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# BALANCING PATENT RIGHTS AND PUBLIC HEALTH: THE ROLE OF COMPULSORY LICENSING

## INTRODUCTION

A patent is a form of intellectual property protection that grants its holder the exclusive right to exploit an invention, such as making, using, selling, or distributing it for a limited period, typically twenty (20) years from the date of filing. In the pharmaceutical industry, patents are granted for innovations such as new drugs, formulations, and manufacturing processes, provided they meet key criteria of novelty, inventive step, and industrial applicability.

Drug development is a lengthy, complex, and high-risk process involving basic research, preclinical studies, multiple phases of clinical trials, and regulatory approvals. It is estimated that the average cost of bringing a new drug to market exceeds $2.6 billion, with only a small percentage making it through to commercialisation.

Patent protection enables pharmaceutical companies to recoup their substantial investments by granting a temporary monopoly over the invention. This exclusivity allows for pricing that reflects the cost of development, thereby supporting further research and the discovery of new therapies. Without the incentive of patents, the financial risks may deter investment in innovative treatments, thereby stifling innovation in healthcare.

## LEGAL FRAMEWORK FOR PATENT PROTECTION

- **Patents and Designs Act, Cap P2, LFN 2004**

The primary legislation governing patents in Nigeria is the Patents and Designs Act (PDA). It outlines the process for patent application, rights conferred by a patent, duration, licensing arrangements, and enforcement provisions.

- **The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement**

The TRIPS Agreement is administered by the World Trade Organisation (WTO). It sets minimum standards for the protection and enforcement of intellectual property rights. The agreement aims to promote innovation while balancing public interest.

- **The Paris Convention for the Protection of Industrial Property (1883)**

The Paris Convention, administered by the World Intellectual Property Organisation (WIPO), is one of the oldest and most influential international IP treaties. It introduces principles such as national treatment, right of priority, and the independence of patents.

- **The Patent Cooperation Treaty (PCT) – 1970**

Also, under the auspices of WIPO, the Patent Cooperation Treaty (PCT) provides a unified procedure for filing patent applications in multiple countries. Instead of filing separate applications in each country, inventors can submit a single international application, which is recognised by over 150 contracting states.

## BALANCING PATENT RIGHTS AND PUBLIC HEALTH

Patents and other forms of intellectual property rights are essential for encouraging innovation and advancing research and development (R&D) in the pharmaceutical sector. Patents grant inventors or businesses unique rights to commercialise their creations and repay the costs associated with creating them. This protection promotes R&D spending, which results in the development of novel treatments and advancement in medical knowledge.

However, while intellectual property rights incentivise innovation, they can affect access to medicines and public health, particularly in low and middle-income countries. For the sake of public health, it is crucial to strike a balance between patent rights and advancing access to medications.

### Mechanisms for Balancing Interests

- Voluntary Licensing and Technology Transfer: Patent holders may grant licences to third parties, facilitating the production of affordable generics and the transfer of know-how.

- Differential Pricing and Access Programmes: Pharmaceutical companies may offer tiered pricing based on national income levels or contribute to access initiatives that distribute essential drugs in low-income countries.

- Government Use: Governments may use patented inventions without prior authorisation for public interest purposes, especially in times of national crisis.

- Compulsory Licensing: A legal mechanism where governments authorise the use of a patented invention without the consent of the patent holder, typically in situations of public health concern.

## COMPULSORY LICENSING

> "By enabling the controlled use of patented inventions without the patentee's permission, compulsory licensing aims to facilitate technology transfer and diffusion, increase access to essential products and services and prevent the abuse of patent monopolies."

**The TRIPS Agreement (Article 31)** recognises compulsory licensing as a legitimate mechanism for balancing public health and IP rights. A compulsory licence allows a third party to use a patent without the owner's consent under specified conditions.

The **Doha Declaration** on the **TRIPS Agreement and Public Health (2001)** reaffirmed the right of WTO members to issue compulsory licences and determine what constitutes a national emergency. It specifically highlighted epidemics such as HIV/AIDS, tuberculosis, and malaria as valid grounds.

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### Conditions for Compulsory Licensing

The TRIPS Agreement, building upon the provision in Article 5A of the Paris Convention, recognises the right of members to authorise compulsory licences subject to conditions aimed at protecting the legitimate interests of the right holder. Instances where compulsory licensing is permitted include national emergencies, other circumstances of extreme urgency and anti-competitive practices.

