
THE LIMITS OF SOVEREIGN EQUALITY UNDER TRIPS: A TWAIL ANALYSIS OF THE PHARMACEUTICAL PATENT REGIME IN INDIA

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The concept that there is a law in the international space implies the existence of international law as one set of legal rules, principles, and institutions that govern behavior of different States at a global scale.¹ This law has tried to base its premise on the concept of neutrality, equality, and consent. Despite this, the Third World Approaches to International Law (TWAIL) seek to critique the consequences of globalizing international law.² TWAIL scholarship further argues how formally universal legal orders reproduce unequal material power, thus becoming a way of hegemony for particular states.³ The following paper will be analyzing this very dynamic through the case of Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as a hegemonic actor and its consequences on the earlier emancipatory Indian patent regime.

The premise of international law is based on the fact that states are legal persons and equal bearers of rights and voluntary consent.⁴ It is on upon this basis that one could argue that the TRIPS agreement ought to be universally beneficial or harmful, equally, to all members of the WTO. This *'rather formal concept of equality'* is central to international law, in order for the treaties to be seen as politically neutral.

Originally, India's Patent Act, 1970⁵ only dealt with process patents, leaving behind the notion of product patents.⁶ This was a deliberate attempt by the government that allowed others to make the same product as long as they used a different method.⁷ TRIPS, on the other hand, set

¹ Arnulf Becker, 'Universal International Law: Nineteenth-Century Histories of Imposition and Appropriation' (2010) 51 *Harvard International Law Journal*, 475-552.

² B.S. Chimni, 'Third World Approaches to International Law: A Manifesto' (2006) 8 *International Community Law Review* 3, 9.

³ Antony Anghie, *Imperialism, Sovereignty and the Making of International Law* (Cambridge University Press 2005).

⁴ Roland Portmann, *Legal Personality in International Law* (Cambridge University Press 2010) 6.

⁵ *Patent Act 1970*.

⁶ 'History of Indian Patent System' (Intellectual Property India) <https://ipindia.gov.in/history-of-indian-patent-system> accessed 24 July 2026.

⁷ Jayashree Watal, 'A Brief History of Pharmaceutical Product Patent in India' (The NLS Blog)

out minimum standards of patent protection that must be met by all WTO members.⁸ In order to align itself within the ambit of TRIPS and WTO, India had to introduce the amended Patent Act in 2005.⁹

The objective of TRIPS includes an act of balancing private and public interests. It leads to protection of interests of the pharmaceutical companies which tend to invest more in research and development of drugs while at the same time also allowing nations that belong to the World Trade Organization (WTO) to promote public health in their respective countries.¹⁰ Parallely, it was also reiterated at WTO Doha Declaration on TRIPS Agreement and Public Health (2001) that countries have the sovereign right to enact laws that safeguard domestic interests.¹¹

Before the amended act came to existence, an estimate 70% of the 25,000 AIDS patients that were treated by Médecins Sans Frontières in 27 countries were consuming Indian generics. It was the absence of product patents that gave space to Indian generic manufacturers who could combine several pills produced by different companies into a single tablet that is easy to consume. This simplification of treatment was crucial to the scale-up of AIDS treatment programs in poor countries.¹² The 2005 amendment changed this; it disbalanced the rights between the patent holders and consumers in favor of the former. As a result, the net result of the TRIPS has been high cost of medicines and at the same time denial of access to medicines to the income poor across the globe.¹³ The only exception that the 2005 act provided was the presence of Section 3(d). India took the advantage of this limited flexibility, by adding Section 3(d)¹⁴ to the Act, which later went on to be of utmost importance in the case of *Novartis AG v. Union of India*¹⁵. Section 3(d) became one way of preventing the ‘evergreening’ of patents

(<https://forum.nls.ac.in/nls-blog/a-brief-history-of-pharmaceutical-product-patents-in-india/> accessed 24 July 2026).

⁸ Médecins Sans Frontières *Will the lifeline of affordable medicines for poor countries be cut? Consequences of medicines patenting in India* (External Briefing document February 2005)

<http://www.who.int/hiv/amds/MSFopinion.pdf> accessed 23 July 2026.

⁹ *Patent Act 2005*.

¹⁰ Vishwas H Devaiah, ‘Trips & Public Health’ (InfoChange India May 2004)

<http://infochangeindia.org/200405096068/TradeDevelopment/Intellectual-Property-Rights/TRIPS-and-public-health.html> Accessed 23 July 2023.

¹¹ Amit K Kashyap and Anjani Singh Tomar, ‘Trips and Public Health : With special Reference to Doha Declaration & Indian Patent Law’ (2013) 1 International Journal of Health Sciences 1.

¹² WHO Regional office for South East Asia, *Globalization, Trade and Public Health : Tools and Training for National Action* (Report of an Intercountry Expert Group Meeting, WHO Project , 2000).

¹³ Amit Sen Gupta, ‘Final Amendment to India’s Patent Act (3 october 2004) http://pd.cpim.org/2004/1003/10032004_snd.htm accessed 12 November 2012.

¹⁴ *Patent Act, 2005*. S 3(d).

¹⁵ *Novartis AG v Union of India* (2013) 6 SCC 1.

by refusing patent grants on the basis of '*mere discovery of a new form of a known substance*'¹⁶. The courts in the above-mentioned case concluded that Novartis's beta-crystalline form did not meet the requirements as mentioned under S 3(d), thus failing the test of Efficacy.

