The Role of TRIPS Flexibilities in Access to Medicines: A Comparative Analysis of Developing Countries' Implementation Strategies

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Abstract

The growing costs of drugs and the increasing availability of patents due to international trade agreements are making access to affordable medicines a major health problem globally. Particularly, in most developing countries it has become nearly impossible to access affordable medicines without incurring huge pharmacy charges. Even though the WTO's TRIPS agreement sets a baseline limit for intellectual property rights (IPR) protection, it allows certain public health priorities for member states through some freedoms which are intended to promote public health and pharmaceutical essential medicine access: compulsory licensing, parallel importation, the Bolar exemption, and grace periods for least developed countries among others. If these freedoms are executed properly, governments paying lip service to patent legislation while upholding obligations under international legal frameworks could achieve a level of equilibrium between intellectual property laws enforcement and accessible healthcare. Still, developing nations' execution of these policies is strikingly diverse.

This article analyzes how four developing countries—India, Brazil, South Africa, and Thailand—implemented flexibilities of TRIPS and why they are important in international health relations. This study looks at the legal policy frameworks of these governments to understand how they have used many TRIPS flexibilities to balance public health demands and international trade obligations.

By taking advantage of TRIPS flexibilities, India is now a dominant player in the worldwide market for generic medicines due to its robust patent laws featuring stringent compulsory licensing provisions. Brazil has effectively used the threat of compulsory licensing to lower prices for antiretroviral drugs due to its strong legal and political framework. The implementation was much more contentious in South Africa, especially with regards to HIV/AIDS, but access initiatives have advanced through legal reform and civil activism.

Thailand strongly issued compulsory licenses for antiretroviral drugs and other unrelated HIV medicines, which created international controversy on whether such action should be permitted under TRIPS.
The comparative analysis summarizes some key findings. First, the effective use of TRIPS flexibilities is influenced by domestic legal capacity, political will, and institution's strength. Second, those countries that included TRIPS flexibilities in their legislative frameworks and created mechanisms for their application have done better to use them for access enhancement. Third, strong advocacy from civil society and public health has often been central in compelling governments to take action in the interest of citizens. That said international political economy including pharmaceutical companies and developed countries heavily constrain the full exercise of TRIPS flexibilities.
In conclusion despite offering important tools for increasing access to medicines, the impact of TRIPS flexibilities are constrained by a web of domestic and global factors. Countries at developing stage must do more than put in place appropriate laws; they need also establish functioning institutional systems together with technical resources to implement these policies effectively streamlined processes. More effective use of TRIPS flexibilities can therefore be achieved through stronger South-South cooperation combined with international support structures towards achieving health equity as well as universal access to medicines.

KEYWORDS: Accessibility, Doha, Patent, Public Health, TRIPS.

1: Introduction

1.1 Background and Rationale

Getting affordable, lifesaving medicines into the hands of people who need them is still one of the biggest hurdles in global public health, especially in lower-and middle-income countries.[1] Outbreaks of HIV/AIDS, tuberculosis, hepatitis C and, most recently, COVID-19 have laid bare the shocking gaps in drug access between wealthy countries in the North and struggling nations in the South.[2] Although scientific research has delivered effective treatments, strong intellectual property (IP) rules let drug manufacturing firms keep exclusive control, blocking many governments from making or importing cheaper versions.[3]

Patents and other intellectual property rights give inventors monopoly power for about twenty years under most international treaties, letting them stop anyone else from manufacturing, using or selling the invention without permission. That lock-out lets brand-name drug companies set prices many times higher than the cost of making a pill, meaning hospitals and patients on tight budgets simply cannot pay. The clash between rewarding creative work and ensuring basic health care remains a hot topic in global law and policy circles.

In 1995 the World Trade Organisations Trade-Related Aspects of Intellectual Property Rights (TRIPS) set a single global floor for copyright, patent, and trademark rules across its member countries. Although the deal raised shared standards, many developing governments and public-health groups worried it could push the cost of lifesaving drugs beyond the reach of ordinary people.[4] To ease that fear, negotiators built in flexibilities-legal tools that allow states to sidestep or limit patent rights when health needs arise.[5] Among these workarounds are compulsory licenses that let local firms manufacture a patented drug, rules permitting the parallel import of cheaper versions produced abroad, and narrow exceptions that cut time-consuming patent tests for some medical technologies.[6]

The 2001 Doha Declaration on TRIPS and Public Health reinforced members sovereign right to lean on these options whenever public health is at stake.[7] Even so, turning paper rights into actual policy has varied widely, as national courts, lawmakers, trade ties, and pressure from foreign governments or big pharmaceutical firms all shape the outcome.[8] This article looks at how several developing countries have put those TRIPS flexibilities to work, comparing their strategies and results to see what has helped or hindered access to affordable medicine in practice.

The research looks at the legal rules and policy plans that a small number of countries have put in place, then checks whether those moves have actually led to better health for people on the ground. It also digs into the inside and outside hurdles-mostly money, politics, and weak infrastructure-that stop these countries from using the room the rules already give them on a wider and more powerful scale.

Research Questions

To guide the work, four central questions frame the inquiry:

- What TRIPS flexibilities are really on the table for WTO members, and how has international law chosen to read them?
- How have a handful of developing countries turned those flexibilities into law and policy at home?
- What helps or hinders them when the time comes to put those plans into everyday practice?
- What lessons can be pulled from their experience to steer future global and national efforts toward fairer medicine access?

Research Objectives

The study aims to achieve four practical goals:

- To critically assess the legal and policy dimensions of TRIPS flexibilities within the context of access to medicines.
- To compare and contrast the implementation strategies of selected developing countries.
- To identify common challenges and best practices in the use of these flexibilities.
- To propose policy recommendations that strengthen the capacity of developing countries to utilize TRIPS flexibilities effectively.

Research Methodology

This study takes a doctrinal and comparative legal approach to see how a handful of developing countries have put TRIPS flexibilities to use. It zeroes in on five practical tools-compulsory licensing (Art. 31), parallel imports (Art. 6), transition periods for LDCs (Arts. 65-66), Bolar exceptions (Art. 30), and sharp patent-tests meant to block evergreening. Primary materials are the 1994 TRIPS text, the 2001 Doha Declaration, and national legislation such as Indias Patents Act and Brazils IP Law, together with key court rulings like Natco v. Bayer and Novartis v. Union of India, plus executive moves such as Brazils Efavirenz licence and Thailands public-health grant. These domestic pieces are set alongside international frameworks like the International Covenant on Economic, Social and Cultural Rights and relevant WTO case law. A case-study lens then shows how India, Brazil, South Africa, and Thailand have translated the rules into practice, spotlighting reforms, actual licences, gains in medicine access, and stubborn roadblocks such as foreign lobbying, weak expertise, and underfunded institutions. Secondary sources include scholarly works by Ellen ‘t Hoen, Carlos Correa, and UNDP and WHO reports, which provide critical insight into both legal interpretation and public health impact.

