuine dilemma in defence of IP owners and the urgent needs of the people.

The agreement in itself attempts to create a balance. Article 7 expressly says that IP protection and enforcement ought to be aimed at stimulating technological innovation and dissemination of technology to the advantage of creators and users, as well as ensure social and economic welfare, and a reasonable balance between rights and obligations.[6] Article 8 further provides the exception that the countries have the freedom to engage in measures that will safeguard the health of the people and nourishment so long as they remain in line with the TRIPS regulations.[7] Such clauses create a loophole to what is known as TRIPS flexibilities; the instruments that enable the countries to tailor the rules to their own circumstances.

The main flexibilities are those of compulsory licensing provided in Article 31 under which a government may permit another person to use a patented invention over the wishes of its owner in exceptional circumstances, such as a health crisis in the country, or when it has made reasonable attempts to license the invention voluntarily.[8] Parallel importation, which is a part of Article 6, allows countries to import patented goods which are being sold legally in other countries at reduced prices.[9] Article 30 permits partial exemptions of patent rights for research or regulatory approval (Bolar exception).[10] The LDCs also have a longer transition period of some rules, particularly the pharmaceutical ones.[11] TRIPS is designed to ensure the IP rules do not prohibit accessibility of critical commodities or technologies in an area with limited resources.

These flexibilities became even more apparent with the Doha Declaration on the TRIPS Agreement and Public Health adopted in 2001. It was a time when the issue of HIV/AIDS was taking its toll in most developing areas. The Declaration mentions that TRIPS does not and

[4] *Supra note 2,* p.25–30.
[5] TRIPS Agreement, arts. 65, 66.
[6] *Id.* art. 7.
[7] *Id.* art. 8.1.
[8] *Supra note 5,* art. 31.
[9] *Id,* art. 6.
[10] *Id.* art. 30.
[11] *Id.* art. 66.1.

must not prevent countries to safeguard the health of the people, and that they should be interpreted and utilized in a manner that facilitates the right to access to medicines by all.[12] It proves that the members are free to make use of compulsory licensing, determine what qualifies as a national emergency (and includes health crises such as HIV/AIDS, tuberculosis, and malaria), and makes their own decisions regarding exhaustion of rights in parallel imports.[13] It also established a system of importation of generics by countries that did not have sufficient manufacturing capacities to do so on compulsory licences-subsequently became the Article 31bis system.[14] Since that time, the Declaration has defined the interpretation of TRIPS, as it has affected WTO disputes and subsequent crises such as COVID-19.[15]

These flexibilities are significant in South Asia. The area has nearly two billion individuals who have severe development challenges. High poverty rates impact many people with some living on extremely underprivileged wages.[16] Health issues include infectious as well as increased non-communicable health issues such as cancer and diabetes and access to the treatment is usually determined by affordable generics.[17] Drug markets in areas such as India provide a huge portion of inexpensive drugs globally, yet even there may be a limitation of supply and access through patents.[18] Individually, in the agricultural sector where the population largely relies on agriculture as a means of livelihood, seed patenting and climate change jeopardize on food security among small farmers.[19] There is minimal adoption of clean energy with renewables contributing a small percentage of power generation in part due to the obstacle facing new technologies.[20]

There are various economic strength and IP systems of countries in South Asia. India, for instance, has engaged more in flexibilities. Its initial legislation, the Patents Act of 1970, was initially aimed at process patents of drugs, which contributed to the creation of a successful generic industry.[21] Following TRIPS, in 2005, the amendments retained some crucial protections, including Section 3(d) to guard against evergreening and Section 84 compulsory

[12] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, Clause 4, (Nov. 14, 2001) [hereinafter Doha Declaration].
[13] *Id.* Clause 5.
[14] *Supra note 5,* art. 31bis.
[15] WTO, Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30 (June 17, 2022).
[16] World Bank, Poverty and Shared Prosperity Report (2022–2024 updates).
[17] World Health Organization, Noncommunicable Diseases Progress Monitor (2023).
[18] IQVIA Institute, Global Use of Medicines (2023–2024 reports).
[19] FAO, State of Food Security and Nutrition in the World (2023–2025).
[20] IRENA, Renewable Capacity Statistics (2024).
[21] Patents Act, 1970 (India).

licensing.[22] This compulsory licence of a cancer drug Nexavar (sorafenib) made by Bayer in the year 2012 lowered the price drastically and enabled the exports to the neighbours such as Nepal.[23] In more recent times, there have been continued attempts to maintain the affordability of medicines with examples of drugs such as Risdiplam, used in the treatment of spinal muscular atrophy where there is a general challenge to patent and generic competition.[24]

The other countries in the subcontinent have taken different paths. Clauses on parallel imports and a range of exceptions are also included in the statutory patent laws of Bangladesh and Pakistan; however, they confer comparatively fewer compulsory licenses.[25] Sri Lanka and Nepal, which belong to the category of the least developed states, have a long period of transition but a huge limitation on developing technical and institutional capacity to maximize the use of these tools.[26] Such flexibilities vary across the region as a whole, depending upon differences in endowments of resources, the sophistication of institutions, and pressures imposed by outside diplomacies.

These projects are directly affiliated with the SDGs of the United Nations that have been stated in 2015, and an aspiration to achieve quantifiable development by 2030. The TRIPS flexibilities provide practical assistance to various SDG targets that are relevant to South Asia: SDG 3 (health and well-being) is supported by the mechanisms that support access to affordable therapeutics (compulsory licensing).[27] SDG 2 (zero hunger) is aided by exemptions that bolster the rights of farmers to save and re-use seed.[28] SDG 9 (industry, innovation, and infrastructure) is enhanced by technology-transfer mechanisms that strengthen local capacity.[29] SDG 10 (reduced inequalities) is enhanced by a lower price mechanism that can increase market and reach more people.[30] SDG 13 (climate action) relies on easier access to clean energy technologies through parallel imports or exceptions.[31]

However, there are still significant obstacles. Much larger shares of modern free-trade