While looking at this conception of TRIPS through the lens of TWAIL, scholars would argue that there exists an embedded relationship between the legal systems and the global political economy. Another TWAIL scholar, BS Chimni argues international law cannot be understood without accepting the existence of its material structures within. Furthermore, universality in application, which is often claimed by international law, is the idea of the dominant capitalist powers.¹⁷ The emergence of this Agreement majorly happened by lobbying the developed Quad countries (Japan, US, Australia), which still hold maximum power within the WTO, to influence the developing countries, thus clearly disregarding the idea of neutral multilateral consensus within all WTO countries.¹⁸ Time and again, international legal norms have reflected the preferences of economically and politically stronger states.¹⁹ This helps one further question the idea of a legal entity being an orthodox concept where every state possesses an equal footing in all treaties.²⁰ A direct consequence of this includes not only the unequal application of law, but also in turn legitimizing the present inequalities.

It is further understood that, sovereignty was never seen as a purely egalitarian concept, it rather made its way through colonialism where it was the power of the Europeans to determine which socio - political communities were fully "civilized" to participate and have autonomy within the brackets of international law.²¹ Although there exist no actual language of civilization, recent events within international economic law still distinguish between States that are allowed to produce global legal norms and others, who are expected to quietly follow and implement them.²² Thus, the hierarchy still exists, though now in '*so called*' transformed institutional forms.

¹⁶ *Patent Act, 2005*. S 3(d)

¹⁷ BS Chimni, 'Customary International Law: A Third World Perspective' (2018) 112 *American Journal of International Law* 1.

¹⁸ Peter Drahos and John Braithwaite, 'Hegemony Based on Knowledge: The Role of Intellectual Property' (2003) 21 *Law in Context* 204.

¹⁹ 'Law and Power in International Society' (Diplomacy and Law) <https://www.diplomacyandlaw.com/post/law-and-power-in-international-society> accessed 24 July 2026.

²⁰ Roland Portmann, *Legal Personality in International Law* (Cambridge University Press 2010) 6.

²¹ Antony Anghie, *Imperialism, Sovereignty and the Making of International Law* (Cambridge University Press 2005).

²² *Ibid.*

The effects of it within the State of India were also a lot similar. TRIPS ended up reducing the policy space available to this developing country by restricting its ability to tailor intellectual property regimes in accordance to its own nation's priorities.²³

What one ought to understand is not what TRIPS does, but who does it serve? The '*minimum standards*' that have been set seek to serve the interest of the narrow group of the west. It does not emerge from any neutral consensual process, but from systemic coalition within the powerful nation states.²⁴ Noncompliance with these hegemonic standards could lead to disputes within trade relations.

The hegemony of the standards set is even more visible in its application. If the States fail to comply with rules under TRIPS, they end up facing trade sanctions. Consequently, when a sovereign state does not ensure affordable medicines to the people of their country, they do not seem to face any punishment for the same. The gap is now revealed because even though access to health in a human right, the State in this circumstance is not held accountable. This reveals that international law gives protection and legal backing to only the patent, i.e. intellectual property Right, rather than the right of health of citizens within a State. A TWAIL analysis would help one notice the fact that this imbalance is a sign that the international legal order gives priority to the patent holders over the citizens who would need help in developing countries.

India's patent regime before 2005 had a different meaning of innovation, it was one that put forward the needs of its people by including industrial development for pharmaceutical companies and at the same time providing cost effective access to medicines. Following TRIPS, and the amendment in 2005, the Act did not fall into the category of legal normality. Instead, now, India was being required to provide for justifications for departures from the TRIPS standard in intellectual property while trying to balance and carve out exceptions like Section 3(d). Patent protection within WTO became the universally accepted rule, thus legitimizing hegemony while flexibility that the developing nations needed became the exception.

Further, some may argue the presence of flexibilities as a defense to these standards, but one

²³ Carlos M Correa, *Interpreting the Flexibilities Under the TRIPS Agreement* (South Centre Research paper 132, June 2021).

²⁴ Susan Sell, *Private Power, Public Law; The Globalization of Intellectual Property Rights* (Cambridge University Press 2003).

must realize that this flexibility is so narrow and costly, that the Natco license emerging from the case of *Bayer Corporation vs. Natco Pharma*²⁵ is still the only compulsory license that has been granted under pharmaceuticals in India. In addition, constant attempts to use these exceptions is what leads to staggering diplomatic relations, like the addition of India in the 'Special 301 Watch List'.²⁶ The gap present between the formal and substantive equality is where the rules of the dominant seek to fit in. TRIPS continues to be defended as a body serving universal interests, but its consequences seem to violate the sovereignty of a country.

Thus, the situation drawn here includes emancipation as a prior patent act of 1970 within India. It was one based on the sovereign capacity of the developing country, based on its own needs. The hegemon here is the Treaty, that has weaved and implemented by the power of a few, making the consequence disproportional and unequal for all signatories.

Even after some exceptions such as Novartis and Natco, the structure of TRIPS within WTO remains the same, by prioritizing patent protection. This portrays that the idea of sovereign equality does not lead to elimination of hegemony. Rather, it gives legitimacy to a system that puts forth the views of the developed nations only. Thus, through a TWAIL analysis India's example helps one understand that even though international law might promise equality and sovereignty, it still has time until it can truly achieve its promised emancipation. TRIPS, thus helps understand that international law can change historical choices including innovation and property into binding legal responsibility. While doing this, it reduced the flexibility that the developing states had without any need for coercion or any political domination by the developed states.

²⁵ *Bayer Corporation v Natco Pharma Ltd* (2013) 56 PTC 545 (IPAB).

²⁶ <https://www.thehindu.com/business/india-stays-on-ustr-priority-watch-list-on-ipr/article70927412.ece>