JSDC
Journal of Studies in Dynamics and Change (JSDC);
Vol-12, Issue-3, ISSN: 2348-7038
International Peer Reviewed Quarterly Journal
www.jsdconline.com

The TRIPS Agreement and Public Health: Analyzing the Impact on Access to Medicines

Agamyaa Methei

ABSTRACT

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) adopted under the World Trade Organization has introduced comprehensive and enforceable standards of intellectual property (IP) for its member states. While it has been touted for its role in innovation and global harmonization of IP protection, TRIPS has engendered a great deal of controversy in public health, especially with reference to its impact on access to essential medicine in developing countries. This research paper attempts to explore the relationship between the TRIPS Agreement and public health and examine how the provisions of TRIPS affect the availability and affordability of life-saving medicines.

The study looks at the legal framework of TRIPS with a special focus on pharmaceutical-related provisions and with a particular emphasis on flexibilities emanating from the Doha Declaration on TRIPS and Public Health, adopted in 2001. Through a case-study-based comparative analysis of India, Brazil, and South Africa, the paper critically engages with a number of ways in which countries have exploited TRIPS flexibilities such as compulsory licensing in balancing the enforcement of IP with public health needs.

In addition, the research notes regulatory and geopolitical obstacles impeding the effective implementation of TRIPS flexibilities, including political pressure from developed countries and restrictive provisions in TRIPS-plus agreements. It concludes with a discussion of emerging patterns, such as the suggested TRIPS waiver addressing the COVID-19 pandemic, and proposes reforms to establish a globally applicable IP regime that is fair and health-oriented.

In sum, the paper asserts that, while presenting formidable obstacles to access to medicines, TRIPS does incorporate built-in flexibilities that offer legal opportunities that can, with genuine support and Implementation, promote public health without stamping on innovation.

Keywords: Public Health Law, Intellectual Property Rights (IPR), Global Health Equity, Innovation vs. Access, Covid-19 and IP Waiver, Neglected Tropical Diseases

Author Details:
Agamyaa Methei is a student in LL.B. (H), School of Law, University of Petroleum and Energy Studies, Dehradun, Email: agamyaamethei499@gmail.com

Suggested Citation:
Methei, A. (2025). The TRIPS Agreement and Public Health: Analyzing the Impact on Access to Medicines, *Journal of Studies in Dynamics and Change (JSDC), 12*(3), 9-20.
DOI: www. https://doi.org/10.5281/zenodo.18614624
Published on: 01 July 2025

I. INTRODUCTION

Indeed, a right that is of paramount consideration for health is the access to affordable and effective medicines. However, there has been very uneven distribution across the world in terms of accessing life-saving pharmaceuticals because of various legal and economic barriers created by the patent protection of such pharmaceuticals. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which became enforceable in the year 1995, laid down a minimum standard on intellectual property provisions and requirements consistent for all World Trade Organization (WTO) member states. The agreement is quite general in its aim, although it is also the basis for consistent source of sharp debates about adverse effects resulting from it on access to medicines, especially for low- and middle-income countries (LMIC).

Pharmaceutical patents give the assignee the right to charge exclusive prices for these medicines in leg of the applicable TRIPS provisions and give the patent inventor exclusive rights for a minimum period of 20 years. The low prices demanded for new medicines conflict with urgent public health needs of populaces unable to access essential drugs. It was an effect of the HIV/AID pandemic that dominated the world's discourse on the subject between the 1990s and the early 2000s, keeping millions in the Global South out of antiretroviral therapy.

With the rising chorus of voices critical of current World Trade Organization (WTO) policies, the organization declared in 2001 that it accepted the Doha Declaration on the TRIPS Agreement and Public Health. The declaration holds that member states may give precedence to public health and make use of the flexibilities of TRIPS (such as compulsory licensing and parallel importation) in response to public health crises. Notwithstanding this, however, these flexibilities are still poorly utilized because of various political, legal, and economic barriers.

This paper sets out to establish how the TRIPS Agreement impacted access to medicines through a relationship with public health policy and laws in various countries. The legal framework of TRIPS will be explored, along with its flexibilities. Important national case studies will be analyzed, and challenges to their implementation will be identified to complete the emergence of a recommendation for much-needed reform. This research thereby seeks to contribute to on-going global debates on issues of intellectual property rights, trade law, and health equity.

