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Research Article

Intellectual Property Rights (Patent Protection) and "Compulsory Licensing" in the Pharmaceutical Industry in "The Gambia" – Its Legal Implications

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Abstract

The intersection of Intellectual Property Rights (IPR) and public health constitutes one of the most contentious normative conflicts in international trade law. For Least Developed Countries (LDCs) like The Gambia, the harmonisation of patent standards under the World Trade Organization's TRIPS Agreement presents a formidable challenge: how to incentivise innovation without rendering essential medicines unaffordable for the populace. This article examines the legal regime governing pharmaceutical patents in The Gambia, with a specific focus on the mechanism of Compulsory Licensing as a safeguard for public health. This study examines the balancing of innovation and access within the legal Analysis of Patent Protection and Compulsory Licensing in The Gambia's Pharmaceutical Sector. Adopting a doctrinal and comparative legal research methodology, this study analyses the text and application of The Gambia's Industrial Property Act 2010 and the Medicines and Related Products Act 2014. It evaluates the domestic domestication of international obligations, contrasting The Gambia's statutory framework against the flexibilities authorised by the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health (2001). Furthermore, the research draws comparative lessons from jurisdictions such as India and South Africa to highlight best practices in balancing proprietary rights with human rights obligations. Objectively, the research establishes that while The Gambia possesses the statutory architecture to issue Compulsory Licenses – (authorisations to use a patent without the holder's consent), the practical utilisation of this tool is non-existent. Subjectively, the article argues that the current legal environment is characterised by "legislative dormancy - Nwele 2019." The fear of trade retaliation and a lack of administrative expertise have created a "TRIPS-plus" environment where patent protection is prioritised over the "Right to Health" enshrined in international human rights covenants. The findings reveal a critical gap: The Gambia, as a part of Least Developed Countries, has failed to fully leverage the WTO transition period (currently extended to 2034) which exempts it from granting pharmaceutical patents. Instead, through membership in regional bodies like ARIPO, The Gambia inadvertently validates patents that block generic competition. Additionally, the study finds that the lack of domestic manufacturing capacity renders standard Compulsory Licensing ineffective unless coupled with the specific import mechanisms provided under TRIPS Article 31bis. The article concludes that for Compulsory Licensing to move from a theoretical legal provision to a practical public health tool, The Gambia must reform its Industrial Property Act to explicitly define "national emergency" broadly and streamline the administrative procedures for granting licenses. It advocates for a legal paradigm shift that views access to

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medicines not merely as a trade exception, but as a sovereign constitutional imperative.

Keywords

The Gambia, TRIPS Agreement, Compulsory Licensing, Pharmaceutical Patents, Public Health, Intellectual Property Law, Access to Medicines

1. Introduction

1.1. Opening Statement

The global discourse on Intellectual Property Rights (IPR) has long wrestled with the tension between protecting proprietary innovation and ensuring the fundamental human right to health. For Least Developed Countries (LDCs) like The Gambia, this is not merely an academic debate but a matter of life and death [1].

The pharmaceutical industry operates at the intersection of intellectual property law and public health policy. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), adopted in 1994 under the auspices of the World Trade Organization (WTO), established a global standard for patent protection, including for pharmaceutical products and processes [1].

Under Article 27 of the TRIPS Agreement, WTO members are required to make patents available for any inventions, including pharmaceuticals that are new, involve an inventive step, and are capable of industrial application. However, Article 31 provides for compulsory licensing, allowing a government to authorize the use of a patented product or process without the consent of the patent holder in certain circumstances—such as public health emergencies or cases of anti-competitive practices [1].

The Doha Declaration on the TRIPS Agreement and Public Health (2001) reaffirmed that TRIPS "should not prevent Members from taking measures to protect public health." It clarified that each country has the right to grant compulsory licenses and determine the grounds upon which such licenses are granted [1]. This principle enables developing countries to import or produce generic versions of essential medicines to combat diseases such as HIV/AIDS, malaria, and tuberculosis [2].

The balance therefore lies in protecting innovators' rights to encourage research and development (R&D), while allowing flexibility to ensure access to affordable medicines for the public. This dual protection represents the policy tension between pharmaceutical innovation and public health equity.

