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PATENT PROTECTION AND PHARMACEUTICAL INNOVATION: BALANCING U.S INNOVATION INTERESTS WITH HEALTHCARE NEEDS IN NIGERIA

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Abstract

Pharmaceutical patents play an important role in encouraging innovation in the global healthcare industry. By granting inventors exclusive rights for a defined period, patent protection enables pharmaceutical companies, particularly those in countries such as the United States, to recover the high costs associated research, development, and clinical testing of new medicines. However, while strong patent protection supports innovation, it can also create challenges for developing countries where the high cost of patented medicines may limit access to essential healthcare. Nigeria, like many developing nations, therefore faces the difficult task of balancing its respect for international intellectual property obligations with ensuring its population can obtain affordable medicines. The objective of this article is to explore how a balance can be struck between protecting pharmaceutical patents and addressing public health needs in Nigeria and countries in the global south. It examines the legal frameworks governing pharmaceutical patents at the international, United States, and Nigerian levels, with particular emphasis on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the public health safeguards recognized under the Doha Declaration. The article also analyzes Nigeria's patent system under the Patents and Designs Act and considers the legal mechanisms available for improving access to medicines. The study argues that Nigeria can respect U.S. pharmaceutical innovation interests while still protecting public health by making effective use of legal mechanisms permitted under international law. These include compulsory licensing, parallel importation, voluntary licensing arrangements, and the promotion of generic drug competition. Ultimately, the article concludes that a carefully designed legal and policy framework can enable Nigeria to maintain compliance with international intellectual property standards while ensuring that essential medicines remain accessible and affordable to its population

Key words: Pharmaceutical patents; Access to medicines; TRIPS; Compulsory licensing; Nigeria

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1.1 Introduction

Patent protection plays an important role in promoting pharmaceutical innovation by granting inventors exclusive rights over their inventions for a limited period.[1] These rights allow pharmaceutical companies to recover the enormous costs associated with research, clinical trials, and regulatory approval.[2] In advanced markets such as the United States, strong patent protection has long been viewed as a major driver of innovation and has significantly influenced global intellectual property standards, particularly under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[3] However, strong patent protection may also increase medicine prices and limit access to affordable drugs, especially in developing countries.[4] This creates an important policy challenge for countries like Nigeria: how to encourage innovation while ensuring access to essential medicines.

Pharmaceutical research and development (R&D) is one of the most expensive and uncertain forms of technological innovation. Developing a new medicine requires years of testing, regulatory approval, and substantial financial investment.[5] Without patent protection, competitors could easily copy successful medicines and sell them at lower prices without bearing the original research costs, making it difficult for innovating companies to recover their investments.[6] Patent protection therefore serves as an important incentive for continued investment in pharmaceutical innovation.[7] Despite these benefits, the international patent system raises concerns for public health because patents can increase drug prices and limit the availability of affordable generic medicines.[8] This issue is largely governed by TRIPS,[9] which establishes minimum intellectual property standards for members of the World Trade Organization. Although TRIPS requires member states to provide pharmaceutical patent protection, it also recognises the need for safeguards aimed at protecting public health. These safeguards were reaffirmed under the Doha

[1] Gaur, K S and Chugh, J 'The impact of patent law on innovation and technological advancements' (2026) 12(1) International Journal of Law 90; Dosi G, Palagi E, Roventini A and Russo E 'Do patents really foster innovation in the pharmaceutical sector? Results from an evolutionary, agent-based model' (2023) 212 Journal of Economic Behavior & Organization 564; Gawel, C R 'Patent protection as a key driver for pharmaceutical innovation' (2016) 18 Pharmaceuticals Policy and Law 45.

[2] Gawel, C R 'Patent protection as a key driver for pharmaceutical innovation' (2016) 18 Pharmaceuticals Policy and Law 45.