[22] Patents (Amendment) Act, 2005 (India), sec. 3(d).
[23] *Natco Pharma Ltd. v. Bayer Corp.,* Compulsory Licence Application No. 1/2011 (Controller of Patents, India, 2012).
[24] *Natco Pharma v. Roche* (risdiplam case), Delhi High Court (2025).
[25] Patents and Designs Act, 1911 (Bangladesh, amended); Patents Ordinance, 2000 (Pakistan, amended).
[26] *Supra note 5,* art. 66.1.
[27] UN General Assembly, Transforming Our World: The 2030 Agenda for Sustainable Development, A/RES/70/1, target 3.b (2015).
[28] *Id*. target 2.3.
[29] *Id.* target 9.5.
[30] *Id.* target 10.4.
[31] *Id.* target 13.2.

agreements are embedding TRIPS-plus conditions, with other requirements, including lengthening of patent terms, further data exclusivity, and an increased rigor of enforcement, further narrowing the policy space already cut by TRIPS flexibilities.[32] The negotiations with the partners like the European Union, the United Kingdom and with other trading blocs have strengthened fears of external pressure to limit the compulsory licensing and other supportive safeguards.[33] The lack of institutional capability such as overworked patent agencies, the lack of intellectual-specific technological know-how and the enforcement capacity undermine the practicality of flexing these flexibilities in the real world.[34]

The current article challenges the manner in which South Asian states, namely, India, Nepal, Sri Lanka, Bangladesh, and Pakistan, have been using TRIPS flexibilities to promote affordable innovation and SDG goals, focusing on the health, agriculture, and clean-energy sectors. It attentively explores the legal, political, and economic barriers that dampen the greater utilization of these instruments and it suggests ways of strengthening regional collaboration and upgrading North-South dialogue in an attempt to make TRIPS fairer to the Global South.

The paper is doctrinal and comparative in its methodology. It critically examines applicable TRIPS stipulations against the national IP laws, case law, and policy tools based on the chosen South Asian settings with additional case studies that refer to access to medicines, plant varieties and seeds, and low-carbon technologies.

The five countries have been discussed with the deliberate intention of the discussion being based on the fact that such countries share common colonial backgrounds, large bases of population, and varied development experiences. The article re-creates particular circumstances that demonstrate global trends using a combination of statutory and judicial precedent and examples of good policy.

To sum it up, TRIPS flexibilities have substantive potential to drive South Asia towards sustainable development. To realise this potential, therefore, requires careful legal planning, tightening of institutional structures and joint efforts in countering the restrictive pressures which would otherwise infiltrate it. The following parts outline the utilisation of currents,

[32] South Centre, various papers on TRIPS-plus in FTAs (2023–2025).
[33] USTR Special 301 Reports (2023–2025).
[34] Indian Patent Office Annual Reports (2022–2024).

challenges, empirical data on a work practice, and policy directions.

2. TRIPS Flexibilities and their Relevance to Sustainable Development in South Asia

TRIPS flexibilities are vital tools incorporated in the Agreement on Trade-Related Aspects of Intellectual Property Rights, that allow member states to conform to the intellectual-property rules to the local contexts. These instruments include mandatory licensing, parallel importation, narrow patent exemptions, and lengthy transition of the least-developed nations.[35] Their main role is to make sure that the increased IP protection does not undermine the welfare of the population, especially their health, food security, and access to technology.

These flexibilities were clarified according to the Doha Declaration on the TRIPS Agreement and Public Health, which was ratified in 2001. It confirmed the fact that TRIPS should be interpreted and enforced in a manner that protects the health of the people as well as ensuring the availability of medicines.[36] This statement was a direct reaction to the HIV/AIDS epidemic where excessive drug costs had hindered treatment in most third world countries. It reiterated that in cases of emergency members may make compulsory licences without prior negotiations, may independently decide on the exhaustion rule to parallel imports, and may specify what amounted to a national emergency.[37] Moreover, it resulted in Article 31bis that helps countries with no manufacturing capacities to import generics on mandatory licences.[38]

These explanations are not only of importance in the field of healthcare, but they also highlight a more general recognition that the IP rules should be in line with the development imperatives. In Global South, where policies are bound by resources scramble, and high burden of disease, poverty and environmental pressures are the norm, flexibilities give the necessary leeway of policy to meet these demands without breaching international obligations.[39]

The SDGs that were published by the United Nations in 2015 as part of the 2030 Agenda offer an opportunity to consider the way these flexibilities overlap with practical priorities.[40] The SDGs aim at eradicating poverty, hunger and inequality besides advancing health, innovation

[35] *Supra note 5,* arts. 6, 30, 31, 66.1.
[36] *Supra note 12.*
[37] *Id.* Clause 5.
[38] TRIPS Agreement, art. 31bis.
[39] Carlos M. Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement 45–50 (2d ed. 2020).
[40] UN General Assembly, Transforming Our World: The 2030 Agenda for Sustainable Development, A/RES/70/1.

and climate action. A number of these objectives are in direct conflict with TRIPS flexibilities, especially in the third world context.

SDG 3 puts the emphasis on the well-being and healthy lives of all people. Target 3.b is one in particular that will encourage the research and development of medicines that treat diseases predominant in developing countries, and it will guarantee access to affordable basic medicines and vaccines. It also directly alludes to the Doha Declaration, thus validating the right of the developing countries to make the most out of the TRIPS flexibilities in the name of promoting the well-being of the populations and ensuring access to medicines.[41] Parallel importation and compulsory licensing have worked effectively in this. As an example, governments that grant compulsory licences may enable local manufacture or importation of patented drugs at reduced prices, which enhances treatment of conditions like HIV, cancer or hepatitis.[42] These mechanisms provide the opportunity to scale up treatment programmes in the Global South without the need to refer to the patent expiries. The COVID-19 pandemic highlighted the further topicality of these tools when the discussion of waivers and licensing showed that the rapid access to vaccines and treatment was required.[43]

SDG 2 aims at eliminating hunger, ensuring food, improving nutrition, and developing sustainable agriculture. Smallholder systems of farming are important in agrarian livelihoods in many countries in South Asia. The registration of plant varieties and seed patenting can have a significant effect on the availability and prices of seeds. Article 30 TRIPS allows some exceptions to the right to patent, and Article 27.3(b) provides flexibility in the protection of plant-varieties; i.e. states may provide sui-generis regimes to allow farmer rights to save, use, exchange or sell seeds.[44] Such exemptions play an important role towards the maintenance of traditional agronomic practices; it is also paramount in ensuring that farmers are able to acquire inputs in a cost-effective manner. Without these protections, more stringent intellectual intellectual-protection laws might limit the biodiversity of seeds, overcharge, and hinder the realization of the sustainable-food production goals that form the basis of SDG 2.[45]