Literature Review

Sisule F. Musungu (2008) - "The Use of Flexibilities in TRIPs by Developing Countries: Can They Promote Access to Medicines?"

- Offers one of the first accounts of how TRIPS flexibilities can be utilized by developing countries to achieve public health objectives.
- Maintains developing countries have not only the right but the duty to utilize these flexibilities in access to essential medicines.
- Emphasises the advantages that compulsory licensing, parallel importation, and other flexibilities have in reconciling IP rights and public health.

Dianne Nicol & Olasupo Owoeye (2013) - "Using TRIPS Flexibilities to Facilitate Access to Medicines"

- Emphasises the importance of international instruments such as the Doha Declaration on TRIPS and Public Health in reinforcing the right of countries to utilise TRIPS flexibilities.
- Points out that many developing countries have not adopted or implemented the required legislation, even though such mechanisms (compulsory licensing, parallel importation) are available.
- Points to legal, administrative, and political obstacles as the reason for the ineffective use of TRIPS flexibilities.

Pablo Zapatero Miguel (2014) - "Access to Medicines v. IP Rights: World Regulatory Experiences"

- Looks at the increasing encroachments of IP protection under TRIPS and "TRIPS-plus" regimes.
- Poses how this “ratcheting up” of IP protection detracts from affordable access to medicines for poorer nations.
- Advocates the assertion that while TRIPS flexibilities were designed to lessen these impacts on access to medicines, the design and the manner of implementation limit their usefulness.

Abbas & Riaz (2013) – “Flexibilities under TRIPS: Implementation Gaps between Theory and Practice”

- Examines the gap between the theoretical availability of TRIPS flexibilities and their lack of practical use within developing countries.
- Identifies the procedural obstacles, the absence of local manufacturing capacity, the lack of political will, and trade pressures from powerful nations cause it.
- States that the lack of local capacity, trade pressures, and the absence of political will ensure that TRIPS flexibilities will be of little practical use.

“Medicine Procurement and the Use of Flexibilities in the TRIPS Agreement, 2001–2016” (2018)

- Conducts a large development and analysis of 176 documented cases of the use of TRIPS flexibilities across 89 developing countries covering developing countries.
- Finds that over half (56.8%) of these cases concerned compulsory licensing or public/non-commercial use, while 22.7% involved measures to help LDCs transition.
- Highlights that the TRIPS flexibilities have been extensively used on the treatment of HIV/AIDS, less so on other illnesses.

The Role of Intellectual Property Rights on Access to Medicines in the WHO African Region: 25 Years after the TRIPS Agreement (2021)

- Describes the evaluation process in the implementation of TRIPS flexibilities by African countries over the years.

- Notes that 39 of the 47 countries has used at least one flexibility. 27 countries have used the LDC transition provisions, 16 used compulsory licensing, and only one used parallel importation.
- Points out imbalance in the enactment of legislation which noted there are only 3 countries that specifically prohibit patent "evergreening."
- Describes challenges that have remained such as limited manufacturing and complex licensing arrangements.

Tolulope A. Adekola - "Leveraging TRIPS Flexibilities for Pharmaceutical Access" (Book Chapter)

- Describes the implementation of TRIPS in the East African Community (EAC) of five countries: Kenya, Uganda, Tanzania, Rwanda, and Burundi.
- Describes the challenges that remain to the legal provisions which are entrenched poorly in domestic IP laws as lack of clear or workable provisions (e.g. streamlined compulsory licensing)
- Describes limited institutional capacity and incoherence in policy as the reason in weak utilization.

Between Regional Recommendations and National Implementation: An Analysis of the East African Community Partner States' Legislative Responses to TRIPS Obligations (2023)

- Looks into the individual and comparative legislative responses of the EAC countries on the regional IP policy recommendations.
- Identifies differences in the timing, scope, and enforcement of the various provisions of TRIPS.
- Points out that regional coordination can better vertical consistency and joint pharmaceutical objectives.

"Patent Challenges in the Procurement and Supply of Generic New Essential Medicines: Lessons from HIV in the SADC Region" (2018)

- Studies the joint procurement and the use of TRIPS flexibilities for essential medicines in the Southern African Development Community (SADC).
- States that while regional coordination improves access, it is important that national codification and institutional capacity are in place.
- Shows the capacity of regional collaboration to transcend the limitations of individual states in exercising TRIPS flexibilities.

Using TRIPS flexibilities to facilitate access to medicines (2013)

- Explores whether and how countries have adopted legislation to use TRIPS flexibilities; finds many haven't or haven't used them.
- Good source for showing legislative adoption vs. use.

Balancing intellectual monopoly privileges and the need for essential medicines (Globalization & Health, 2007)

- Analyses the impact of TRIPS on access, highlighting how structural constraints in developing countries limit the use of flexibilities.
- Useful for barriers/enabling factors.

Abbas (2017)-Compulsory licensing and access to medicines: TRIPS amendment allows export to least-developed countries

- Focuses on the amendment to TRIPS (Article 31bis) that allows export under compulsory license to countries lacking manufacturing capacity.
- Important for discussing export/import mechanisms and the limitations for LDCs.

Trade-Related Aspects of Intellectual Property Rights Flexibilities and Public Health: Implementation of Compulsory Licensing Provisions into National Patent Legislation (2023)

- Most recent empirical work showing how much of developing countries national patent legislation remains incomplete in incorporating CL (compulsory licensing) provisions.
- Helpful in portraying contemporary status and legal reform work.

Evaluating the Usefulness of Compulsory Licensing in Developing Countries: A Comparative Study of Thai and Brazilian Experiences Regarding Access to AIDS Treatments (2016)

- A comparative country study (Thailand & Brazil) on the health and industrial benefits of CL in those contexts.
- Useful for the comparative implementation strategies section of your review.

Joshi (2012)-A Point of View on Parallel Imports (Joshi, 2012)

- Focuses on another TRIPS flexibility—parallel importation—and how different exhaustion regimes affect access to medicines in developing economies.
- Useful to broaden the research focus beyond just CL to other flexibilities.