1.1.1. Nature and Meaning of IP in Pharmaceuticals

There is an extensive international system for defining, protecting, and enforcing intellectual property rights, comprising both multilateral treaty schemes and international organizations. Examples of such treaties and bodies include the Trade-Related Aspects of Intellectual Property Rights (TRIPs), World Intellectual Property Organization (WIPO), World Customs Organization (WCO), United Nations Commission on International Trade Law (UNCITRAL), World Trade Organization (WTO), and European Union (EU). Nonetheless, there are variations in the respect for and enforcement of rights at a local level.

Intellectual property is a general term for the set of intangible assets owned and legally protected by a company from outside use or implementation without consent [3]. Stemming from its ability to provide a firm with competitive advantages, defining Intellectual Property as an asset aims to provide it the same protective rights as physical property. Obtaining such protective rights is critical as it prevents replication by potential competitors - a serious threat in a web-based environment or the mobile technology sector.

According to Nwele 2019, intellectual property is the result of the fruit of mental labour and original creative work of individuals, a body or organisation: published writings and, expressive arts, inventions of a specific function like; machines, chemicals, medications, and technology - including the unique way a manufactured object appears; plant varieties that are asexually reproduced including hybrids, etc [4].

Intellectual property law is the area of law that deals with protecting the rights of those who create original works or some of the greater manifestations of human achievements through regulating the creation, use and exploitation of mental or labour of creativity, like in patent. It covers everything from original authorship of writings including novels and plays to inventions and company, or business identification marks [3].

While patents incentivise research and development, strict enforcement can create monopolies that drive up the cost of essential medicines.

1.1.2. Contextualising "The Gambia"

The Gambia relies heavily on imported pharmaceuticals [2]. With a high disease burden (Malaria, HIV/AIDS, Tuberculosis), the affordability of medicines is paramount. Reference is made to the Industrial Property Act 2010 and the Medicines and Related Products Act 2014 as the primary domestic vehicles for managing this tension.

1.1.3. The TRIPS Dimension

The World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration (2001) which confirmed that TRIPS should be interpreted in a manner supportive of WTO members' right to protect public health and promote access to medicines for all is emphasised.

1.2. Background of the Study

By historical context the evolution of IP law in West Africa from the colonial era (British Copyright/Patent extension) to the post-independence adoption of national statutes centered on:

Public Health Profile that provide statistics on The Gambia's health sector. (e.g., dependency on the Global Fund for ARVs).

The LDC Waiver as a crucial point clarifies that, The Gambia benefits from a transition period (currently extended until 2034) where it is not required to grant or enforce pharmaceutical patents. The context now is why, despite this waiver, a robust Compulsory Licensing regime is still necessary for the future and for non-waived technologies [3].

Tracing the jurisprudential shift from "imperial extension" to "national sovereignty," while analyzing the specific flexibilities afforded by the WTO TRIPS Agreement under a legal structure, the following provides a comprehensive legal and historical analysis of Intellectual Property (IP) law in The Gambia, and by extension Nigeria, and Cameroon.

1.3. Problem Statement

Despite having legal frameworks, The Gambia does not effectively utilise "TRIPS Flexibilities" -specifically Compulsory Licensing - to secure generic drugs and the legal framework seems to be dormant due to internal capacity gaps.

1.4. The Jurisprudential Foundation

The evolution of IP law in West Africa is a transition from a Mercantilist/Extractive Model (colonial era) to a Developmental/Public Health Model (post-independence). This review examines how these legal frameworks intersect with the Public Health Profile of the sub-region, specifically regarding the Least Developed Countries (LDC) Waiver and Compulsory Licensing (CL) regimes.

1.5. Historical Context: From Imperial Extension to National Statutes

1.5.1. The British Colonial Era: The Doctrine of Imperial Extension

In the late 19th and early 20th centuries, IP law in British West Africa (Nigeria and The Gambia) was governed by the Registration of United Kingdom Patents/Designs Ordinances.

Mechanism: These were not independent grants but "dependent registrations." A patent holder in the UK could extend protection to the colonies by merely registering the UK grant.

Nigeria: The 1912 Copyright Order in Council extended the English Copyright Act of 1911 to the colony. Patents were similarly governed by the Registration of United Kingdom Patents Ordinance (1925).