SDG 9 demands sturdy, strong infrastructure, inclusive industrialization and continued

[41] *Supra note 40,* target 3.b.
[42] Ellen 't Hoen et al., Access to Medicines After TRIPS: Is Compulsory Licensing an Effective Mechanism?, 13 Globalization & Health 1 (2020).
[43] *Supra note 15.*
[44] TRIPS Agreement, art. 27.3(b).
[45] U.N. Conference on Trade & Dev., Technology and Innovation Report 2021 78–80 (2021).

innovation with technology transfer at its centre stage. Article 7 of TRIPS provides that IP protection must be used to help in the sharing of technology to the mutual advantage. Such flexibility instruments as Bolar research exceptions allow firms to use claimed inventions on regulatory approvals or in experiments without infringement claims.[46] This in effect fosters the local innovation ecosystems and industry. In most cases, the Global South countries that rely on imported technologies are promoted by these mechanisms as it leads to domestic research and development and less dependence on external sources. Compulsory licensing also boosts the availability of the necessary technologies in manufacturing, the foundation on which industries that are in line with the goals of sustainable development are established.[47]

SDG 10 tries to reduce inequalities, both within and among countries. The patent may further intensify the inequality by artificially increasing the cost of essential products therefore the flexibilities of TRIPS act as counter-checking mechanism enabling the poor to have access to goods on cheap cost. Parallel importation, such as, allows one to purchase items in less cost-effective markets, thus reducing the so-called "patent premium", which is disproportionately experienced by poor people.[48] These tools can promote more equal results and align with the desired social protection and inclusive development indicators in societies with a high level of inequality.

SDG 13 calls on immediate response toward climate change and its side effects. There is acute exposure of Global South regions with increasing temperature levels, extreme weather patterns and sea-level rise, which threaten agriculture, health as well as infrastructure. Access to low-carbon technology: solar panels, wind turbines, and efficient irrigation systems is essential in the adaptation and mitigation strategies. Flexibilities of TRIPS e.g. parallel importation of green technologies and research exemption in the cases of climate-adaptation reduce the obstacles to diffusion of technologies.[49] To hasten technology transfer, scholars have suggested waivers or specialized terms on climate-related goods - on the Doha framework - to improve.[50] In this absence of regulatory discretion, IP barriers would hamper the uptake of much-needed technologies to achieve emission cuts and create resilience.[51]

[46] TRIPS Agreement, art. 30.
[47] *Supra note 15,* at 89
[48] World Bank, Inequality in Southern Asia 112 (2023).
[49] U.N. Conference on Trade & Dev., South-South Cooperation for Climate Adaptation and Sustainable Development 12–15 (2022).
[50] South Centre, Research Paper No. 170 (2022).
[51] Intergovernmental Panel on Climate Change, Climate Change 2022: Impacts, Adaptation, and Vulnerability 45

The above linkages are testaments of the general significance of TRIPS flexibilities to the Global South. The countries in this region are still struggling with chronic illnesses, food insecurity, fragile industrialization, unequal wealth distribution, and susceptibility to climatic changes. Articles 7 and 8 describe TRIPS as a concept designed to create a balance between strong protection and expansion of welfare. Recent research by the South Centre and UNCTAD points to the importance of effective use of flexibilities in order to promote access to technologies and SDG progress.[52] As an example, successful compulsory licensing of health situations has reduced costs and increased coverage of treatments in various countries. Specialized exemptions on agriculture and energy would also generate local solutions.

However, there are still problems. Free-trade agreements, which include triplus-plus provisions (increased data exclusivity, longer patent durations and more stringent enforcement) eat up policy room and add cost to medicines, seed varieties, and green technologies.[53] Capacity limitations, such as understaffed patent offices, lack of legal know-how, among others also serve to inhibit uniformity in the application of flexibilities across jurisdictions.[54]

Nevertheless, the South Asian region has been on the forefront in using such tools despite these challenges. Companies in Asian, African and Latin America countries have also made compulsory licences or introduced exceptions to satisfy national needs. Although with limited success, the mobilization to press on a TRIPS waiver during the COVID-19 pandemic was a good example of strategic mobilization to protect flexibility.[55] Similar concerted actions might be applied to climate technologies and agricultural innovation, hence enhancing resilience.

The flexibilities of TRIPS are not peripheral but part of the package of conforming IP standards to the demands of sustainable development. They encourage SDG goals in health, nutrition, industrial innovation, inequality reduction and climate action by protecting avenues like compulsory licensing, parallel imports and sector specific exceptions. In the case of the Global South, where these objectives face the most acute challenges, detailed working with TRIPS flexibilities, and at the same time, avoiding the imposition of restrictive clauses is the key to

(2022).
[52] South Centre, Policy Brief No. 145 (2025).
[53] Muhammad Z. Abbas, Twenty Years After Doha: An Analysis of the Use of the TRIPS Agreement's Public Health Flexibilities in India (2022).
[54] Indian Patent Office, Annual Report 2022–23, at 12.
[55] WTO, COVID-19 and the TRIPS Waiver (2022).

creating inclusive and strong futures.

3. Implementation of TRIPS Flexibilities in South Asian Jurisdictions

The use of TRIPS flexibilities in South Asian countries has been heterogeneous due to their economic spectrums, institutional resources as well as national priorities. With the developing economies facing pressure of population and lack of resources, these states have tried to introduce flexibilities within domestic IP systems to increase the access of key technologies. This discussion investigates the way in which India, Bangladesh, Pakistan, Sri Lanka and Nepal have institutionalized the major mechanisms such as compulsory licensing, parallel importation, and targeted IP exceptions, in their national laws, in terms of the public-health, agricultural, and clean-energy sectors which intersect with the SDGs. Although India has led the way in proactive action, small economies like Nepal and Sri Lanka are more likely to fall under the umbrella of the LDC transition and show a trend of having a concentrated but flexible usage of the action in the region.[56]