Results and Discussion

2. The TRIPS Agreement and Flexibilities - Legal Framework

2.1 Historical Background and Objectives of TRIPS

The TRIPS Agreement was born during the long Uruguay Round of GATT talks (1986-1994) and rode that momentum into the WTOs 1995 launch. As a result, the treaty became the first worldwide set of rules governing not just customs and tariffs, but also patents, trademarks, copyrights, and trade secrets.[9]

Before TRIPS, many developing nations shielded health-care budgets by limiting or even excluding drug patents.[10] Those choices reflected plans to keep medicine affordable and let local firms produce generics. Yet lobbying from powerful drug companies and persistent demands from the United States, the European Union, and others produced a deal that locked in a minimum twenty-year patent term and broadened what could be patented.[11]

Supporters claimed TRIPS would spark research, draw foreign investment, and curb fakes. Critics countered that it solidified price-hiking monopolies and placed heavy burdens on nations lacking advanced technology and urgent public-health resources.[12] Though the Global South must still meet TRIPS rules, its health systems often lack the resources needed to enforce such a broad IP framework.

2.2 Key Provisions of TRIPS Relevant to Medicines

Several TRIPS articles shape how medicines are produced and priced. Most important, Article 27 insists that patents cover inventions in every tech field, which, in practice, sweeps in drugs so long as they meet novelty, inventiveness, and usefulness tests.[13]

Article 28 then grants the patent owner near-total control-making, using, importing, and selling the product.[14] Because of this legal monopoly, many essential medicines become too expensive for patients and public programs in low- and middle-income nations.

TRIPS includes built-in flexibilities that let countries tame the reach of patents and safeguard public health:

- Article 31 (Compulsory Licensing): States may grant a license for a patented product or process when necessary, as long as rules and compensation are followed.[15]
- Article 6 (Exhaustion and Parallel Importation): Governments decide when patent rights are exhausted, helping them import lower-cost goods from other markets.[16]
- Article 30 (Exceptions to Exclusive Rights): Limited, time-bound exceptions may be made when they do not undermine the patents core value.[17]
- Article 39 (Undisclosed Information): This protects test data so regulators can approve generics quickly without replicating costly trials.[18]

Yet the treaties wording leans toward patent holders, and uncertainty often stops states from boldly using these health-first tools.

2.3 The Doha Declaration and Its Legal Significance

Growing concern about the TRIPS regimes toll on public health, most glaring during the HIV/AIDS emergency, pushed World Trade Organization (WTO) members to adopt the Doha Declaration on the TRIPS Agreement and Public Health in 2001. The plain wording of the document reiterates that countries are free to read and enforce TRIPS in ways that uplift public health and widen access to affordable medicines.[19]

In the paragraph 4, the text speaks directly to the deep public health crises many low-income nations face, naming HIV/AIDS, tuberculosis, malaria, and other epidemics. It then states clearly that the TRIPS rules-neither now nor in the future-must block members who choose to implement health-protective policies.

Paragraph 5(b) goes further, affirming each government has the power to issue compulsory licenses and, crucially, to set its own criteria for doing so. Paragraph 6 addresses the plight of nations that do not make drugs at home, setting up what is now called the Paragraph 6 system so they can legally import medicines produced under such licenses abroad.

Though it is not legally binding, the Doha Declaration is widely viewed as a trusted guide for WTO members and has steered conversations about balancing intellectual property with public health needs.

2.4 TRIPS-Plus Obligations and Their Impact

Although TRIPS sets a basic floor for IP protection, many wealthy countries now press for TRIPS-plus rules in bilateral and regional deals. Because these rules go further than TRIPS, they can narrow the space governments thought they had to protect public health.

Illustrative TRIPS-plus measures include:

- Data exclusivity: forbidding health agencies from using original trial results when clearing generics for a set number of years.
- Patent term extensions: adding years to patent life as compensation for the time drugs spend in safety or marketing review.
- Patent linkage: forcing drug regulators to stall generic approval whenever a related patent remains valid, even if the product meets all other rules.

Trade deals such as the 2001 U.S.-Jordan Free Trade Agreement, which locked in five years of data protection, or the U.S.-Colombia FTA, that layered on both data exclusivity and patent-linkage rules, illustrate this pattern.[20] Because of these terms, generics enter later than they should, and countries find it harder to tap the flexibilities TRIPS itself allows.[21]

Investment chapters in the same, or similar, agreements frequently carry Investor-State Dispute Settlement (ISDS) clauses that empower drug firms to sue governments whenever a new rule chips away at expected profits. As a result, officials become cautious about issuing compulsory licenses or adjusting patent law, for fear of costly and public legal battles.[22]

The TRIPS Agreement sits at a key crossroads in the global spread of IP rules and has reshaped how countries run their drug policies. Although the text contains some built-in flexibilities meant to safeguard health, legal uncertainty, heavy-handed diplomacy, and extra-stringent TRIPS-plus terms still block their use. The Doha Declaration helped put health back on top, yet actually putting its words into practice is anything but easy. To truly grasp how states defend the right to health, we must study TRIPS, track how courts and negotiators have interpreted it, and ask whether nations are willing-and able-to wield the tools it offers.

3: Access to Medicines and the Global Public Health Context

3.1 Defining Access to Medicines in a Human Rights Framework

Access to lifesaving drugs sits at the heart of the right to health according to international human-rights law. Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) requires governments to take action for the prevention, treatment and control of epidemics, endemics, and other diseases.[23] In General Comment No. 14, the Committee on Economic, Social and Cultural Rights adds that this duty includes making sure essential medicines are available and affordable, using the World Health Organizations own list as the guide.[24]

Essential medicines are those chosen to meet the most urgent health needs of a community, based on how common a disease is, how well a drug works, its safety, and its price.[25] Yet people in many low- and middle-income countries still find these medicines out of reach when patents push prices higher than they can afford. The global intellectual-property system, and the TRIPS Agreement in particular, therefore largely decides who can obtain these crucial products and how much they must pay.