The Gambia: Followed a similar path with the Registration of United Kingdom Patents Act (Cap 163), which persisted until the late 20th century.

1.5.2. The Cameroon Anomaly: Dual Heritage and OAPI

Cameroon's history is unique due to its split British (Southern Cameroons) and French (French Cameroun) administrations.

Post-independence, Cameroon opted for a unified regional approach via the Libreville Agreement (1962), which established OAPI (Organisation Africaine de la Propriété Intellectuelle). This created a unified IP law (the Bangui Agreement) where a single registration covers all member states, moving away from the colonial individual extension models.

1.5.3. Post-Independence National Statutes and Regional Alignment

Table 1. *PINSRA 1.*

Country	Principal IP Statute (Patents/Designs)	Regional Membership
Nigeria	Patents and Designs Act (PDA), Cap P2 LFN 2004	ARIPO (Observer/Signatory)
The Gambia	Industrial Property Act (1989, amended 2007/2015)	ARIPO (Harare Protocol)
Cameroon	Bangui Agreement (OAPI) - Annex I	OAPI (Unified Law)

1.5.4. Public Health Profiles and the LDC Waiver

The legal distinction between LDCs and Developing Countries under the WTO TRIPS Agreement defines their capacity to bypass patent rights for medicine [3].

1.5.5. The Gambia: The LDC Advantage

Status: Classified as an LDC.

The Waiver: Under the TRIPS Pharmaceutical Waiver (extended to 2033), The Gambia is not required to grant or enforce patents on pharmaceutical products [5].

Health Profile Intersection: Facing a high burden of malaria and TB, The Gambia utilizes the waiver to import generics. However, the Industrial Property Act (2007) remains "TRIPS-compliant" by choice, which sometimes creates a "legal chill" where officials are hesitant to ignore patents even when the waiver permits it.

1.5.6. Nigeria and Cameroon: The Developing Country Constraint

Status: Classified as Developing Countries (Non-LDCs).

Legal Limitation: Unlike The Gambia, they must enforce pharmaceutical patents. They cannot use the "No-Patent" LDC waiver and must rely on Compulsory Licensing or Parallel Importation.

Health Profile: Nigeria (the "malaria capital" of the world) and Cameroon (experiencing a double burden of infectious and NCDs like diabetes) are heavily reliant on imported patented drugs (70-80% of consumption).

1.6. Compulsory Licensing (CL) Regimes: Non-Waived Technologies

For technologies not covered by the LDC waiver (e.g., medical devices, diagnostics, or general industrial tech), countries must use the specific CL provisions in their statutes.

1.6.1. Nigeria: Section 11 & First Schedule of the PDA

Grounds: Non-working (if a patent is not manufactured locally within 4 years of filing) or if the demand is not met on reasonable terms.

Public Health: Paragraph 13 of the First Schedule allows the Minister to authorize the use of a patent for "the service of a government agency" in cases of public interest.

Challenge: The procedure is judicial/administrative and highly cumbersome, leading to zero recorded uses for pharmaceutical products in recent decades.

1.6.2. Cameroon (OAPI): Article 56 of Annex I (Bangui Agreement)

Grounds: Article 56 allows for "Non-voluntary Licenses" where a patent is of "vital interest to the economy, public health, or national defense."

The "Administrative Enactment" Theory: Unlike Nigeria's court-heavy process, the OAPI model allows a Minister to issue a CL via administrative decree, which is theoretically faster for public health emergencies.

1.6.3. The Gambia: Section 14 of the Industrial Property Act

Provision: Allows the Minister of Justice to grant a non-voluntary license for public interest, including health [6].

Non-Waived Tech: Even though pharma is waived until 2033, The Gambia still applies Section 14 to "non-waived" health tech like diagnostic machines and ventilators, which were critical during the COVID-19 pandemic [3].

1.7. Legal Theories and Analytical Framework

Social Contract Theory: IP is a contract where the state grants a monopoly in exchange for disclosure. In West Africa, the "contract" is often imbalanced because the technology is rarely "worked" locally, justifying CL as a remedy for breach of the social utility requirement.

Public Interest vs. Private Monopoly: Under the Doha Declaration (2001), TRIPS must be interpreted to support the right to protect public health. This creates a "Health-First" canon of construction for national courts [3].