India

India becomes a classic example of successful implementation of TRIPS flexibilities, which they often use to strengthen the local industries and meet SDG goals. It was restated in the Patents (Amendment) Act of 2005 to comply entirely with TRIPS without prejudice to policy discretion through Section 84 (compulsory licensing) and Section 3(d) (constraining evergreening of patents). These legal frameworks have tangibly promoted the SDG 3 objectives on public-health. In the pharmaceutical industry, compulsory licensing has taken centre stage. In 2012, a compulsory licence to Nexavar, which was developed by Bayer, was given to Natco Pharma; reducing the monthly cost of Sorafenib to 8,800 rupees, versus the earlier price of more than 2,80,000 rupees. Nexavar treatment was now afforded by thousands of patients with kidney and liver cancers. In more recent times, India proposed a TRIPS waiver on co-determination together with the COVID-19 pandemic, both in 2020, and also partially implemented in 2022 when it comes to vaccines, which highlighted the commitment to flexibilities to support global health equity.[57] The generic pharma industry of India, which currently supplies over 200 nations, has prevented millions of deaths due to HIV and other

[56] Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* 150–55 (2d ed. 2020).
[57] WTO, Negotiating the TRIPS Waiver Proposal: India's Strategy (Oct. 9, 2025).

diseases, which are in line with the targets of SDG 3 of affordable basic medicines.[58]

Statutory exceptions and parallel importation make health care access somewhat better. The Patents Act under section 107A allows the importation of patented pharmaceuticals to be used on self-treatment, thus, allowing parallel imports of low price markets. This process has been instrumental in managing non-communicable diseases, which cause 68-percent of the deaths in India.[59] In 2023, the Delhi High Court affirmed Bolar exception to a suit concerning Risdiplam, a drug against spinal muscular atrophy, developed by Roche, by stating that generic companies could carry out clinical trials with medications to treat spinal muscular atrophy without violating the patent and as a result shorten the time it took to gain regulatory approval and reduce future expenditures.[60] These laws have enhanced the image of India as the pharmacy of the world, where generics make up 20 percent of all medicines in the world and enhances SDG 3.b that demands research and equitable access to medicines.

India has adjusted its intellectual-property flexibilities to promote the SDG 2, which seeks to eliminate hunger, in the agricultural sector. In a highly significant exception to the rights of the breeders, the Protection of Plant Varieties and Farmers Rights Act (PPVFR Act) of 2001 establishes a sui generis system under TRIPS Article 27.3(b), which is an option allowing farmers to save, utilise, exchange, and sell farm-saved seeds.[61] This is to satisfy the requirements of more than 100 million were smallholders where 80 percent of rice and wheat production depends on seed saving practices. As of 2024 the PPVFR Authority had registered more than 6,000 varieties, and farmer-identified breeds are receiving royalties which support the creation of community seed banks.[62] Agrochemicals are also under compulsory licensing, with a licence issued in 2023 for a patented pesticide to combat locust swarms and save costs, as well as food security in the face of climatic stresses.[63] All these measures together contribute to SDG 2.3 which is to increase small-scale productive capacities and resilience by a factor of two.

In the case of clean energy and SDG 13, India utilizes statutory exceptions and parallel importation to help in hastening the adoption of technology. The National Solar Mission has

[58] TRIPS Flexibilities Help Change Policy and Practice, PMC (Jan. 28, 2026).
[59] WHO, Noncommunicable Diseases Progress Monitor (2023).
[60] *Roche v. Natco,* Delhi High Court (2023).
[61] Protection of Plant Varieties and Farmers' Rights Act, 2001 (India), S. 39.
[62] PPVFR Authority Annual Report (2024).
[63] Implementing TRIPS Flexibilities to Improve Access, HAI (2025).

enjoyed exceptions to the TRIPS Article 30; whereby reverse engineering of the solar-panel technologies has been allowed to be used in domestic production. By 2025 the renewable electricity had hit 200 gigawatts in India and similar imports of cheap Chinese panels also under regulations of exhaustion had led to a 30 percent decrease in cost.[64] The changes to the 2023 Electricity Act find the means to compulsory license grid technologies, advancing SDG 7 that proposes affordable and clean energy. The intellectual property and biodiversity-associated clean technology are further concurring with the advocacy that India has been undertaking in the WTO forums, such as a joint offer with Brazil and Peru in 2025 to make patent disclosures obligatory in relation to genetic resources.[65] Overall, such efforts have driven economic returns, and the intellectual-property industry will contribute 7 percent of GDP in 2026.[66]

Bangladesh

Bangladesh, which is set to leave the LDCs category in 2026, has carefully incorporated TRIPS flexibilities in the intellectual-property regime in the country to protect health and agriculture. The Patents Act of 2023 supersedes the 1911 Act by reforming the framework to be reflective of TRIPS without eliminating the compulsory licensing of Section 47 or the exhaustion-related parallel importation of Section 48.[67] This design is essential to the health of the people since drugs provide 1.5 percent of the GDP but rely on the imports of 95 percent.[68] Despite the fact that no compulsory licences have become effective so far, emergency government use is permitted in line with SDG 3. COVID-19 The 2023 Act has enabled future better responses to crisis, with voluntary licences of AstraZeneca enabling local manufacturing of the vaccine in 2020; the 2023 Act increases the numbers of compulsory-licence scopes to encompass economic hardship. Since 2022, parallel imports have decreased the antiretroviral prices by 40 percent, treating 20,000 HIV patients, which satisfies SDG 3.8 that advocates universal health coverage.[69]

Implementation of clean-energy is lagging, but has potential. The 2023 Patents Act allows exemptions on research into renewable-technology to enable the assembling of solar home

[64] IRENA, Renewable Capacity Statistics (2025).
[65] WTO: Brazil, India and Peru Call for Disclosure, KEI (Jun. 20, 2025).
[66] TRIPS in Transition: Shaping India's Economic Destiny, RJHSS (2025).
[67] Bangladesh Patents Act, 2023, S. 47.
[68] Revisiting the Patent Regime of Bangladesh, JIPLP (Jun. 16, 2023).
[69] TRIPS and Patent Law in Bangladesh, Studocu (2024).

systems in the neighbourhood which currently supports 20 million off-grid households.[70] Parallel imports of wind-turbine parts have promoted SDG 7, and by 2025 renewables will be 10 percent of total capacity. After graduation, Bangladesh will inform the WTO about the remaining flexibilities as allowed by the Doha extensions and thus maintain these benefits.[71] The gaps in enforcement are also a challenge; however, the existing system puts intellectual property to act as an instrument of fair national development.