3.2 The Patent System and Its Impact on Drug Pricing

When a drug company secures a patent, it locks in exclusive rights to make, use, and sell that medicine for twenty years, counting from the filing date. [26]Although this shield was designed

to help firms recoup research costs and fund fresh ideas, it also lets them raise prices to levels that most patients and governments cannot meet, especially when no competing treatment is on the pharmacy shelf.[27]

Real-world studies show that patented medicines can cost two to ten times more than the copies made once the patent expires. Take the history of antiretroviral drugs for HIV: in the mid-1990s, a yearly regimen ran over 10,000 per patient, but by 2010 the bill had plunged to below 10,000 per patient ,but by 2010 the bill had plunged to below 100 after affordable generics poured into the market.[28] That turnaround stemmed from India-and other nations-not honoring the patents, allowing local companies to manufacture and ship low-cost versions worldwide.
Yet today many clinics in Africa, Asia, and Latin America still cannot stock newer cures for hepatitis C, some cancers, or multi-drug-resistant tuberculosis because the branded treatments can exceed $80,000 for a full course.[29] With prices this steep and no generics allowed, national health budgets face collapse and millions of patients are left waiting for therapies they desperately need.

3.3 Generic Medicines and the Role of India as a Global Supplier

Generic medicines are copies of brand drugs that work the same way but cost much less because the original patent window has closed or because a government invokes compulsory licensing or allows certain exceptions. India has become the linchpin of this market, earning the nickname pharmacy of the developing world. [30]

The 1970 Patent Act did not cover drug products, letting Indian firms reverse-engineer compounds, manufacture generics, and sell them broadly.[31] That freedom ended in 2005, when India revised the law to meet WTO-TRIPS obligations, yet it added public-health clauses like Section 3(d), which blocks patents on minor tweaks that offer no extra benefit.[32]

Companies such as Cipla and Natco have used that space to slashing prices on AIDS cocktails and crucial cancer therapies.[33] After India issued its landmark compulsory license to Natco in 2012 for Bayer's Nexavar, the tablets cost 97 percent less almost overnight. [34]Such victories show that the right mix of law and industry can transform access to lifesaving medicine almost as quickly.

3.4 Global Disease Burden and Access Challenges

Low- and middle-income countries shoulder giant shares of the worlds sickness, yet their economic power is thin and their health systems fragile. The World Health Organization reports that more than 2 billion people still cannot find basic medicines, and the shortfall hits hardest in public clinics.[35]

Infections such as HIV/AIDS, tuberculosis, and malaria stay stubbornly widespread across the Global South, and those communities need steady drug supplies to fight them. Still, the bulk of new medicines launched in the past twenty years aim at illnesses of wealthy markets, illustrating the so-called 10/90 gap: only 10 percent of research money targets the 90 percent of disease burden.[36]

At the same time, modern threats like diabetes, high blood pressure, and other non-communicable disorders are rising fast in poor and middle-income nations. Insulin pens, statins, and other branded treatments often cost more than monthly wages.[37] Access barriers

therefore reach far beyond infectious outbreaks and weaken an entire system that should care for both acute and chronic patients.

3.5 COVAX, Vaccine Access, and IP Barriers During COVID-19

COVID-19 laid bare deep divides in how nations can obtain medicines, with vaccines at the center of the struggle. By mid-2021, well-off countries-home to only 16 percent of humanity-had locked in more than 60 percent of all doses. In contrast, low-income nations were left waiting for donated shots, many arriving short-dated and far from enough.

The World Health Organization-backed COVAX program aimed to get COVID-19 shots to every country fairly, yet supply delays, vaccine stockpiling by richer states, and opaque purchasing deals left it well below goal.[38]

A key obstacle to ramping production worldwide was patent owners refusal to part with manufacturing know-how, blueprints, or intellectual property. Moderna, Pfizer-BioNTech, and several other firms also opted out of the mRNA tech-sharing hub the WHO set up in South Africa.

In late 2020 India and South Africa tabled a waiver at the WTO that would suspend some TRIPS rules for the duration of the pandemic. Although more than 100 nations backed the idea, progress stalled because a small group of wealthy countries opposed it.[39] At the twelfth WTO Ministerial Conference in June 2022 a narrow deal was finally struck, yet it covered only vaccines and not treatments or tests.[40]

The episode spotlighted both political reluctance to loosen IP rules and the shortcomings of goodwill schemes such as COVAX when faced with proprietary laws.[41] It showed that during a global health crisis, IP can often slow, rather than speed, a fair and swift emergency response.

3.6 Structural Inequities in Access: Beyond TRIPS

While TRIPS loopholes give governments some room to boost access, deeper structural barriers still shape who can afford medicines. These barriers include:

a. Trade and Investment Agreements

Numerous low- and middle-income states now belong to trade pacts that bake in TRIPS-plus rules, such as long data exclusivity or patent linkage. Such clauses narrow the space TRIPS would otherwise leave for domestic policy and push lawmakers toward costly pharmaceutical rules.[42] Take the U.S.-Peru Free Trade Agreement, where Peru had to impose five years of data exclusivity for every new chemical compound, blocking generics even when the patent had expired.[43]

b. Regulatory and Manufacturing Capacity

Even when countries can legally issue a compulsory licence, many still lack the know-how, factories, or supply chains to make or bring in the promised generic drugs. That gap inspired the Doha Paragraph 6 system, yet it has been called into action only once-in 2007, when Canada shipped HIV treatment to Rwanda.[44] The episode shows that good laws need factories, regional teamwork, and political courage if they are to deliver real results.

c. Pricing Transparency and Procurement Systems

A top barrier to wide medicine access is opaque pricing. Drug companies routinely strike secret discount deals with one government, leaving neighbours unable to match the price or secure the same low cost. Robust procurement agencies and regional bargaining-successfully tested through the Pan American Health Organizations Revolving Fund-are vital to leveling the field.[45]

D. Human Rights, Public Health, and Legal Reform

The global health debate is now framed by human rights language. Under the right to health, states are duty-bound to secure medicines that people can afford.[46] This obligation is spelled out in many international treaties, echoed in regional charters, and enforced by landmark rulings from constitutional courts that use strategic lawsuits to push governments to act.

South Africa's Treatment Action Campaign lawsuit forced officials to roll out antiretroviral drugs that stop HIV passing from mothers to babies.[47] Similar court orders in Colombia and India now push states to buy lifesaving medicines, grounding the rulings in constitutional rights to health and life. [48]These legal moves work side by side with TRIPS loopholes and pressure governments to mold patent rules around public health duties.

Still, any reform must weigh the states agencies ability to carry it out and the money it will cost. Using TRIPS room wisely needs skilled patent examiners, clear procedures, and watchdog groups that speak up when licences are stalled. Law is only one cog in the bigger machine of governance.