II. RESEARCH GAP

Understanding these flexibilities' real-world effectiveness and the systemic barriers inhibiting their widespread use are concepts still relatively lacking in discourse, while the TRIPS Agreement's contributions to public health have remained contentious for decades. The legal commentaries and policy discussions about flexibilities like compulsory licensing and parallel importation rarely get on "(theoretical) availability," with far fewer investigations assessing the political, economic, and institutional; factors that account for their gradual realization, especially in low- and middle-income countries.
Further, most existing literature has mostly focused on early 2000s case studies, especially which on the HIV/AIDS treatment crisis, while paying scant attention to

changing dynamics in global health governance, intellectual property norms, and pharmaceutical innovations. With outbreaks like the COVID-19 pandemic rekindling global health equity discussions and pointing to gross inadequacies in the present day international legal framework, such global health inequities add to the urgency of viewing the TRIPS Agreement and its public health provisions through the lens of emerging challenges and changing geopolitical realities.

This paper fills an existing gap by providing a composite and contemporary analysis of the TRIPS regime, which also highlights the doctrinal legal framework and one of its applications within different national scenarios. It adds to the discussion on TRIPS by discussing not only the attempts of various countries to utilize TRIPS flexibilities, but also why many failed to do so successfully, through an analysis of hurdles unique to individual countries: including legal capacity, international pressure, and TRIPS-plus agreements limiting policy space.

The findings of the study call for an urgent reassessment of the existing intellectual property paradigm to meet global public health needs, particularly those affecting diseases that largely affect poor populations with very little commercial interest. By placing the issue at the convergence of international trade law, human rights, and global health, the paper calls for an urgent need to design a global structure that equitably blends innovation with access.

Therefore, the remainder of the analysis provides advice that is also timely for policymakers, legal scholars, and public health advocates who are interested in reforming the present regime or in acquiring new avenues to promote access to medicines consistent with international trade law obligations. The TRIPS Agreement is not merely a legal instrument; it remains an on-going policy issue, and the interpretation of its practical consequences is vital for health justice worldwide.

III. METHODOLOGY

This research undertakes an investigation of the relationship between the TRIPS Agreement and access to medicines using qualitative, doctrinal methods alongside a comparative case study approach. The doctrinal aspect includes critical analysis of the legal text of the TRIPS Agreement, along with the Doha Declaration on TRIPS and Public Health (2001) and relevant WTO Dispute Settlement Body (DSB) reports. An interest in TRIPS provisions relating to patent protection, compulsory licensing, and exceptions to exclusive rights, as contained in Articles 27, 30, 31, and 31bis , is highlighted.

In addition to the legal analysis, the paper also draws from an extensive range of secondary literature, scholarly works, reports published by NGOs, WHO documents, and government publications. These sources provide insights into how various states have differently interpreted, and implemented, TRIPS flexibilities including the political and economic contexts that drive such choices.

The comparative case-study methodology is employed to illustrate how India, Brazil, and South Africa have navigated the TRIPS framework to bolster access to medicines. Due to their epistemic intervention on the TRIPS flexibilities, the selected cases will engender discussions on their broader geopolitical ramifications with respect to the active engagement of TRIPS-flexibility. The research draws upon

these examples to articulate both successes and obstacles that have been faced in the real-life application of TRIPS public health provisions.

This will facilitate a deep understanding of the interplay between international legal norms and domestic policy frameworks. With a solid grounding of legal inquiries in practical experiences, the paper thus has a wide reach that transcends abstract legal debates and offers tangible illustrations of challenges and possible solutions when it comes to intellectual property law and public health considerations.

IV. LEGAL FRAMEWORK: TRIPS AGREEMENT AND PUBLIC HEALTH PROVISIONS

Adopted in 1994, as part of the Uruguay Round of the GATT negotiations, the TRIPS Agreement represented the first major change in the international legal environment, establishing minimum standards of the protection of intellectual property for all WTO members. This was the first time a system of patent protection for pharmaceuticals was considered globally, with immense consequences for the affordability and accessibility of medicines, more so in developing countries.

Patent Protection under TRIPS

Article 27 of the TRIPS Agreement makes it mandatory for WTO members to make patents available for any inventions, including pharmaceuticals that are new, involve an inventive step and are capable of industrial application. The other requirement in TRIPS is a minimum patent term of 20 years from the date of filing (Article 33). The patent holder thus has exclusive rights over the patented invention, preventing others from making, using, selling, or importing it without the patent holder's consent.