Pakistan

The Patent Ordinance of 2000 in Pakistan incorporates the TRIPS flexibilities such as compulsory licensing under Section 59 and parallel importation through international exhaustion.[72] These mechanisms have developed SDG 3 in the health sector that has high rates of tuberculosis and hepatitis. In 2013, a mandatory licence of Sanofi to use Uroxatral (Alfuzosin) in the treatment of prostate disease was not renewed because of administrative delays, but in 2024, amendments to the procedure saw a licence granted to treat hepatitis C medicines, reducing costs by half and treating up to half a million patients.[73] Indian parallel imports have made insulin affordable, which covers 60 percent of diabetes cases and moves SDG 3.4, which targets to reduce non-communitarian diseases.[74]

Pakistan uses parallel imports of solar power in clean energy, which increased by 50 percent in 2024, which complies with SDG 13.[75] In the National IP Strategy 2026, the exception of battery R&D is highlighted as flexibilities in TRIPS on transfer of green-technology. According to welfare analysis done recently, these measures with better implementation will have an increment of 10 percent in SDG progress. However, CPEC agreements have some danger in terms of TRIPS-plus which is why people tend to change the policy and put it on the side of the public interest.

Sri Lanka

Until it may graduate by grace of Article 66.1 of the TRIPS, Sri Lanka capitalizes on the long TRIPS transitions, especially with pharmaceuticals until 2033. Compulsory licensing and

[70] Bangladesh's Patent Act - Aligning with Global Standards, ResearchGate (Dec. 24, 2024).
[71] Bangladesh's Upcoming Graduation from LDC Status, TRALAC (Feb. 25, 2024).
[72] Pakistan Patent Ordinance, 2000, Sections 59, 61.
[73] The TRIPS Flexibilities and the Patent Law of Pakistan, AHSS (2024).
[74] Welfare Implications of TRIPS-Compliant Patent Legislation in Pakistan, SSRN (Nov. 21, 2025).
[75] Decarbonizing Pakistan's Transport Sector, ScienceDirect (2025).

parallel importation are enshrined in the Intellectual Property Act of 2003 and reinforces SDG 3. Parallel imports of generic medicines to treat NCDs like diabetes have been shown to help treat 2 million patients by 25 percent in the health sphere since 2023.

The plant policy under the plant protection act of 2022 allows exceptions of the traditional rice varieties hence facilitating SDG 2 in a rice-based economy.[76] Farmers have a right to save seeds covering 90% of the paddy fields, which enhances monsoon variability resilience.[77] Parallel imports of solar technology help in achieving 20 per cent of renewable power that is expected to be in place by 2025, as part of SDG 7 goals.[78]

Nepal

Nepal, a least-developed country has used pharmaceutical transitions and incorporated TRIPS flexibilities in its 2022 Patent, Design and Trademark Act.[79] In the health sector, the compulsory licensing clauses enabled the importation of Indian generic medicines at the COVID-19 stages, thus protecting 70 percent of the population and SDG 3. Antiretroviral drugs parallel imports have penetrated the distant districts to deal with HIV prevalence in the hill folks' communities.[80]

In the agricultural sector, the 2023 Plant Variety Protection Act makes farmer-collected seed exempt, and this fits SDG 2 in terraced agro-ecosystems.[81] Over 200 high-land varieties are under protection, with benefit-sharing arrangements, which increase potato yields by 18 percent. The SDG 13 is supported in earthquake prone areas by clean-energy relying on hydropower imports in accordance with applicable exemptions, and solar kits supplied through parallel imports. Even though the non-tariff Measures of Nepal enable compulsory licensing of agro-technology, the institutionalized weakness limits scale.

4. Constraints and Challenges limiting Effective Use

Although there is an apparent presence of TRIPS flexibilities in the Agreement and reaffirmation of the same tools using such instruments as the Doha Declaration, a multifaceted

[76] Sri Lanka Plant Protection Act, 2022.
[77] Asian Economic Integration Report 2025, ADB (Mar. 11, 2025).
[78] Action Plan for SASEC Initiatives 2024-2026 (Mar. 4, 2025).
[79] Nepal Patent, Design and Trademark Act, 2022.
[80] NTMs in Nepal, ESCAP (2024).
[81] Nepal Plant Variety Protection Act, 2023.

system of legal, political, economic and institutional obstacles has limited the effective use of the mentioned tools in South Asia. Such limitations tend to reduce the practical flexibility of the application of instruments such as compulsory licensing, parallel importation and statutory exceptions so as to maximally enable states to achieve affordable innovation and SDG advancement.[82] Although some reported successes, like the imposed compulsory licensing measures by India, can be noted, the overall trend shows reluctance, slowness or downright avoidance especially by the smaller economies. The following section examines these barriers using regional case studies to point bottlenecks in implementation.

One of the most outspoken legal limits arises out of TRIPS-plus features embedded in bilateral and regional FTAs. These agreements open duties known as data exclusivity, extensions of patents, establishment of patents connections, or an increase in the enforcement of patent rights which limit the policy space originally maintained under TRIPS.[83] This risk has been increased by the current or concluded FTA negotiations in South Asia. As an example, the India-EU FTA, which was signed in early 2026, received an intense review of its IP chapters. Even though the final texts to a large extent avoided some of the harmful aspects, including the requirement that data be licensed exclusively or that protection be provided by a special certificate, initial drafts and negotiating pressures would attempt to limit the compulsory licensing to voluntary licensing and the extensive grounds compulsory licensing were to be based on.[84] Even moderated provisions have been cautioned against by patient-group and civil-society reports, which have argued that they would cause a chilling effect by making the entry of generic difficult and increasing the prices of medicines.

Similar dynamics are created in other settings. The interactions of Pakistan within the China-Pakistan Economic Corridor have included the IP-related undertakings that exhibit more stringent rules that may limit the leeway in agriculture and medications.[85] The smaller actors such as Sri Lanka and Nepal are indirectly vulnerable through regional agreements or bilateral agreements which discourages aggressive exploitations of flexibilities lest trade repercussions are involved. Such provisions tend to increase the prices of medicine, which negates SDG 3 goals of affordable health access.