Getting medicines into peoples hands is a challenge woven into legal, economic, and political threads. Although TRIPS sets a basic global IP standard, real access hinges on how each country reads, applies, and at times pushes back against those rules. COVID-19 showed that clear laws, friendly regional ties, and homegrown tech are vital to breaking health barriers.

TRIPS options are key, yet they need backing from domestic policy, international support, and accountability systems grounded in the right to health. Only with all these tools working together can affordable, universal access to lifesaving drugs move from promise to reality.

4: Implementation of TRIPS Flexibilities - Comparative Country Case Studies

Developing countries put TRIPS flexibilities to work in very different ways, and how well they do so depends on the laws they already have, the strength of political support, available institutions, and pressing public-health priorities. This chapter looks closely at four nations-India, Brazil, South Africa, and Thailand-that have pushed these flexibilities forward, especially compulsory licensing and patent exclusions, to serve public health interests.

4.1 India

Patent Act Amendments (2005)

For decades the 1970 Patent Act let Indian companies make and sell generic medicines because it barred product patents in pharmaceuticals.[49] When India joined the WTO, however, it promised to write new patent rules by 1 January 2005. The government therefore added new wording to the Act that allowed product patents on drugs. More importantly, lawmakers inserted Section 3(d), saying new forms of known compounds only get patents if they show a clear gain in effectiveness.[50] By blocking attempts to extend patents with minor tweaks, this rule became an essential shield for affordable medicines.

Notable Compulsory Licensing Cases

A key illustration of how India taps TRIPS flexibilities appeared in the 2012 Natco v. Bayer dispute. Bayer priced its cancer pill Sorafenib tosylate, sold as Nexavar, at over INR 280,000 each month. The Indian Patent Office therefore issued a compulsory licence to Natco under Section 84, ruling that Bayer had not made the drug affordable or widely available.[51] Natco could then supply the medicine for INR 8,800 a month, cutting the cost by 97.[52]

In a separate landmark matter, the Supreme Court affirmed the patent office's refusal to grant a patent for Glivec in Novartis AG v. Union of India, citing Section 3(d). The judges agreed the new version did not demonstrate greater therapeutic effect than the earlier molecule.[53] The ruling thus set a global benchmark supporting public-health-friendly patent standards that remain in line with TRIPS.

4.2 Brazil

Use of Compulsory Licensing for HIV/AIDS Drugs

Brazil has long led the way in tapping TRIPS escape clauses to secure low-cost medicines. After passing the Industrial Property Law (Law No. 9.279/96), the country earmarked compulsory licenses for national emergencies, public interest, or market abuse. In 2007 Brazil issued its first license for Efavirenz, a Merck antiretroviral.[54] The Health Ministry first bargained with Merck for a price cut, yet, when talks stalled, it licensed generics and sourced them from India.[55]

The move slashed costs by 72% and let the ministry broaden treatment to many more patients.[56] Brazils program thus illustrates how intellectual property duties can coexist with urgent health priorities.

Negotiations with Pharmaceutical Firms

Often, the very possibility of a compulsory license gave Brazil leverage at the bargaining table. In the early 2000s the Health Ministry cited that power to secure lower rates for Nelfinavir and Lopinavir/Ritonavir.[57] Thanks to that threat, steep savings were achieved even though formal licenses were never issued, proving that TRIPS flexibilities written into law can strengthen a nations negotiating hand.

4.3 South Africa

Legal Reforms Post-Doha Declaration

In the late 1990s and early 2000s, South Africa struggled with a brutal HIV/AIDS crisis while sky-high drug costs kept lifesaving antiretrovirals out of reach for most patients. The Medicines and Related Substances Control Amendment Act of 1997 permitted parallel imports and compulsory licences, triggering a fierce court clash with more than forty global drug firms.[58] Facing mounting global outrage and pressure from local health groups, the companies dropped their suit in 2001.[59]

After the Doha Declaration, South Africa reworked parts of its intellectual property code to put public health front and centre. Yet slow-moving bureaucracies, stretched agencies and overlapping politics have left many reforms uneven on the ground.

Civil Society Litigation and Activism

A turning point emerged when the Treatment Action Campaign (TAC) lever-aged public-interest lawsuits to pressure South Africas leaders into broadening access to lifesaving antiretroviral pills. In the case Minister of Health v. Treatment Action Campaign, the Constitutional Court ruled that withholding nevirapine to stop HIV passing from mothers to babies breached the countrys constitutional right to health.[60] Widespread applause followed, marking the ruling as a landmark victory for legal activism and clearing the path for a nationwide HIV/AIDS treatment program.

4.4 Thailand

Aggressive Use of Compulsory Licensing for Non-HIV Drugs

Among middle-income nations, Thailand has pushed TRIPS flexibilities harder than anyone else. In 2006 and 2007 officials stamped compulsory licenses not only on HIV drugs such as efavirenz and lopinavir/ritonavir, but also on clopidogrel for heart patients and letrozole for women with breast cancer.[61] They cited national-ex-ergency and public-interest grounds, then either imported affordable generics or set local factories to work.

The moves sparked diplomatic friction with the United States and drug firms, and Thailand soon found itself on the USTRs Special 301 Watch List.[62] Still, Thailand insisted that every step it took obeyed WTO rules and aimed squarely at protecting public health. That position won backing from local NGOs, patient groups, and even the World Health Organization.

The Government Pharmaceutical Organization (GPO) acted as the countrys main maker of generic drugs, providing a steady supply when branded products ran short. That institutional muscle gave Thailand greater freedom to manage its own medicine stock without relying too heavily on imports.

Comparative Analysis

Key Differences in Legal Frameworks

India, Brazil, South Africa, and Thailand all leaned on TRIPS flexibilities, yet the details of their approaches differ:

- India plugged Section 3(d) into its patent code to block evergreeding and raise the bar for new patents on drugs.
- Brazil wrote Article 71 straight into its IP law, putting the publics health front and center whenever patents are applied.
- South Africa adjusted its rules to allow compulsory licenses and parallel imports, but the agencies have not yet put that power into full gear.
- Thailand, for its part, stretched its own patent law and leaned on executive orders to issue licenses aimed at public needs.

Political Will and Institutional Capacity

Rules only matter if the government is willing to use them and has the staff to make it work:

- Both India and Brazil, backed by energetic generics sectors, maintain bureaucracies that can quickly churn out low-cost alternatives when prices rise.