[3] William S Comanor, 'Pharmaceutical Markets in Japan and the United States' (2022) 16 *International Journal of Economic Policy Studies* 355

[4] Roberto Mazzoleni and Richard R Nelson, 'The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate' (1998) 27(3) *Research Policy* 273

[5] João Henrique Santana Stacciarini, 'Pesquisa e Desenvolvimento (P&D) no Setor Farmacêutico: Avanços, Limitações, Seletividade e Negligência' (2024) 14(1) *Revista Terceiro Incluído* e14109.

[6] David B Resnik, 'Science and Patents' (2020) 29(1) *Metascience* 171.

[7] Joseph E Stiglitz, *Making Globalization Work* (W W Norton 2006) 118.

[8] Dai R and Watal J 'Product patents and access to innovative medicines' (2021) 291 Social Science & Medicine 114479.

[9] Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299 (TRIPS Agreement).

Declaration on the TRIPS Agreement and Public Health 2001, [10] which confirmed that countries may utilise TRIPS flexibilities such as compulsory licensing, government use, and parallel importation to improve access to medicines. [11]

Nigeria faces this balancing challenge in a particularly significant way. As a WTO member with substantial healthcare needs, Nigeria must comply with international intellectual property obligations while ensuring access to essential medicines. The Nigerian patent system is principally governed by the Patents and Designs Act,[12] which establishes the legal framework for patent protection in Nigeria.[13] Although the Act recognises safeguards such as compulsory licensing, there remains limited evidence of their effective practical utilisation. This raises important questions regarding the institutional, economic, and regulatory barriers preventing the effective implementation of TRIPS flexibilities in Nigeria. Nigeria must also consider the wider economic and diplomatic implications of its intellectual property policies. The United States remains home to many of the world's leading pharmaceutical companies, and its innovation-driven pharmaceutical sector depends heavily on strong patent protection to support research and development activities.[14] Consequently, pharmaceutical patent protection continues to play a significant role in shaping global intellectual property standards and influencing developing countries such as Nigeria.

This article adopts a doctrinal legal methodology supported by comparative and policy analysis. It examines international instruments such as TRIPS and the Doha Declaration alongside Nigerian and United States patent laws. The study is guided by the following research questions: to what extent does Nigeria's patent regime balance pharmaceutical innovation with access to medicines? How effective are TRIPS flexibilities within Nigeria's legal framework? What barriers continue to hinder the practical use of compulsory licensing and related mechanisms? The article is divided into five sections. Following this introduction, the second section examines pharmaceutical patent protection and innovation in the United States. The third section analyses the international legal framework under TRIPS and the Doha Declaration. The fourth section evaluates patent protection and access to medicines under Nigerian law. The fifth section examines mechanisms for balancing patent rights with public health needs in Nigeria and proposes legal and policy reforms aimed at improving access to medicines while maintaining compliance with international intellectual property obligations.

[10] WTO, *Doha Declaration on the TRIPS Agreement and Public Health* (adopted 14 November 2001) WT/MIN(01)/DEC/2.
[11] TRIPS Agreement, Article 66, Preamble, and Article 21.
[12] Patents and Designs Act Cap P2 Laws of the Federation of Nigeria 2004
[13] Yue Hu and others, 'Is the United States Still Dominant in the Global Pharmaceutical Innovation Network?' (2013) 8(11) *PLoS One* e77247.
[14] The Act's preamble reads, "An Act to make comprehensive provisions for the registration and proprietorship of patents and designs in Nigeria and other matters ancillary thereto."