But these rights provide the monopolistic incentive for innovation but drug prices skyrocket, limiting access to life-saving medicines in cash-strapped countries and those having poor health infrastructure.

Exceptions and Flexibilities within TRIPS

While maintaining high borders for IP protection, TRIPS provisionally allows states to promote public health and access to medicines. Articles 30 and 31 provide exceptions to patent rights and include arrangements such as:

- Compulsory Licensing (Article 31): permits a government to authorize the making of a patented product without the consent of the patent holder under conditions such as national emergency or public non-commercial use. However, the overriding purpose for granting such exceptions is public interest, and while the patent holder may have some claim to "adequate remuneration," the government first and foremost acts in the general interest.
- Parallel Importation (Article 6): states may determine the rules of exhaustion of IP rights, which allows them to import patented medicines for which they pay lower prices in a foreign country, without the consent of the patent owner.

- Research exceptions (Article 30): this can include limited exceptions to patent rights pertaining to research for experimental use, including regulatory approval (the "Bolar exception").

The problem is that the wording of those provisions is semantically broad and assesses their application differently, creating further confusion and inconsistent implementation on the level of many countries.

The Doha Declaration on TRIPS and Public Health (2001)

On the TRIPS and Public Health Doha Declaration (2001), this was the Declaration that the WTO members passed from growing public outrage that TRIPS obstructed access to medicines in the South. The Declaration reaffirmed the member's rights to use all the flexibilities of TRIPS for that protection of public health, stating:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. We affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."

In particular, this Declaration made it clear about the following:
- Defines that each member defines what is a national emergency;
- Public health emergencies such as HIV/AIDS, tuberculosis, and malaria are emergencies;
- Issue compulsory licenses; lay down the grounds for that.

Even though the Doha Declaration has been a political and legal milestone, there have been mixed results for it to be practical. Most developing nations still suffer an impediment to make use of TRIPS flexibilities by agents like unsatisfactory domestic legislation which inhibits provisions, lack of technical expertise domestically, and other external political and economic pressures.

Article 31bis and Export Flexibilities

On one of the major issues that the post-Doha talks missed was that countries that had no pharmaceutical manufacturing capacity were not able to fully utilize compulsory licensing. This has been addressed with the amendment of Article 31bis by the WTO in 2005 by allowing the exportation of these pharmaceutical products to those countries without capacity to use them. However, this has been criticized for the procedural complexity and limited use of this measure, as in the example of only Canada's exporting generic drugs to Rwanda in 2008.

V. TRIPS - PLUS AGREEMENTS AND EROSION OF FLEXIBILITIES

An increasingly burning issue is the proliferation of TRIPS-plus obligations embedded in the Free Trade Agreements and Bilateral Investment Treaties negotiated by developed countries. These agreements tend to mandate IP protections that go beyond those set out in the TRIPS Agreement. These include:
- Data exclusivity requirements,
- Patent term extension,

- Restrictions on compulsory licensing.

These tend to considerably restrict the public policy space that governments can have in promoting public health and hence the use of TRIPS flexibilities.

VI. KEY CASE STUDIES: COUNTRY APPROACHES TO COMPULSORY LICENSING AND ACCESS

To understand the real-world impact of TRIPS flexibilities on access to medicines, it is essential to examine how different countries have implemented them, particularly the mechanism of compulsory licensing. This section focuses on three prominent case studies India, Brazil, and South Africa that have engaged with the TRIPS framework in diverse ways to advance public health objectives.

India: Compulsory Licensing and Generic Production

India has emerged as a global leader in the production of generic medicines, often referred to as "the pharmacy of the developing world." Its domestic patent law, the Patents Act, 1970, initially excluded product patents for pharmaceuticals, allowing Indian manufacturers to produce cheaper generic versions of patented drugs. However, following TRIPS compliance, India amended its patent law in 2005 to include product patents while simultaneously embedding TRIPS flexibilities.

A landmark moment came in 2012, when India's Patent Controller issued the country's first compulsory license to Natco Pharma for the cancer drug sorafenib tosylate (Nexavar), patented by Bayer. The grounds were that Bayer's drug was:

- Not available at an affordable price,
- Not sufficiently available to the public, and
- Not manufactured in India.

The license allowed Natco to sell the drug at □8,800 per month, compared to Bayer's price of □280,000 a 97% price reduction. The decision was upheld by the Intellectual Property Appellate Board (IPAB) and later affirmed by the Supreme Court of India.