**Key provisions of TRIPS on Compulsory Licensing**

- **Article 31(a):** Each application is to be considered on its merits.
- **Article 31(b):** A prior attempt to obtain a voluntary licence on reasonable terms must be made, unless the case involves a national emergency, public non-commercial use, or an adjudicated anti-competitive practice.
- **Article 31(c):** The scope and duration of compulsory licences must be limited to the purpose for which they were authorised.
- **Article 31(d):** Licences must be non-exclusive. i.e. the licensee must not have the right to prevent the grant of other licences or the use of the invention by the patent owner.
- **Article 31(e):** Compulsory licences should mainly be used to supply the domestic market of the country that grants the licence. In other words, countries are generally not allowed to use compulsory licences to produce and export medicines to other countries.

However, there are two important exceptions to this rule:

**Article 31(k)** allows this restriction to be relaxed when the government grants a compulsory licence to remedy anti-competitive practices.

**Article 31bis.1** (an amendment to the TRIPS Agreement) allows countries that issue a compulsory licence to export generic medicines to other countries that do not have the capacity to manufacture those medicines themselves. This is especially important for countries facing public health problems but lacking the necessary pharmaceutical production facilities.

- **Article 31(h):** Patent holders are entitled to adequate remuneration.
- **Article 31(I):** Decisions on grant and remuneration to be subject to judicial or other independent review.

## NATIONAL EMERGENCIES AND PUBLIC HEALTH CRISES

National emergencies are a recognised basis for granting compulsory licences. The Doha Declaration clarified that members have the right to determine what constitutes a national emergency or other circumstances of extreme urgency, with the understanding that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

*Historical Examples of Health Crises as National Emergencies*

- **American polio epidemic: 1916**

A polio epidemic that started in New York City caused 27,000 cases and 6,000 deaths in the United States. The disease mainly affects children and sometimes leaves survivors with permanent disabilities.

**Asian Flu: 1957-1958**

With its roots in China, the disease claimed more than 1 million lives.

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- **AIDS pandemic and epidemic: 1981-present day**

AIDS has claimed an estimated 35 million lives since it was first identified. About 64% of the estimated 40 million people living with human immunodeficiency virus (HIV) live in sub-Saharan Africa.

- **West African Ebola epidemic: 2014-2016**

Ebola ravaged West Africa between 2014 and 2016, with 28,600 reported cases and 11,325 deaths.

- **COVID-19 pandemic: 2019-present day**

The COVID-19 pandemic, caused by the novel coronavirus **SARS-CoV-2,** is one of the deadliest viral outbreaks in modern history. Since its emergence in late 2019, it has spread globally, affecting nearly every country and straining healthcare systems, economies, and public infrastructure.

As of the latest data reported to the World Health Organisation (WHO), there have been approximately **778 million confirmed COVID-19 cases** worldwide. **The number of reported deaths** stands at around **7.1 million.** However, this figure likely underrepresents the true death toll due to limited testing, underreporting, and discrepancies in cause-of-death recording across countries.

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As of 2023, an estimated 39.9 million people were living with HIV globally. Low-income countries often face significant barriers to accessing affordable treatment, making compulsory licensing a critical tool.
To overcome these barriers, several African countries, including Eritrea, Ghana, Zimbabwe, Guinea, Mozambique, Swaziland and Zambia, relying on the TRIPS Agreement, have issued compulsory licences for Antiretroviral therapy.
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**Compulsory Licensing During Pandemics**

During large-scale outbreaks, demand for life-saving medicines often outpaces supply. While licensing proprietary technology to third-party manufacturers could accelerate production, companies may refuse, set excessive prices, or prioritise high-income countries over low- and middle-income ones. In such situations, compulsory licensing can help ensure broader and timelier access.

***HIV/AIDS***

HIV/AIDS provides a prominent example of how compulsory licensing can be used to tackle public health crises. Acquired Immunodeficiency Syndrome (AIDS) is the advanced stage of HIV infection, characterised by life-threatening cancers and opportunistic infections that emerge due to a weakened immune system.

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**Conclusion**

Patent protection is vital for incentivising pharmaceutical innovation, yet it must not become a barrier to access, especially during times of public health crisis. Compulsory licensing serves as a legal and ethical bridge between proprietary rights and societal needs.

Both international frameworks, such as TRIPS and the Nigerian Patents and Designs Act, support the judicious use of compulsory licensing to protect public health. A balanced and predictable approach guided by fairness, urgency, and accountability can ensure that innovation and access are not mutually exclusive but mutually reinforcing.

For further questions or enquiries please contact the following:

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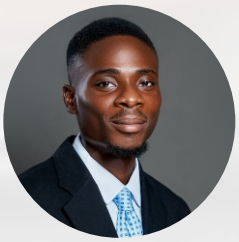

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