Human Rights Theory: Access to medicines is an extension of the Right to Life (Section 33, Nigerian Constitution; Preamble, Cameroon Constitution). IP laws are subordinate to these fundamental rights.

1.8. Summary of Legal References

International: TRIPS Agreement (Art. 2,3, 31, 66.1); Doha Declaration (Para 4-6); 2003 Waiver (Decision on Para 6).

Nigeria: Patents and Designs Act (PDA) 2004; Copyright Act 2022.

The Gambia: Industrial Property Act 2007; Constitution of The Gambia.

Cameroon: Bangui Agreement (Revised 2015).

It is therefore recommended that while The Gambia has the broadest legal freedom (LDC Waiver), Nigeria and Cameroon possesses the legal tools (Compulsory Licensing) but lack the institutional capacity and local manufacturing base to operationalise them – and these need to be addressed.

1.9. Objectives and Research Questions

1.9.1. Objectives

To examine The Gambia's Industrial Property Act 2010 regarding patent protection and compulsory licensing.

To analyse the compatibility of Gambian law with the TRIPS Agreement and the Doha Declaration

To identify legal and administrative barriers preventing the effective use of compulsory licenses in The Gambia

To propose legal reforms to enhance access to medicines without violating international obligations

1.9.2. Research Questions

Does the current Gambian legal framework provide adequate flexibilities (specifically Compulsory Licensing) to address public health crises?

What are the implications of "TRIPS-Plus" provisions in bilateral trade agreements on The Gambia's public health?

How does the lack of domestic pharmaceutical manufacturing capacity affect the utility of Compulsory Licensing in The Gambia?

What are the legal reforms necessary to enhance access to medicines without violating international obligations?

2. Literature Review

The tension between the Global North and the Global South regarding Intellectual Property (IP) rights represents one of the most significant schisms in international trade and development policy. This conflict is primarily centered on the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) and the balance between rewarding innovation and ensuring public welfare. Below is a literature analysis of this divide, incorporating the perspectives of Carlos M. Correa and Joseph Stiglitz.

2.1. The Global North Perspective: Intellectual Property as an Incentive for Innovation

Developed nations (the Global North), led by the United States, the European Union, and Japan, argue that stringent Intellectual Property protection is a prerequisite for global economic growth. Their position is built on the "Incentive Theory" on Recouping Research & Dev Costs: Developing new technologies, particularly in pharmaceuticals and software, requires massive investment. Without a period of market exclusivity (patents), companies would have no incentive to innovate, which makes knowledge as private property a concern that compels the North to view Intellectual Property as a private asset that must be protected against "theft" or "piracy" in foreign markets.

TRIPS-Plus: Recently, Northern nations have pushed for "TRIPS-plus" provisions through bilateral trade agreements, which extend patent terms and restrict the use of generic alternatives beyond the original requirements of the WTO.

2.2. The Global South Perspective: Intellectual Property as a Barrier to Development

Here the developing nations (the Global South) argue that the current Intellectual Property regime serves as a mechanism for "kicking away the ladder," as they contend that access to essentials - high Intellectual Property protection leads to monopoly pricing, making life-saving medicines (HIV/AIDS, COVID-19, Hep-C) and educational materials unaffordable. On impediment to learning which developed nations (like the US and Germany in the 19th century) believed, grew by imitating and adapting foreign technology - a pathway now blocked for the Global South by strict Intellectual Property laws.

2.3. Analysis by Joseph Stiglitz: The Economic Inequity

Joseph Stiglitz, a Nobel laureate, provides a scathing critique of the Global North's approach, primarily in his works Making Globalization Work and The Price of Inequality [7].

Knowledge as a Public Good: Stiglitz argues that knowledge is a "global public good." Unlike physical goods, one person's use of an idea does not subtract from another's. IP rights create artificial scarcity, which is economically inefficient [7].

The "Rent-Seeking" Argument: Stiglitz asserts that the Global North uses IP not just to encourage innovation, but for "rent-seeking" - extracting wealth from the Global South. He points out that the TRIPS agreement was essentially "drawn up by the pharmaceutical and entertainment industries" to suit their own balance sheets rather than global health.

Inequality of Health: Stiglitz famously argues that the current IP regime prioritizes "profits over people," noting that the cost of drug development is often subsidized by public taxes in the North, yet the benefits are locked behind private patents that the South cannot afford [7].