India's approach demonstrates the effective use of TRIPS flexibilities to balance patent rights with public health needs. However, subsequent political and economic pressure particularly from the United States and the European Union has led to a more cautious approach toward compulsory licensing.

Brazil: Strategic Use of the Threat of Compulsory Licensing

Brazil adopted a more strategic, negotiation-driven use of TRIPS flexibilities, often using the threat of compulsory licensing as leverage to reduce drug prices. Under Brazil's Industrial Property Law (1996), the government is empowered to issue compulsory licenses in cases of national emergency or public interest.

One of the most cited examples occurred in 2007, when Brazil issued a compulsory license for efavirenz, a first-line HIV/AIDS drug patented by Merck. Prior to this, Brazil engaged in several rounds of price negotiations with multinational

pharmaceutical companies, effectively using the mere threat of compulsory licensing to obtain significant discounts.

Brazil's action was legally justified under Article 31 of TRIPS and aligned with the Doha Declaration. The government cited public interest and the need to ensure sustainability of its free national HIV treatment program.

Brazil's approach reflects a hybrid model—leveraging TRIPS flexibilities as a negotiation tool while maintaining compliance with international obligations. However, as with India, the country has faced diplomatic pressure, especially during bilateral trade negotiations, to limit such practices.

South Africa: Litigation, Activism, and Policy Reform

South Africa's experience highlights the intersection of legal reform, grassroots activism, and international pressure in asserting TRIPS flexibilities. During the late 1990s and early 2000s, the country faced a severe HIV/AIDS epidemic, with limited access to antiretroviral drugs (ARVs) due to prohibitively high prices and patent restrictions.

In response, the South African government passed the Medicines and Related Substances Control Amendment Act (1997) to facilitate generic competition and parallel importation. This led to a legal challenge by 39 multinational pharmaceutical companies, who argued that the law violated TRIPS.

The case became a global flashpoint, with widespread civil society mobilization led by groups like the Treatment Action Campaign (TAC) and international criticism of the pharmaceutical industry. Under immense public pressure, the companies eventually withdrew the lawsuit in 2001.

Following this, South Africa began reforming its IP and health laws to better accommodate TRIPS flexibilities. However, the country continues to struggle with legal and institutional challenges, such as:
- Weak patent examination processes,
- Limited government capacity to issue compulsory licenses, and
- On-going influence of TRIPS-plus provisions in external trade negotiations.

VII. COMPARATIVE REFLECTIONS

These case studies collectively illustrate the potential of TRIPS flexibilities to improve access to medicines when supported by robust legal frameworks, political will, and civil society engagement.

However, they also reveal common barriers:
- International trade and diplomatic pressure,
- Legal ambiguities and administrative hurdles,
- The chilling effect of TRIPS-plus obligations.

While India and Brazil have used these flexibilities to assert sovereignty over health policy, South Africa's experience underscores the importance of activism and legal reform in resisting external pressure and reorienting national policy toward public health goals.

This incoherence at press and governmental levels is a restriction on the translational legal right into effective public health outcomes and retains the disparities of access to medicines in the world.

Legal and Institutional Constraints

The lack of adequate legal and institutional frameworks within the borders of many countries forms an enigma to counter extremely pressing demands. Most countries have failed to transpose TRIPS flexibilities into their national laws, or have done so in a vague and inconsistent manner; and, for example, though the TRIPS Agreement allows compulsory licensing, national patent laws may lack clear-cut and longstanding procedures regarding:

- When and how licenses can be issued,
- How remuneration should be determined, and
- Whether the process can be fast-tracked during public health emergencies.

Moreover, even in their existence, the developed laws are not operational for the most part due to inefficiencies and unskilled manpower in patent administration. A government may not be aware of what legal tools are available to it or may not have the manpower to negotiate for or issue compulsory licenses swiftly and legally.

It, of course, includes outside difficult pressures experienced through developed countries and close-ended multinational pharmaceutical corporations. When a country is forced to open a compulsory license or challenge patent rights, it eventually results in political retaliation in the form of:

- Trade sanctions or threats of sanctions;
- Downgrading in trade reports (such as the U.S. Special 301 Report);
- Suspension of bilateral aid or preferential trade terms.

As a result, there is what is termed a “chilling effect” where countries are forewarned not to have their fabulous TRIPS. Most especially, countries that should be reliant on foreign investments or foreign aid are thus dissuaded from exercising their TRIPS rights due to fears of diplomatic fallout. Both India and Brazil-their assertive approaches have been fronted by what pressure in the past.