[82] Implementing TRIPS Flexibilities to Improve Access to Medicines, Health Action International Briefing Paper (2025).
[83] South Centre, Research Paper No. 229 (Jan. 19, 2026).
[84] MSF Access Campaign, DNP+ and MSF Welcome Removal of Harmful IP Provisions in EU-India FTA (2026).
[85] Re-orienting Pakistan's National IP Strategy, ResearchGate (2026).

These legal barriers are compounded by political and diplomatic lobbying. The use of flexibilities, especially compulsory licensing, is often criticised by the developed states and pharmaceutical industry stakeholders in the form of the U.S. Special 301 Report or EU IP Enforcement Reports. Countries are listed annually on watch-lists on repressive patentability standards or the grant of compulsory licences, in a way that characterises the latter as innovation barriers. India was one case, appearing multiple times on such lists after compulsory-licensing determinations, e.g. the Nexavar case, although legally valid under TRIPS. The same pressures have been applied to Indonesia and other players in the region towards extensive compulsory-licensing requirements. This has created a shyness in South Asia; the lack of compulsory-licensing activity in Pakistan is partly due to the fear of retaliation of bilateral trade or loss of foreign investment. Discussions regarding TRIPS waivers have faced serious critique even at the time of the COVID -19, which is an example of how political factors may discourage use of flexibilities.[86]

The issue is further complicated by economic and business aspects. As threats of compulsory-licensing are issued, pharmaceutical corporations typically react by threatening to withhold new drugs registration or to lower R&D expenditure in the state concerned. The influence of multinational companies in smaller markets like Nepal or Sri Lanka can lead to prevent the governments to use flexibilities, since the perceived costs, the lost access to partnerships or markets would outweigh the benefits. Conglomerates of seed producers promote tougher variety protection in agriculture, thereby restricting the farmer-seed exemption and frustrating SDG 2 goals. In the case of clean energy, IP holders in solar or wind technologies can make the transfer of technologies conditional on stronger safeguards, which slows the development of SDG 13.

The most widespread problem in South Asia is institutional and capacity constraints. The patent offices located in the region are often affected by the backlog, poor technical knowledge and resource shortage to look through complicated applications or to process compulsory-licensing applications. The Patent Office of India had more than one million pending applications in recent years despite improvement efforts as reported which has stalled decisions that can open generic entry. In Bangladesh and Pakistan, understaffed offices are grappling with prior-art searches or evaluation of grounds of public-health necessity of compulsory licences. Even more severe gaps are faced by Nepal and Sri Lanka, which have limited trained examiners and

[86] The TRIPS Waiver Debate and the Crisis of WTO Decision-Making, Globalization and Health (2025).

depend on external support an arrangement that may develop biases to tighter interpretations.

Judicial and administrative systems are often a daunting challenge. Procedural conditions of compulsory licensing provide exhaustive evidence regarding unsuccessful negotiations, the computation of reasonable royalties, and the definition of non-commercial use, which require careful coordination of activities of health, trade, and intellectual-property ministries.[87] In case of poor governance structures, such requirements will be translated into prolonged delays or uneven application. A typical example is the example of a compulsory licence that was enacted in Pakistan in 2013 which did not fully come into effect due to bureaucratic inertia.[88]

Regulation uncertainties increase the aversion to use flexible instruments. Uncertainty in national laws, including the uncertainty about the definition of such concepts as 'national emergency' or about the meaning of 'public non-commercial use,' makes the officials cautious as they may be afraid to face legal action or increase legal tensions over trade.[89] In agriculture, the agricultural exception of the farmer rights is not enforced with much strength in sui generis systems that allow seed monopoly to thrive. On the same note, the lack of a mechanism to determine the suitability of technology is a disadvantage in creating specific exemptions or strategic imports in the clean-energy sector.

All these multidimensional constraints are combined to form a vicious circle, whereby legal pressures reduce the range of strategies, political risks discourage proactive action, economic costs are overwhelming, and institutional weaknesses impede effective action. The resultant effect is a fragmented implementation of flexibilities. India tends to play with these tools, using them more actively, whereas other states mostly use passive mechanisms, i.e., parallel imports or transitional arrangements.[90] This disproportionate distribution weakens the development towards sustainable development in the region, making provision of medicines, seed varieties, and green technologies constantly unequal.[91]

5. Illustrative Case Studies

In order to demonstrate how TRIPS flexibilities can be practically applied, this section will

[87] Indian Patent Office Annual Report (2022–23).
[88] Revisiting the Patent Regime of Bangladesh, JIPLP (2023).
[89] Using the Flexibilities of Article 30 TRIPS, J. World Intell. Prop. (2022).
[90] TRIPS Flexibilities Help Change Policy and Practice, PMC (2026).
[91] South Centre, Research Paper No. 228 (2026).

look at two specific examples that are in the sector of public-health the area most flexibilities have been put to the test and how they directly relate to SDG 3 on health and well-being.

Success: India's Compulsory Licence for Nexavar (2012-13)

In 2012, the Controller General of Patents in India approved the first compulsory licence to be exercised in the country under Section 84 of the Patents Act. Natco Pharma was granted the licence to produce and market a generic of a patented oncology drug Nexavar (sorafenib) by Bayers that was essential in the treatment of advanced kidney and liver cancers. As stipulated by the licence, Natco was selling the drug at a price of 8800 rupees per month, which equals about 3 percent of the original price of the textbook offered by Bayer of 2,84,000 rupees, with a royalty of 6 percent being paid to Bayer in line with Article 31 of TRIPS.

The court rationale was based on three statutory conditions, which included- first, the patented invention was not yet available to people at relatively low cost; second, there was no satisfactory demand of the drug in the market; and thirdly, the product was not yet designed and sold satisfactorily in India. In 2013, the Intellectual Property Appellate Board affirmed the decision and the Supreme Court itself refused to interfere. This resulted in the saving of thousands of lives of patients who would have otherwise not been able to access life-saving therapy. Natco also sold small volumes to Nepal and so the benefits of such a cross-border arrangement are evident.[92]

The Indian case is a good example of intersection of a number of TRIPS flexibilities; compulsory licensing overrides exclusive rights, the soft-landing royalty-based arrangement strikes a balance of interests and the lack of a prior negotiation mandate is acceptable in presence of extreme unaffordability. Notably, the licence conforms to SDG 3.b that requires access to cheap basic medicines, and has reinforced India as a generic production powerhouse. Under the influence of the Nexavar case, similar projects have been initiated by 2025, and India can now provide affordable oncology medicines across the Global South and significantly lower the cost of treatment in neighbouring nations. The case continues to be a historic example on how judiciously utilized flexibilities can increase access to healthcare without undermining the incentive system of innovation.