2.4. Analysis by Carlos M. Correa: The Policy Space and Legal Struggle

Carlos M. Correa, Executive Director of the South Centre, focuses on the legal and systemic hurdles the Global South faces. His work, including Intellectual Property Rights, the WTO and Developing Countries, highlights [8]:

TRIPS Flexibilities: Correa is a leading advocate for the use of "flexibilities" within the TRIPS agreement, such as compulsory licensing (where a government allows a local company to produce a patented product without the owner's consent during emergencies) [8].

Protection of Biodiversity: Correa highlights how Northern corporations often engage in "biopiracy" - patenting traditional knowledge and biological resources (like neem or turmeric) from the Global South without compensation to the original communities [8].

The Institutional Constraint: Correa argues that the Global North exerts "technical assistance" and political pressure to prevent developing countries from utilizing the legal loopholes available to them. He posits that a "one-size-fits-all" IP system is detrimental because the Global South has different industrial capacities and social needs [8].

2.5. Summary of the Conflict

Table 2. SC 2.

Feature	Global North (Push for Strength)	Global South (Advocacy for Access)
Primary Goal	Protect R&D investment and corporate profit.	Ensure public health, food security, and education.
View of IP	A private property right.	A tool for social and economic development.
Key Scholars	Industry-aligned economists.	Stiglitz (Economic justice); Correa (Legal sovereignty).
Preferred Strategy	TRIPS-plus, strict enforcement, sanctions.	Compulsory licensing, patent pools, and "fair use."

This literature suggests that while the Global North views IP as a bridge to the future, the Global South, supported by the theories of Correa and Stiglitz, views the current rigid IP framework as a wall. Stiglitz emphasises the economic inefficiency and moral cost of this wall, while Correa provides the legal roadmap for how developing nations can navigate and challenge these global mandates to protect their citizens.

Compulsory Licensing (CL): Is an authorisation granted by the government to a third party to produce a patented product without the patent holder's consent.

TRIPS Article 31bis - allows countries with no manufacturing capacity (like The Gambia) to import generic drugs made under a compulsory license in another country.

What is a generic drug in pharmaceuticals?

In pharmaceuticals, a generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics [9].

When the patent protection on a brand-name drug expires, other manufacturers are allowed to produce and sell the same chemical formulation. These versions are known as generics.

Here is a detailed breakdown of what defines a generic drug [9]:

1) The Principle of "Sameness"

For a generic drug to be approved by regulatory bodies (like the FDA in the US or the MCA in The Gambia), it must be bioequivalent to the brand-name drug [10]. This means: Active Ingredients: It must contain the same active pharmaceutical ingredient (API) as the brand name.

Strength: If the brand is 500mg, the generic must be 500mg. Dosage Form: If the brand is a capsule, the generic must be a capsule (not a liquid or injection). Effectiveness: It must deliver the same amount of the drug into the patient's bloodstream in the same amount of time.

2) What Can Be Different?

While the active part must be the same, generic drugs are not exact clones in every way. They may differ in: Inactive Ingredients: These include binders, fillers, flavorings, and colours (excipients). As long as these do not change how the drug works or cause safety issues, they can vary. Appearance: Due to trademark laws, a generic cannot look exactly like the brand-name pill. It may have a different shape, colour, or packaging. Price: This is the most significant difference. Generics are typically 80% to 85% cheaper than the brand-name version [10].

3) Why Generics are Cheaper

The lower cost of generic drugs is not a reflection of lower quality; Instead, it is due to the economics of drug development: No R&D Costs: Generic manufacturers do not have to pay for the initial "discovery" of the drug or the expensive animal and human clinical trials required to prove the drug works from scratch. There is No Marketing Costs: They do not spend billions on advertising or "detailing" (sending sales representatives to doctors). Competition: Multiple companies usually start making the same generic once the patent expires, which drives the price down through market competition [10].

4) Regulatory Approval

Generic manufacturers do not have to repeat the years of clinical trials that the original developer did; instead, they must submit an Abbreviated New Drug Application (ANDA). In this application, they only need to prove that their version performs the same way in the human body as the original (bioequivalence).