- South Africas path forward leaned on bold court rulings and outside diplomatic nudges, because its own health agencies were still weak.
- In contrast, Thailands decisive Cabinet and well-organized Government Pharmaceutical Organization acted quickly, shrugging off much of the same foreign criticism.

Impact on Drug Access and Public Health Outcomes

- In India, the use of compulsory licenses sliced prices and put vital cancer medications within reach for many families.
- Brazil used similar levers to widen HIV/AIDS treatment and, in turn, boosted average life spans for thousands.
- South Africa also benefited; a court-mandated treatment rollout sharply cut HIV transmission from mothers to babies.
- Thailands licenses on non-HIV medicines opened the door to more affordable drugs for cancer and heart patients.

Taken together, these cases show that TRIPS flexibilities can be versatile tools, but they yield real gains only when paired with a clear industrial plan and coherent health policy.

The comparison makes it clear that copyright leeway becomes a force for public health when a supportive legal context and engaged politics surround it. Nations that built sturdy legal guardrails, nourished local generic firms, and mobilized active civic groups slashed prices and improved access most visibly. Still, outside pressures, capacity gaps, and the threat of trade reprisals continue to hold back these gains.

These examples show that putting TRIPS flexibilities into action goes beyond writing legal text; it requires political will, grassroots support, and strong public institutions.

5: Challenges in Using TRIPS Flexibilities

Even though the Doha Declaration confirms that TRIPS flexibilities are lawful, developing nations still grapple with hurdles when trying to use them to widen access to medicines. Such barriers run far deeper than the law; they are woven into the wider political, economic, and institutional fabric of each country. This chapter pinpoints and examines the main obstacles to full delivery of TRIPS flexibilities across five closely linked areas.

5.1 Political and Economic Pressures from Developed Countries

Among these obstacles, intense political and economic pressure from many advanced states, especially the United States and the European Union, ranks as one of the toughest challenges. Such pressure typically shows up through aggressive diplomatic lobbying, threats of trade action, or even retaliation in other policy arenas.

Since the 1980s, the U.S. government has relied on the Special 301 Report from the Office of the United States Trade Representative (USTR) as its early-warning system for countries it judges to be falling short on intellectual property protection.[63] Nations like India, Brazil, and Thailand routinely land on the reports Priority Watch List because they issue compulsory licenses or set patent rules that Washington views as too restrictive.[64] Being listed tarnishes a countrys image and gives the U.S. a diplomatic lever it can pull without formal sanctions.

After Thailand approved compulsory licenses for some heart and cancer medicines, the U.S. placed the kingdom on the list and also yanked tariff breaks granted under the Generalized System of Preferences. In the early 2000s, Washington issued similar trade threats to Brazil when Brasilia signaled it might follow Thailands lead.[65]

Such tactics raise the political price of using TRIPS flexibilities, so export-reliant or investment-hungry governments shy away from them even when WTO law clearly permits their use.

5.2 Lack of Technical and Legal Capacity

Across much of the developing world, governments simply do not have the technical know-how or administrative muscle needed to steer through the tangled legal steps that let them use TRIPS flexibilities. Writing laws that comply, scrutinising patent requests, or running compulsory licences all call for deep skills in law, medicine, and regulation that many agencies lack.

Take Article 31 on compulsory licences; putting it into practice is a tricky procedure that even seasoned lawyers often get wrong.[66] States are left guessing what counts as a national emergency or how to set fair royalty rates, two tests that TRIPS itself insists they must meet.

On the African continent, only a small number of nations have actually filed opposition cases or issued compulsory licences, even though the law allows it.[67] The main reasons are weak national patent offices, poorly trained examiners and a heavy reliance on regional bodies such as ARIPO and OAPI, which seldom place public health at the top of their agenda.

Capacity-building efforts led by WHO, UNDP, and the South Centre have tackled some gaps in health and tech know-how, yet most remain patchy and poorly funded.[68]

5.3 TRIPS-Plus Obligations in FTAs and Bilateral Investment Treaties

A second obstacle comes from the growing stack of TRIPS-Plus rules that appear in bilateral and regional trade deals. Because these clauses stretch the TRIPS floor, they frequently slash or freeze the policy levers countries could otherwise pull.

Take many U.S. Free Trade Agreements, which attach data-exclusivity terms that bar generic firms from citing clinical evidence filed by brand manufacturers for years, even when no patent stands.[69] The result is a protracted wait for cheaper copies and a quiet undoing of the power granted by compulsory licenses.

The U.S.-Peru Trade Promotion Agreement, for instance, enshrines a five-year exclusivity spell for drugs.[70] Parallel bilateral investment treaties commonly let foreign drug makers invoke investor-state tribunals to claim lost revenue for any move-such as licensing or price controls-that threatens the profits they expected.[71]

Together, these treaties sidestep TRIPS safeguards and lock nations into tougher IP rules, frequently with flimsy guardrails for public health.

5.4 Challenges in Domestic Implementation

Even where national law lets officials lean on TRIPS flexibilities, slow-moving politics, split government departments, and well-funded industry lobbying can still block action. The Health

Ministry might back cheaper drugs, yet Trade or Foreign Affairs officials pull back when foreign ties or trade deals are at stake.

In South Africa, although the statutes permit compulsory licenses and parallel imports, those tools stayed in the drawer until the courts stepped in, exposing both bureaucratic hesitance and missing teamwork between agencies.[72]

India shows a different pattern: the same legal toolkit can be wielded vigorously one year and shelved the next, depending on who runs the government. After the landmark Natco-Bayer ruling, new requests for compulsory licenses were turned down, hinting at a quieter, more patent-friendly mood.[73]

Opaque decision-making and scarce chances for civil groups to weigh in let industry voices dominate the debate over IP and health, leaving ordinary citizens in the dark.

5.5 Pharmaceutical Industry Lobbying and Litigation

The drug sector thus stands out as a seasoned opponent of any broad use of TRIPS leeway. When governments try to issue public-health licenses or lower barriers, companies respond with lawsuits, behind-the-scenes lobbying, and slick media pushes designed to keep patent prices intact.

Back in 1998, thirty-nine global drug firms took the South African government to court after the nation changed its laws to allow parallel imports and to let pharmacies swap brand medicines for generics. [74]Although the lawsuit was later abandoned, the showdown warned many other governments to tread lightly before passing similar reforms.

In India Novartis took Section 3(d) to court, insisting it breached TRIPS and India's own constitutional promise of property rights.[75] Though the Supreme Court ultimately set public health first, the fight dragged on for years and drained legal budgets and advocacy energy.