As that, even the international financial institutions might coerce or induce conditions that would favor structural adjustment programs whose benefit would be strong IP enforcement as precondition to obtaining loans or grants that threaten the policy space for public health-friendly IP regimes.

Political and Economic Pressures

External pressure from developed countries and multinational pharmaceutical corporations now constitutes another challenge. Compulsory licensing or challenge of patent rights will usually attract political retaliation in the following forms:

- Trade sanctions or threats of sanctions,
- Downgrading in trade reports (like the U.S. Special 301 Report),
- Suspension of bilateral aid or preferential trade terms.

The creation of the "chilling effect" has basically changed the scenario as many countries, now relying almost entirely on foreign investment or aid, fear exercising their TRIPS rights due to possible consequences on diplomacy. India and Brazil are among the aggressive advocates for compulsory licensing and have, in the past, succumbed to such pressure.

International financial institutions are known to induce or impose structural adjustment programs that condition offers of loans or aid on the enforcement of strong IP, denying space for policy that would favor public health.

Pacts beyond TRIPS and Policy Investigation

Increased TRIPS-plus provisions in free trade agreements (FTAs) and bilateral investment treaties (BITs) are becoming the bane of many. Such agreements are often imposed by tighter IPR obligations than the TRIPS itself, e.g.

- Patents term extension after expiration of 20 years;
- Data exclusivity provisions that prohibit the marketing of identical generics;
- Restrictions on compulsory licensing and parallel importing.

Such provisions would severely restrict countries' attitude towards applying the various flexibilities contained in TRIPS while locking them into stricter regimes of IP practice. For example, many developing countries in Latin America and Asia have signed bilateral trade agreements recently with the United States and the European Union covering such provisions locking further that country's capacity to apply public health measures in the future.

Insufficient Global Support

For instance, WHO and WIPO as well as countries relying on the UNDP receive technical support from the international organization in implementing the TRIPS-flexibility provisions. This support has, however, mostly been patchy and hardly sufficient. Many countries need to develop their institutional and legislative capacity in order to buffer themselves against the peculiarities of international IP law and public health policy.

The state of pharmaceutical innovation, as much as market-driven incentives propel it, is such that diseases associated with the wealthy will always predominate over diseases affecting the poor. Issues such as neglected tropical diseases, plus many other public health concerns, remain inadequately addressed. Without addressing these, one cannot hope that TRIPS flexibilities will be the solution.

Future Trends and Possible Reforms in Global IP and Public Health Law

The evolving relationship between intellectual property (IP) rights and public health continues to generate legal and policy debates, especially in the wake of global health emergencies like the COVID-19 pandemic. As countries grapple with balancing innovation incentives and equitable access to medicines, several future trends and possible reforms are emerging in both national and international contexts. These trends reflect growing recognition that the current IP regime centered on the TRIPS Agreement requires significant adaptation to meet global health challenges more effectively.

Rethinking Unpatented R&D

Among the various critiques of pharmaceutical innovation today is the mounting evidence of overreliance on market-based incentives. The TRIPS framework also generally encourages investment in drugs that showcase high profits-and these 'profitable drugs' are usually associated with non-communicable diseases from developed countries-only to forget those diseases like malaria, tuberculosis and other neglected tropical diseases that afflict people within developing countries.

In order to address this issue, therefore, calls from the policy experts and public health advocates are:

- Delinking R&D costs from drug prices, by using prize funds and public financing models.
- Public-private partnerships (PPPs) for priority health needs.
- An increase of funding for open-source drug discovery platforms that foster collaborative innovation in a patent-free manner.

All approaches converge on creating a need-based rather than commercially driven innovation ecosystem.

Revisiting the TRIPS Agreement and WTO Governance

This has raised calls for discussion on the reform of the TRIPS Agreement itself. Some main proposals were stipulating automatic flexibilities during epidemics without the need for lengthy applications; creating differentiated obligations in a tiered system according to development level; and setting up of an independent review mechanism within WTO to monitor misuse or excessive restrictions under TRIPS-plus provisions.

Further, developing countries have claimed to have a bigger voice and representation in WTO decision-making, especially those issues that touch on people's health.

Regulation of TRIPS-Plus Provisions

Presently, growing advocacy exists to slow the export of TRIPS-plus standards in bilateral and regional trade agreements, with civil society organizations and some states having the following demands:

- Impact assessment must be carried out beforehand for any trade agreement signed.
- Public health clauses that ensure access to medicine must be included.
- UN-guided frameworks for trade negotiations that are “health-sensitive” to ensure FTAs do not interfere with pertinent TRIPs flexibilities.