1.2 Pharmaceutical Patent Protection and Innovation in the United States

The United States possesses one of the most advanced and influential pharmaceutical patent systems in the world. The U.S. patent system provides extensive legal protection for pharmaceutical inventions, and these protections encourage companies and research institutions to invest heavily in scientific research, knowing that successful innovations will be legally protected for a defined period. Beyond its domestic importance, the U.S. pharmaceutical patent regime has also exercised considerable influence over the development of international intellectual property standards. Through trade policy, international negotiations, and the global dominance of many U.S.-based pharmaceutical corporations, the United States has played a central role in promoting stronger pharmaceutical patent protection worldwide. Patent protection in the United States is governed mainly by the Patent Act (found in Title 35 of the United States Code [Tite 35]), which outlines the requirements for patentable inventions and the legal rights granted to patent holders. Under Section 101 of Title 35, any new and useful process, machine, manufacture, or composition of matter may qualify for patent protection.[15] Pharmaceutical compounds and many biotechnology products fall within the category of "compositions of matter," making them eligible for patent protection under U.S. law. Once a patent is granted, the patent holder receives exclusive rights to make, use, sell, or import the invention for a specific period of time. According to Section 154 of Title 35, the standard duration of a patent is twenty years from the date of filing.[16] During this period, competitors are not allowed to produce or market the patented drug without permission from the patent owner. This temporary exclusivity enables pharmaceutical companies to recover the large financial investments involved in research and development while also generating profits that can be reinvested into future innovation.

The economic justification for this system is closely connected to the high cost and uncertainty associated with pharmaceutical research and development. Pharmaceutical companies often invest billions of dollars into the development of medicines that may ultimately fail during clinical trials or regulatory review. Patent protection therefore serves as a mechanism for reducing investment risks and encouraging continued scientific innovation. However, critics argue that the strong exclusivity granted under the U.S. patent system may also contribute to excessively high medicine prices, thereby limiting affordability and access even within developed countries. The tension between rewarding innovation and ensuring access to medicines therefore exists not only in developing countries but also within the United States itself.

Court decisions have also played a major role in defining the boundaries of patent protection in the United States, particularly in the area of biotechnology. One landmark case is *Diamond v Chakrabarty*,[17] where the United States Supreme Court ruled that genetically engineered microorganisms could be patented because they were the result of human invention rather than natural processes. This decision significantly expanded the scope of patentable biotechnology

[15] 35 USC §101 (2018).
[16] 35 USC §154(a)(2) (2018).
[17] *Diamond v Chakrabarty* 447 US 303 (1980).

inventions and encouraged further research in pharmaceutical biotechnology. At the same time, the case also reflected a broader judicial willingness to extend intellectual property protection into emerging scientific fields. Critics have argued that such expansive interpretations of patentability may strengthen private control over biological materials and scientific innovation in ways that could affect access to healthcare technologies.

Another important case is *Association for Molecular Pathology v Myriad Genetics Inc*, which dealt with the patentability of genetic material. The Supreme Court concluded that naturally occurring DNA sequences cannot be patented because they are products of nature. However, the Court also held that complementary DNA (cDNA), which is artificially created in laboratories, can qualify for patent protection.[18] This decision helped clarify the limits of biotechnology patents while still preserving incentives for innovation in genetic research and pharmaceutical development. The case illustrates the continuing attempt within U.S. patent law to balance scientific innovation with concerns about monopolisation and access to important medical technologies.

A further important feature of the U.S. pharmaceutical patent system is the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act. This legislation was designed to balance the interests of innovative pharmaceutical companies and generic drug manufacturers. On one hand, the Act allows patent holders to extend the effective life of their patents to compensate for the time spent obtaining regulatory approval for new drugs. On the other hand, it introduced a simplified pathway for generic drug approval through the Abbreviated New Drug Application (ANDA) process.[19] The Hatch-Waxman framework therefore creates a balance by providing pharmaceutical innovators with temporary market exclusivity while also ensuring that generic drug manufacturers can enter the market once patents expire. This system ultimately encourages competition, which helps reduce drug prices and expand access to medicines. Despite its innovation benefits, the U.S. pharmaceutical patent system has been criticised for practices such as evergreening,[20] where companies obtain additional patents for minor modifications to existing drugs in order to extend market exclusivity beyond the original patent period. These modifications may involve slight changes in dosage, delivery methods, formulations, or combinations of previously patented compounds. Critics argue that evergreening delays generic competition, prolongs high medicine prices, and allows pharmaceutical companies to maintain monopolistic control over important medicines for extended periods. Such practices have generated significant debate regarding whether the patent system adequately balances innovation incentives with public health interests.