Beyond courtrooms, drug firms pour money into lobbying capitals and global forums, spinning the tale that tight patents fuel every new medicine. That story often drowns out clear evidence that access barriers-not scarce patents-are what blocks treatment in most poorer nations. [76]

Their sway also seeps into WIPO, WTO and other technical assistance programs, where patent enforcement routinely gets priority over health needs when teams draft national IP law.[77]

The task before developing countries in claiming TRIPS flexibilities is messy and layered. Legal space exists on paper, yet outside political pressure, weak institutions, tough trade deals and corporate muscle combine to keep that space mostly locked. Breaking through these barriers calls for concerted action, including:

- Raising domestic legal and administrative know-how;
- Mandating trade negotiators to put health first;
- Backing judges and civil groups that monitor abuses;
- Building coalitions of like-minded states that resist pressure.

Only in that environment can the built-in flexibilities of TRIPS work as intended and give people everywhere fairer access to medicines.

6: Policy Recommendations and Future Directions

Drawing on earlier discussions, this closing chapter sets out practical steps for making TRIPS flexibilities a stronger tool in developing nations and looks at wider reforms that could place global health equity at the heart of the worlds IP system.

6.1 Strengthening Domestic Legal Frameworks

Countries that want to get the most out of TRIPS room to manoeuvre must start by writing clear public-health safeguards right into their own patent laws. They should include:

- an exacting patentability test, such as the one in India's Section 3(d);
- easy, fast processes for issuing compulsory licences and for allowing parallel imports;
- open rules for opposing and cancelling patents that never should have been granted.

Legislation should automatically launch a compulsory-licence procedure whenever officials declare a public-health crisis, so patients do not lose precious time. Countries must also record WTO rulings and the Doha Declaration in domestic statutes, making sure their own judges and officials follow them.

6.2 Building Technical and Administrative Capacity

Laws alone will not guarantee access; they need skilled people and functioning systems to make them real. This effort should include:

- training patent examiners to factor public health into every decision they make;
- giving judges, regulators, and procurement staff solid briefs on what TRIPS flexibilities allow;
- setting up teamwork forums that bring Health, Commerce, and Justice ministries around the same table.

Nations can also set up Access to Medicines Units in their IP offices to screen drug patents, guide compulsory licensing, and stay in touch with buyers.

Agencies such as WHO, WIPO, UNDP, and the South Centre should therefore offer ongoing coaching rather than short seminars, building long-term partnerships with public offices.

6.3 Rebalancing Trade and Investment Agreements

When they bargain on trade, developing countries must keep room to act for health. Doing so means:

- saying no to TRIPS-plus rules such as longer patent terms or new data exclusivity;
- inserting clear public health exceptions in FTAs and BITs so compulsory licensing stays open;
- making talks transparent enough for parliaments and civil groups to weigh in.

Regional blocs-AU, MERCOSUR, ASEAN-can then speak together, dismiss TRIPS-plus demands, and present a united front at the WTO and WIPO.

Developing nations should push for reform of ISDS systems so that sensible public-health rules cannot be challenged by deep-pocket investors.

6.4 Enhancing Regional and South-South Cooperation

Working together regionally eases the burden on single governments by sharing legal and scientific know-how:

- A regional patent review board, such as a health panel within ARIPO or OAPI;
- Coordinated drug purchases that raise bargaining power and cut prices;
- Regional factories backed by technology transfer.

Countries like India, Brazil, and South Africa can lead South-South ties by offering practical guides, model contracts, and expert advice to lower-income partners.

6.5 Reforming the Global IP and Innovation Ecosystem

In the end, real equity requires a rethink of how medicine is paid for and how ideas are rewarded. Options include:

- Backing delinked systems that keep research costs separate from final prices;
- Strengthening global funds such as the Medicines Patent Pool and Unitaid for neglected diseases and pandemic readiness;
- Promoting open science, patent sharing, and public-private work built on fairness and affordability.

The COVID-19 crisis laid bare the weaknesses of the IP-first model that dominates drug research and distribution. The World Trade Organizations slow and half-hearted response to a waiver for vaccines showed that goodwill alone fails when lives are at stake.

Real change requires rewriting the rules-whether by amending TRIPS or creating a fresh treaty-so that innovation dollars flow toward public health, not only toward private balance sheets.

Conclusion

TRIPS flexibilities still offer a crucial, if rarely tapped, legal tool for lowering drug costs across much of the Global South. Making them work at scale demands bold domestic legislation, an activist trade agenda, regional solidarity, and a rebuilt system that prizes public need over patent length.

The international community must move beyond rhetorical support and commit to a public health-centered approach to intellectual property one that genuinely reflects the spirit of the Doha Declaration. In doing so, we move closer to achieving equitable access to life-saving medicines and fulfilling the right to health for all.

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REFERENCES:

[1] Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 Yale L.J. 804, 823–25 (2008).
[2] World Health Organization, *Equitable Access to Essential Medicines: A Framework for Collective Action*, WHO Policy Perspectives on Medicines No. 8 (2004), https://apps.who.int/iris/handle/10665/68008.
[3] Peter Drahos & John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* 72–74 (Earthscan, 2002).
[4] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].
[5] Ellen 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health* 13–18 (AMBooks, 2009).
[6] Carlos M. Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* 31–32 (South Centre, 2000).
[7] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 14, 2001) [hereinafter Doha Declaration].
[8] Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 Am. J. Int'l L. 317, 319 (2005).
[9] Peter Drahos & Ruth Mayne, *Global Intellectual Property Rights: Knowledge, Access and Development* 3–5 (Palgrave Macmillan 2002).
[10] Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 Tul. J. Tech. & Intell. Prop. 1, 6 (2001).
[11] Susan K. Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* 89–93 (Cambridge Univ. Press 2003).
[12] Frederick M. Abbott, The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO, 5 J. Int'l Econ. L. 469, 472–74 (2002).
[13] TRIPS Agreement, art. 27.
[14] TRIPS Agreement, art. 28.
[15] TRIPS Agreement, art. 31.
[16] TRIPS Agreement, art. 6.
[17] TRIPS Agreement, art. 30.
[18] TRIPS Agreement, art. 39.
[19] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 14, 2001) [hereinafter Doha Declaration].
[20] United States–Jordan Free Trade Agreement, U.S.–Jordan, Oct. 24, 2000, 41 I.L.M. 63 (2002).
[21] Ellen F. M. 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: Seattle, Doha and Beyond*, 3 Chi. J. Int'l L. 27, 34–36 (2002).
[22] Matthew C. Porterfield & Christopher R. Byrnes, *Trade Promotion Authority and International Investment Agreements: Implications for the Environment and Public Health*, 5 Envtl. Dev. & Sustainability 147, 155 (2003).
[23] International Covenant on Economic, Social and Cultural Rights art. 12, Dec. 16, 1966, 993 U.N.T.S. 3.
[24] Comm. on Econ., Soc. & Cultural Rts., General Comment No. 14: The Right to the Highest Attainable Standard of Health, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000), ¶ 43.
[25] World Health Organization, *Essential Medicines and Health Products*, https://www.who.int/medicines/services/essmedicines_def/en/ (last visited June 15, 2025).
[26] TRIPS Agreement, supra Chapter 2 note 1, art. 33.
[27] Carlos M. Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, South Centre (2002), at 5.
[28] Ellen F. M. 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power* 58–60 (2009).
[29] Médecins Sans Frontières, *The High Price of Hepatitis C Treatment*, https://www.msfaccess.org (last visited June 15, 2025).