Some of the new agreements, like the Regional Comprehensive Economic Partnership (RCEP), have had modest success in this regard through provisions for a limited opt-out, or extended implementation period, for less developed countries.

Global Collaboration and the Role of International Organizations

Increasingly, organizations such as the World Health Organization (WHO), UNDP, or Medicines Patent Pool (MPP) are evolving their roles as partners in countries' navigation of IP-and-access challenges. For example:
The MPP offers pathways for voluntary licensing of patents to generic producers.

WHO has proposed a Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property, placing emphasis on access equity and needs-driven research?

These types of initiatives should be seen as evidence of an emerging international consensus on the necessity for collective solutions to global health inequities.

VIII. CONCLUSION

The adoption of the TRIPS Agreement represents one of the most important legal developments in the international regulations of intellectual property, which essentially creates a global minimum patent standard, inclusive of pharmaceuticals. While being envisioned to foster innovation and to ensure homogeneity across various jurisdictions, its effect on access to medicines has often proved far-reaching and even detrimental to developing countries. Patent protections result in exorbitant drug prices, thereby limiting the availability of essential medicines to millions of people and giving rise to very fundamental ethical, legal, and human rights concerns.

In recognition of these difficulties, the WTO members in 2001 endorsed the Doha Declaration on the TRIPS Agreement and Public Health, affirming the right of states to apply TRIPS-related flexibilities towards the promotion of public health. These include mechanisms such as compulsory licensing, parallel importation, and general exceptions to patent rights. Along these lines, however, as the research shows, these flexibilities have not been evenly implemented in practice. Legal uncertainty, lack of administrative capacity, political pressure from developed countries, and restrictive TRIPS-plus agreements have severely inhibited their effective utilization.

Case studies from India, Brazil, and South Africa demonstrate the possibilities and limitations of these instruments. While these countries have made important strides to further access to medicines, their stories also show how the global IP system may burden national health policy when states face external economic or diplomatic pressure. The COVID-19 pandemic further illuminated the urgent need for reforming the IP regime to allow speedy and equitable access to life-saving technologies.

In this regard, new measures should meet global considerations of equity in health. Parameters could strengthen the utilization of TRIPS flexibilities, while at the same time, the pharmaceutical innovation model must be reconfigured to shift towards delinked incentives with international collaboration. The future of global health equity rests on creating an IP system that promotes both innovation and access-a system that views medicines not merely as commodities but as public goods vital for the realization of the right to health.

In conclusion, notwithstanding the TRIPS Agreement given some challenges to access to medicines, it offers a legal and policy tool that can become an instrument for promoting global public health, if sustained political will, legal reform, and international solidarity are behind it.

IX. REFERENCES

Bayer Corp. v. Union of India, (2014) 6 Supreme Court Cases 423 (India).

Brazil. (1996). *Lei No. 9.279, de 14 de maio de 1996*.

Correa, C. M. (2007). *Trade-Related Aspects of Intellectual Property Rights*. Oxford University Press.

India. (1970). *The Patents Act, 1970* (Act No. 39 of 1970).

India. (2005). *The Patents (Amendment) Act, 2005* (Act No. 15 of 2005).

Natco Pharma Ltd. v. Bayer Corp., Compulsory License No. 1 of 2011 (Controller of Patents, India).

Office of the United States Trade Representative. (n.d.). Special 301 Report (relevant years).

Pharmaceutical Manufacturers' Association of South Africa v. President of the Republic of South Africa (2001).

South Africa. (1997). *Medicines and Related Substances Control Amendment Act 90 of 1997*.

Treatment Action Campaign vs. Minister of Health, 2002 (5) SA 721 (Constitutional Court).

United Nations Development Programme. (2015). *Intellectual Property Rights and Access to Medicines*. UNDP.

World Health Organization. (2008). *Global Strategy and Plan of Action on Public Health, innovation and intellectual property*. WHO.

World Trade Organization. (1994). *Agreement on Trade-Related Aspects of Intellectual Property Rights*. 1869 U.N.T.S. 299.

World Trade Organization. (2001, November 14). *Declaration on the TRIPS Agreement and public health* (WT/MIN(01)/DEC/2).

World Trade Organization. (2005, December 8). *Amendment of the TRIPS Agreement* (WT/L/641).