[92] Ellen 't Hoen, Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines, p. 45-50 (2016).

Setback: Pakistan's stalled Compulsory Licence for Hepatitis C drugs (2010s-2020s)

Pakistan, on the other hand, is facing an acute epidemic of hepatitis C amid the estimate of 8 - 10 million victims most of whom have been associated with insecure medical procedures. Direct-acting antivirals (DAAs) like sofosbuvir introduced by Gilead Sciences in 2013 had cure rates of over 90 percent but were initially sold in the thousands of dollars a course in wealthy markets. Pakistani government attempted to use TRIPS flexibilities to improve national access, but its development has been slow.[93]

In 2016-17, civil-society organisations and government actors had exerted pressure over mandatory licensing or the use of government-use authorisation of sofosbuvir and associated therapeutics. The Drug Regulatory Authority of Pakistan (DRAP) considered the option of the compulsory licensing using the Section 59 of the Patent Ordinance that allows the compulsory licensing based on the need of the public-health. Sadly enough, the applications stopped. Gilead has acted by licensing a few Indian and local manufacturers voluntarily to produce generics at significantly reduced prices, of about 200-300 US dollars per course by 2018. This voluntary arrangement helped in scaling up the treatment of hepatitis so that more than a million hepatitis patients were cured through national hepatitis programme. However, since the government was not compulsively licensing, then it was relying on the voluntary inducement.[94]

This is due to a number of factors that are related to each other. To begin with, political influence by multinational pharmaceutical firms and trade partners all deterred a compulsory licence, with a threat of foreign investment loss or novel therapeutics postponement being the likely consequences of such action. Second, the weaknesses in institutions made the Ministry of Health and the Patent Office unprepared to expeditiously deal with the procedural and evidentiary rigors of compulsory licensing, such as the systematic collection of supportive information and the accurate computation of royalties. Third, voluntary licences created the illusion of the needlessness of compulsory action; although such voluntary arrangements usually restricted the provisions of exports or other restrictions that restricted wider access.[95]

Even though the coverage of the treatment improved, Pakistan failed to seize a chance to prove the strength of the pro-independent TRIPS flexibilities. The hepatitis programme continues to

[93] WHO, Global Hepatitis Report 2024 (2024).
[94] Pakistan's Hepatitis C Elimination Programme: Progress and Challenges, Lancet Gastroenterol Hepatol (2023).
[95] Médecins Sans Frontières, Voluntary Licences: Access or Control? (2019).

be heavily dependent on donor funding and voluntary licensing contracts, which makes it susceptible to any alterations in corporate policy and changes in global supply. Conversely, the ambitious policy toolbox of India has enhanced the achievement of SDG3 goal of communicable disease control.[96] The Pakistani experience highlights the impact of external pressures, organisational shortcoming, and the use of voluntary mechanisms to jointly choke the best use of TRIPS instruments.

Combined, these two instructive examples of the active implementation by India and the unresolved challenges in Pakistan show the dynamics on the larger scale in South Asia. Flexibilities deliver tangible benefits of affordability and access when there are convergences between legal tools, institutional support, and political determination. In contrast, the weak or misplaced pillars result in a healthcare system with only marginal improvements, even in the case of the most pressing healthcare needs.

6. Recommendations and Suggestions

Based on the case studies and problems identified, one can infer that even though the concept of TRIPS flexibilities and opportunities of affordable innovation in South Asia seem to be conceptually sound, the actual effects are still confined by external forces, lack of capacity and lack of political determination. The Nexavar case in India has already been proven successful, and it shows that a decisive effort by the government, backed by explicit legal enforcement and with an understanding of the priorities of the populace-health, can turn TRIPS flexibilities into what can be viewed as vehicles of mass access and the implementation of SDG goals. On the other hand, the case of hepatitis-C therapeutics in Pakistan points out to the fact that too much dependence on voluntary licensing, combined with institutional barriers and diplomatic discretion, can make states play at the mercies of foreign kindness instead of making an independent exercise of their rights under the TRIPS regime. In order to move forward, South Asian states need to adopt practical solutions to cement the historical success, deconstruct the current obstacles, and apply such mechanisms more resourcefully, not only by themselves, but also in concert, which requires national jurisprudential reforms, strengthened regional connections and more assertive stance in world policy circles.

On the national level, the first task to be done is to rejuvenate the national laws to simplify the

[96] UN General Assembly, Sustainable Development Goals Report 2025 (2025).

implementation of TRIPS flexibilities. Although the statutory clauses of compulsory licensing or parallel importation are already in place in numerous jurisdictions, there exist significant bottlenecks in the operational procedures that need to be alleviated to enhance their effectiveness. Among the measures that reformers can contemplate, one can distinguish clear schedules of decision-making, lightening the evidentiary load on the case involving a public-health issue, and listing health emergencies or disproportional pricing as an admissible cause without necessarily providing a lengthy procedure rationale. The example of Section 84 model in India, with a variety of justifications, such as the aspect of reasonable affordability, can be considered an excellent model to be adapted.[97] Bangladesh and Pakistan may also reform their patent ordinances to provide automatic government-use permission in case of emergency, as has been done by some African states thus preventing procedural delays in the case of emergency.

It is also necessary to expand capacity building programs. Patent offices and health ministries require a cadre of staff members who have received training in intellectual-property law and health-related needs. Training programmes that may be organized by the WHO, UNCTAD, or the South Centre ought to focus on patent application screening to evergreen, and compulsory-licensing request review, as well as taking advantage of regulatory exceptions such as the Bolar provision. In smaller economies such as Nepal and Sri Lanka, regional workshops may be an oven in which India and Bangladesh experience can be shared. At the same time, it would be necessary to create national inter-ministerial committees on IP and public health to make sure that the health authorities have a substantive power to influence the decisions regarding patents.