5) Context: The Global South and Generics

Connecting back to your previous interest in Stiglitz and Correa:

The availability of generic drugs is the primary tool the Global South uses to provide affordable healthcare. Because the Global South often cannot afford the monopoly prices of brand-name drugs protected by patents (IP), they advocate for: Early entry of generics; Shortening patent lives so generics can enter the market sooner. Compulsory Licensing: Legally bypassing a patent to produce a generic version during a health crisis (e.g., HIV/AIDS or COVID-19).

Summary Example: Brand Name: Panadol (manufactured by GSK). Generic Name: Paracetamol (manufactured by various companies). Both have the same active ingredient and treat pain/fever identically.

2.6. TRIPS Flexibilities in Sub-Saharan Africa

The implementation of TRIPS flexibilities in Sub-Saharan Africa is a critical area of study, as it represents the practical application of the theories proposed by Carlos Correa on legal sovereignty and Joseph Stiglitz on economic equity. While the TRIPS Agreement sets minimum standards for Intellectual Property protection, the 2001 Doha Declaration clarified that these rules should not prevent member states from taking measures to protect public health. Here is a review of how South Africa, Uganda, and Ghana have implemented these flexibilities.

2.6.1. South Africa: The Battle Against "Evergreening"

South Africa has been the primary "legal laboratory" for TRIPS flexibilities in Africa, largely due to its high HIV/AIDS and TB burden. Key Study Focus: The Intellectual Property Policy of the Republic of South Africa (Phase I, 2018). The Implementation: For years, South Africa was a "depository" system - it granted patents without checking if the invention was actually new. This allowed pharmaceutical companies to engage in "evergreening" (extending patent life by making minor, non-inventive changes to a drug).

The Flexibilities Used:

Substantive Search and Examination (SSE): Following years of advocacy by groups like the Treatment Action Campaign, the 2018 policy moved toward examining patent applications strictly to ensure only genuine innovations get protection.

Parallel Importation: South Africa famously legislated to allow the importation of a patented drug from a country where it is sold cheaper (the 1997 Medicines Act), leading to a landmark legal victory against 39 multinational pharmaceutical companies. Scholarly View: Research indicates that while South Africa has the strongest Intellectual Property laws, it has historically struggled to issue Compulsory Licenses due to intense political pressure from the Global North (the US and EU).

2.6.2. Uganda: Leveraging LDC Status and Local Production

Uganda represents the "Least Developed Country" (LDC) strategy. Under TRIPS, LDCs are granted an extension (currently until 2033) during which they do not have to enforce pharmaceutical patents. Key Study Focus: Local Production of Pharmaceuticals in Uganda (various UNDP/UNCTAD reports). The Implementation: Uganda utilised the "LDC Waiver" to foster a domestic pharmaceutical industry.

The Flexibilities Used:

Local Manufacturing (Quality Chemical Industries Ltd - QCIL): In 2007, Uganda partnered with the Indian generic firm Cipla to produce generic ARVs and anti-malarials in Kampala. Because Uganda did not recognise pharmaceutical patents at the time, they could legally produce these generics. TRIPS-Compliant Legislation: The Industrial Property Act of 2014 was specifically drafted (with advice from Carlos Correa) to include broad exemptions for public health, research, and experimental use. Scholarly View: Studies show that Uganda is a success story in using "policy space" to build industrial capacity. However, researchers warn that as Uganda moves toward "Middle Income" status, it will lose these LDC exemptions and face the same pressures as South Africa.

2.6.3. Ghana: The Use of Compulsory Licensing

Ghana provides a notable example of a country using emergency provisions to tackle a specific health crisis. Key Study Focus: Ghana's 2005 Declaration of a State of Emergency regarding HIV/AIDS. The Implementation: In 2005, the Ghanaian government declared a state of emergency, which is a shortcut allowed under TRIPS to trigger a Compulsory License.

The Flexibilities Used:

Government Use/Compulsory License: Ghana bypassed patents to import generic ARVs from India. This significantly lowered the cost of treatment per patient, allowing the government to scale up its national HIV response. Administrative Barriers: Studies of Ghana's Patents Act (Act 657) show that while the law allows for flexibilities, the administrative process is cumbersome. Ghana often relies on "Government Use" provisions rather than formal compulsory licenses to avoid long legal battles. Scholarly View: Literature highlights that Ghana's success was driven by political will. However, critics note that after the 2005 emergency expired, the country did not fully integrate these flexibilities into its permanent "peacetime" procurement laws.