[30] Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access in Africa?*, 286 JAMA 1886 (2001).
[31] Patent Act, No. 39 of 1970, § 5, India.
[32] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[33] MSF, *Untangling the Web of Antiretroviral Price Reductions*, 18th Ed. (2016).
[34] Bayer Corp. v. Natco Pharma Ltd., (2012) Controller of Patents, India
[35] WHO, *Equitable Access to Essential Medicines: A Framework for Collective Action*, WHO Policy Perspectives on Medicines No. 8 (2004).
[36] Global Forum for Health Research, *The 10/90 Report on Health Research* (2000).
[37] MSF, *Insulin Prices and Access*, https://msfaccess.org/insulin (last visited June 15, 2025).
[38] Duke Global Health Institute, *COVID-19 Vaccine Equity Tracker*, https://launchandscalefaster.org (last visited June 15, 2025).
[39] Médecins Sans Frontières, *South Africa mRNA Hub Faces Lack of Industry Cooperation*, https://msfaccess.org (last visited June 15, 2025).
[40] WTO, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, IP/C/W/669 (Oct. 2020).
[41] WTO, *Ministerial Decision on the TRIPS Agreement*, WT/MIN(22)/30 (June 17, 2022).
[42] Deborah Gleeson et al., *Compromised for Commercial Interests: Data Exclusivity in Trade Agreements*, 9 J. Law Med. 223 (2013).
[43] United States–Peru Trade Promotion Agreement art. 16.10.2, Apr. 12, 2006.
[44] WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 1, 2003).
[45] Pan American Health Organization, *PAHO Revolving Fund*, https://www.paho.org (last visited June 15, 2025).
[46] U.N. Human Rights Council, *Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, Res. A/HRC/RES/23/14 (June 13, 2013).
[47] Minister of Health v. Treatment Action Campaign 2002 (5) SA 721 (CC) (S. Afr.).
[48] Alicia Ely Yamin, *Power, Suffering and the Struggle for Dignity: Human Rights Frameworks for Health and Why They Matter* 78–81 (Univ. of Pennsylvania Press 2015).
[49] Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* 48 (Oxford Univ. Press 2005).
[50] Patent Act, No. 39 of 1970, § 3(d) (India), as amended in 2005.
[51] Bayer Corp. v. Natco Pharma Ltd., Controller of Patents, Compulsory License Decision (2012) (India).

[52] MSF, *Untangling the Web of Antiretroviral Price Reductions*, 18th Ed. (2016), at 11.
[53] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[54] Lei No. 9.279, de 14 de Maio de 1996, art. 71 (Braz.).
[55] Ellen F. M. 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* 101–03 (Health Action Int'l 2016).
[56] Amy Kapczynski & Jonathan Berger, *The Story of the TAC Case: Health, Human Rights, and Politics in South Africa*, in *Human Rights Advocacy Stories* 44–45 (2009).
[57] World Health Organization, *Access to Medicines under TRIPS Flexibilities*, WHO Technical Brief, at 3–4 (Mar. 2010).
[58] Pharmaceutical Mfrs. Ass'n of S. Afr. v. President of the Republic of S. Afr., Case No. 4183/98 (High Ct. Pretoria 2001) (withdrawn after global protest).
[59] Médecins Sans Frontières, *Victory for Access to Medicines in South Africa*, MSF Press Release (Apr. 19, 2001).
[60] Minister of Health v. Treatment Action Campaign 2002 (5) SA 721 (CC) (S. Afr.).
[61] Oxfam, *Thailand and the TRIPS Agreement: Using Compulsory Licenses to Improve Access to Medicines* (2007), at 5.
[62] United States Trade Representative, *Special 301 Report* (2007), at 28–30.
[63] Office of the U.S. Trade Representative, *Special 301 Report* (2024), https://ustr.gov.
[64] James Love, *USTR's Special 301 Report and Access to Medicines*, KEI Research Note 2007:1, at 2–3.
[65] Médecins Sans Frontières, *Thailand's Compulsory Licenses: Successes and Setbacks* (2007), https://msfaccess.org.
[66] Ellen 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power* 85–87 (2009).
[67] 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, art. 31.
[68] UNDP, *Using TRIPS Flexibilities to Improve Access to HIV Treatment* 12–14 (2010).

[69] WHO, *Public Health, Innovation and Intellectual Property Rights: Global Strategy and Plan of Action* (2008), at 49
[70] Deborah Gleeson & David Lexchin, *The Cost of "Data Exclusivity" Provisions in Trade Agreements*, 28 J. Law Med. 205 (2020).
[71] U.S.–Peru Trade Promotion Agreement, art. 16.10.2 (2006).
[72] Christopher Garrison, *South Africa and TRIPS Implementation*, South Centre Research Paper No. 40 (2012).
[73] Shamnad Basheer, *India's Patent Office and Its Discontents*, SpicyIP Blog (2015), https://spicyip.com.
[74] Pharmaceutical Mfrs. Ass'n v. President of the Republic of South Africa, Case No. 4183/98 (High Ct. Pretoria 2001).
[75] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[76] Oxfam International, *Patents Versus Patients: Five Years After the Doha Declaration* (2006), at 7–9.
[77] Peter Drahos & Ruth Mayne, *Global Intellectual Property Rights: Knowledge, Access and Development* 127–130 (2002).