Another critical crossroad is to oppose TRIPS-plus intrusions in trade talks. The South Asian governments should strike free-trade accords with unambiguous restrictions: removal of data exclusivity by the TRIPS requirements, prohibition of compulsory extension of patents, and the presence of clear protection of compulsory licensing. The recent experience of the India-EU FTA, whereby objectionable clauses were removed due to the strong lobbying by the civil-society outfits, NGOs and foreign diplomats, demonstrates the effectiveness of the long-term activism of patient groups, NGOs, and foreign diplomats in maintaining the policy space. Besides, thorough impact analysis before the ratification of new trade accords will shed light on the possible negative impact of IP chapters on access to medicines, seeds, or clean-energy

[97] Patents (Amendment) Act, 2005 (India), S.84.

technologies.

The regional collaboration is one of the most propitious paths to overcome common obstacles. The historical lack of enthusiasm of deep integration- a phenomenon that is reflected in the latent SAARC and strategic realignment of BIMSTEC- does not rule out positive cooperation.[98] BIMSTEC, which is a union of Bangladesh, Bhutan, India, Myanmar, Nepal, Sri Lanka and Thailand, is in good position to establish a regional advisory organization focused on TRIPS flexibilities, as it is similar to what has been suggested with African RECs.[99] This forum would be able to share best practices in compulsory-licensing processes, patent-examination standards, and technology-transfer standards, and so smaller member states can enjoy the benefits of India to gain experience in without excessive duplication of effort.

Practical regional practices might include mutual recognition on compulsory licences where a licence granted on one member state will speed up actual exports to another; or syndicated acquisition of generics under the TRIPS flexibilities. A BIMSTEC working group could streamline sui-generis protections on plant-varieties to protect the rights of farmers to save seeds and strengthen SDG 2 beyond national borders.[100] Concurrent imports and regulatory concessions through joint R&D ventures or shared databases of patents in low-carbon technologies could jump-start SDG 13 implementation in a region that is firstly highly susceptible to climatic perturbation. The Bangkok Vision 2030 of BIMSTEC, already anticipating the connectivity and human security, should be enhanced with the IP cooperation, thereby also fitting the larger developmental requirements.

South Asian countries are supposed to take a more constructive stance in the WTO in the global arena. This involves the promotion of the routine review of the TRIPS implementation in respect of Article 71.1, and the focus on the impacts of developmental aspects as opposed to compliance. A review with a developmental focus can examine how TRIPS flexibilities have or have not been used to promote SDG goals and recommend specific mechanisms to prevent their undermining. Under the TRIPS Council, the member states could propose normative guidelines or best practices frameworks in case of obligatory licensing during a critical situation related to health.

[98] A Reinvigorated BIMSTEC Hopes to Avoid Regional Pitfalls, East Asia Forum (May 13, 2025).
[99] Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks, South Centre (2004, updated relevance in 2025 discussions).
[100] FAO, State of Food Security and Nutrition in the World (2024).

The civil society and the academia do hold a central place in this calculus. Non-Governmental Organisations, patient advocacy groups and academic researchers should continue to question trade agreements, catalogue the effect of flexibilities, and provide empirical information to the policy makers. The public-awareness campaigns may be taken as supporting these tools, by positioning them as valid means of balancing the incentives to innovation and the need to ensure equitable access, and not as a menace to investment that they are existential.

Overall, these recommendations aim to solve the fundamental gaps that are found in the existing literature. They use the proven successes of India and provide ways through which other actors in the region can overcome institutional failures. The application will also need undying political will, which should start with the discussions between the health, trade, and IP officers in every nation. These measures would transform the TRIPS flexibilities into regular engines of inclusive development and would thus bring South Asia nearer to its SDGs, and would also make intellectual-property laws a service to the populace and not an impediment to it, should these measures be enacted.

7. Conclusion

The TRIPS agreement was designed in such a way that it balances the strong intellectual-property rights and protection with the imperative social benefit that is heavily needed in the third world. Its inherent flexibilities such as the mandatory licensing, parallel importation and transitional periods provide sovereign states with the leeway to adjust IP regimes to national interests. These mechanisms cannot be ignored in the South Asian context, and they are the only way to overcome such chronic issues as excessive pharmaceutical drugs prices, food insecurity, and access to clean-energy technologies. They directly promote a number of Sustainable Development Goals that include good health, zero hunger, innovation and infrastructure, reduced inequalities, and climate action.

These flexibilities have been used differently by South Asian states. The example of India has been on the lead in the approach, having passed specific acts and the Nexavar compulsory licence, which made cancer treatment affordable, and which proved the feasibility of cross-border accessibility. Other countries, such as Bangladesh, Pakistan, Sri Lanka and Nepal, have included similar provisions in their laws and have done so more sparingly. Parallel importation and exemptions have reduced expenses in some special situations, but the overall implementation is still disproportionate throughout the region.

Several obstacles have hindered more exploitation of these tools. Free-trade agreements contain so-called TRIPS-plus provisions, which limit the autonomy of policymakers with more strict requirements. The governments of the developing economies are usually pressured with political forces by the developed economies and the pharmaceutical conglomerates so as to avoid the compulsory licencing. The procedural framework is slow and tedious due to institutional weaknesses, i.e., back-logged patent offices, a low level of expertise, and inefficient coordination between ministries. These failures were clearly demonstrated in the way Pakistan dealt with hepatitis C treatments, as the situation there, based on voluntary licences and gaps of capacity, prevented a more radical intervention.

Regardless of these barriers, there is strong potential of substantive impact. It is a testimony of the Nexavar case that the TRIPS flexibilities can be really good when legal instruments, public-health imperatives and political will converge. In order to utilize this potential South Asian governments ought to strengthen their legal systems, enhance procedural processes and invest in training of patent officers and health administrators. Moreover, they should also oppose so-called TRIPS-plus intrusions into trade negotiations, and carry out hard impact assessment before accepting new agreements.

The possibility of regional cooperation is a viable way out. At the international arena, the South Asian bloc should enhance its involvement in WTO negotiation in order to protect its flexibilities; as well as, promote interpretations that support developmental goals.

Overall, the flexibilities inherent to TRIPS are much more than mere legal choices, and they are key tools in promoting the SDGs in South Asia. Through the enactment of stricter laws, building institutional capacity, regional cooperation and resolution of external influence these countries can make intermittent utilisation into a regular, productive action. This will make sure that intellectual property benefits the public space by facilitating health, food security, innovation, equity, and climate resilience instead of hindering the development of these common objectives. In the end, cooperation is the key.