2.6.4. Comparative Analysis: Common Themes

Table 3. CA3.

Factor	South Africa	Uganda	Ghana
Main Flexibility	Parallel Importation / Patent Examination.	LDC Transition Waiver.	Compulsory Licensing / Government Use.

Factor	South Africa	Uganda	Ghana
Key Driver	Civil Society Advocacy (TAC).	Local Industrial Development.	State of Emergency (Public Health).
Primary Challenge	"TRIPS-Plus" pressure from US/EU.	Graduating from LDC status.	Administrative/Regulatory capacity.

2.7. Summary of the Literature

The consensus among researchers (often citing Correa) is that:

Legal Drafting is Key: Countries that have updated their laws to include specific TRIPS flexibilities (like Uganda) are better protected than those with colonial-era Intellectual Property laws. Political Pressure (The Stiglitz Concern): Even when a country has the legal right to use flexibility, the fear of trade sanctions or "special 301" reports from the US often discourages them from doing so. Regional Harmonisation: There is a growing push for the African Medicines Agency (AMA) to help these countries use flexibilities collectively, rather than fighting "Big Pharma" individually.

The "Hazardous Drugs" Concept: Note regarding your prompt: The "Hazardous Drugs Act" is largely obsolete or subsumed. The focus should be on the regulation of substandard and falsified medicines under the 2014 Act. The "Hazardous" element relates to the recent strict controls following the Acute Kidney Injury (AKI) scandal in The Gambia (2022) linked to imported cough syrups.

2.7.1. Empirical and Criminological Dimensions

The Counterfeit/Substandard Issue:

Strict Intellectual Property laws sometimes conflate "generics" with "counterfeits."

Criminological perspective: The criminalisation of Intellectual Property Rights infringement should not be used to stop legitimate generic medicines. In the Gambia Context, with reference to the 2022/2023 AKI tragedy; the highlight was that the real danger was not patent infringement, but lack of Quality Control (QC). The legal system focuses heavily on protecting Intellectual Property, but the empirical reality shows a greater need for protecting safety.

2.7.2. Comparative Jurisprudence

South Africa: PMA v. Mandela (1998)

Case: 39 pharma companies sued the South Africa government to stop a law allowing generic substitution and parallel imports. Relevance: Public outcry forced the companies to drop the suit. It established that public health laws are sovereign.

India: Novartis v. Union of India (2013)

Case: The Supreme Court of India rejected a patent for Glivec (cancer drug) because it was a minor modification of an old drug (Section 3(d) of Indian Patent Act). Lesson for Gambia: The Gambia should adopt similar "anti-evergreening" provisions in its Industrial Property Act.

3. Discussion

The legal implications of “patent protection” and “compulsory licensing” in the pharmaceutical industry under the TRIPS Agreement; and how these provisions balance the protection of intellectual property rights with public health needs, particularly in developing countries:

The pharmaceutical industry operates at the intersection of intellectual property law and public health policy. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), adopted in 1994 under the auspices of the World Trade Organization (WTO), established a global standard for patent protection, including for pharmaceutical products and processes.

Under Article 27 of the TRIPS Agreement, WTO members are required to make patents available for any inventions, including pharmaceuticals that are new, involve an inventive step, and are capable of industrial application. However, Article 31 provides for compulsory licensing, allowing a government to authorise the use of a patented product or process without the consent of the patent holder in certain circumstances - such as public health emergencies or cases of anti-competitive practices.

The Doha Declaration on the TRIPS Agreement and Public Health (2001) reaffirmed that TRIPS “should not prevent Members from taking measures to protect public health.” It clarified that each country has the right to grant compulsory licenses and determine the grounds upon which such licenses are granted. This principle enables developing countries to import or produce generic versions of essential medicines to combat diseases such as HIV/AIDS, malaria, and tuberculosis.

The balance therefore lies in protecting innovators’ rights to encourage research and development (R&D), while allowing flexibility to ensure access to affordable medicines for the public. This dual protection represents the policy tension between pharmaceutical innovation and public health equity.

The use of compulsory licenses should be a rare event, considered only under extremely limited circumstances, rather than an instrument of industrial policy. Nonetheless, before a government decides to issue a compulsory license, there are several technical and procedural requirements under the TRIPS Agreement that must first be satisfied. The key provision relating to compulsory licenses in TRIPS is Article 31,

entitled “Other Use Without Authorisation of the Right Holder.” However, this is not the only provision that is relevant for governments wishing to ensure that a compulsory license grant is legally and procedurally compliant with TRIPS. It is first important to look at the general requirements of Article 27, which are imposed on all WTO signatories. Paragraph 1 of Article 27 TRIPS states: Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. The “non-discrimination” clause in Article 27.1 clarifies that a patented invention must be accorded similar rights and protections, regardless whether the manufacturer produces the patented invention locally or chooses to import the invention.

The Gambia, as a WTO member and ARIPO participant, allows compulsory licensing for pharmaceutical patents under its Intellectual Property laws, primarily to ensure public health access, address national emergencies like pandemics, promote local manufacturing, and remedy anti-competitive practices, aligning with TRIPS Agreement flexibilities, allowing government-issued licenses without patent owner consent for domestic use with adequate remuneration, though specific implementation details involve national regulations under the ARIPO framework

The Gambia currently has extremely limited domestic pharmaceutical manufacturing capacity. While the "The Gambia GMP Roadmap" and ECOWAS regional initiatives aim to foster local production, the country remains a "net importer." This makes the TRIPS flexibilities - specifically the right to import generics and the exemption from pharmaceutical patenting - vital. Without these, the cost of newer, patented life-saving treatments (such as those for Hepatitis C, certain cancers, or drug-resistant TB) would be prohibitively high for the Gambian public health system.

4. Findings

Finding 1: The Gambia has the statutory power to issue Compulsory Licenses, but lacks the administrative guidelines to do so quickly.

Finding 2: As part of Least Developed Countries (LDCs), The Gambia is under-utilising the WTO waivers. It continues to grant pharma patents via ARIPO when it is not legally required to until 2034.

Finding 3: The reliance on imports renders standard Compulsory Licensing useless unless combined with TRIPS Article 31bis (importing from a willing partner like India or Bangladesh).

5. Conclusion

Intellectual Property Rights protection is necessary for innovation, but for a country like The Gambia, the immediate priority is access. The legal framework exists but is currently a "paper tiger." It requires political will and regulatory tightening to ensure that patent rights do not become barriers to the fundamental right to health.

6. Recommendations

Administrative Guidelines: Create a simplified, "fast-track" administrative procedure for granting Compulsory Licensings, avoiding the court system.

Legislative Reform: Amend the Industrial Property Act 2010 to explicitly incorporate the TRIPS Least Developed Countries transition period (stop granting pharma patents until 2034).

Define "National Emergency": The law should broadly define health emergencies to include HIV, Malaria, and non-communicable diseases (Diabetes, Hypertension).

The Gambia needs to address the issue of lack of domestic pharmaceutical manufacturing capacity in The Gambia?

Abbreviations

TRIPS	Trade-Related Aspects of Intellectual Property Rights
WTO	World Trade Organisation
ARIPO	African Regional Industrial Property Organization
MGPP	Multisource (Generic) Pharmaceutical Products
IPA	Industrial Property Act
HDA	Hazardous Drugs Act
NE	National Emergency
LDC	Least Developed Countries
QC	Quality Control
QCIL	Quality Chemical Industries Ltd
GPG	Global Public Goods
WIPO	World Intellectual Property Organization
WCO	World Customs Organization
UNCITRAL	United Nations Commission on International Trade Law
EU	European Union
RER	Respect for and Enforcement of Rights
OUP	Oxford University Press
FDA	Food & Drug Administration
MCA	Medicine Control Agency
PMA	Pharmaceutical Manufacturers Association
BCE	British Colonial Era
DIE	Doctrine of Imperial Extension
PPPP	Patent Protection of Pharmaceutical Products

IPR	Intellectual Property Rights
PPCL	Patent Protection and "Compulsory Licensing"
PIPR	Protection of Intellectual Property Rights
PHN	Public Health Needs
HPI	Health Profile Intersection
R & D	Research and Development

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Conflicts of Interest

The authors declare no conflicts of interest.

Appendix

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