The influence of the U.S. pharmaceutical industry extends beyond domestic patent law and has significantly shaped the global intellectual property system. During the negotiations that led to the adoption of the TRIPS Agreement, developed countries, particularly the United States, strongly

[18] *Association for Molecular Pathology v Myriad Genetics Inc* 569 US 576 (2013).
[19] Drug Price Competition and Patent Term Restoration Act 1984 (Hatch-Waxman Act) 98 Stat 1585
[20] Chukwuebuka Festus Okoli, 'The Patentability of AI Inventions: Navigating the Grey Area Between Human vs Computer Innovation' (2024) 10(2) *Open Access Research Journal of Science and Technology*11.

advocated stronger international patent standards for pharmaceutical products. Many developing countries were therefore required to introduce pharmaceutical patent protection even though several had previously excluded medicines from patentability in order to support local generic production and improve access to affordable medicines. Critics argue that this global expansion of pharmaceutical patent protection disproportionately benefits multinational pharmaceutical corporations while placing financial and institutional burdens on developing countries with weaker healthcare systems.

For countries like Nigeria, the influence of the U.S. pharmaceutical industry presents both benefits and challenges. Strong patent protection may encourage pharmaceutical innovation and facilitate international investment in healthcare and biotechnology sectors. However, strict patent enforcement can also limit access to affordable medicines where large sections of the population depend on low-cost generic alternatives. This tension demonstrates the broader challenge facing the international intellectual property system: how to preserve incentives for pharmaceutical innovation while ensuring that developing countries can respond effectively to urgent public health needs. It is partly in recognition of this challenge that the international legal framework, particularly the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), incorporates certain public health flexibilities aimed at balancing patent protection with access to medicines.

1.3 International Legal Framework Governing Pharmaceutical Patents

The global system that regulates pharmaceutical patent protection is largely shaped by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This agreement forms an important part of the legal framework of the World Trade Organization (WTO). TRIPS represents a major development in international intellectual property law because it establishes minimum standards of protection that all WTO member states must adopt in their domestic legal systems.[21] Its broader goal is to create a more consistent global approach to intellectual property protection while also encouraging international trade and technological innovation. At the same time, however, the agreement has generated significant debate regarding its impact on public health and access to medicines, particularly within developing countries.

One of the most important provisions of TRIPS is Article 27(1), which provides that patents must be available for inventions in all fields of technology. This includes both products and processes, provided that the invention is new, involves an inventive step, and is capable of industrial application.[22] As a result, pharmaceutical inventions such as medicines, chemical compounds, and medical technologies must generally be eligible for patent protection under the laws of WTO member states. Prior to the adoption of the TRIPS Agreement, several developing countries either excluded pharmaceutical products from patentability or maintained weaker patent systems in order to support local manufacturing of generic medicines and improve public access to healthcare.

[21] TRIPS Agreement (n 9).
[22] TRIPS Agreement, art 27(1).

TRIPS significantly changed this position by requiring all WTO members to adopt stronger pharmaceutical patent protection. Although TRIPS strengthens global intellectual property rights, it also recognises the need for flexibility in matters affecting public health. A particularly important provision in this regard is Article 31 of the TRIPS Agreement, which allows governments to authorise the use of patented inventions without the consent of the patent holder under specific circumstances.[23] The mechanism created under this provision is commonly known as compulsory licensing. Through compulsory licensing, governments may permit the production or importation of generic versions of patented medicines when public health needs require such intervention. This mechanism is especially important for developing countries facing health emergencies or widespread inability to afford patented medicines.

While compulsory licensing formally exists within the TRIPS framework, its practical utilisation has often been limited by legal, institutional, and political challenges. Article 31 requires that governments must usually attempt to obtain authorisation from the patent owner on reasonable commercial terms before issuing a compulsory licence.[24] Although this requirement may be waived during national emergencies, situations of extreme urgency, or public non-commercial use, the procedural conditions surrounding compulsory licensing can still be complex and difficult for developing countries to implement effectively. In addition, some developing countries may face political or economic pressure from developed countries and multinational pharmaceutical companies when attempting to utilise compulsory licensing measures. Consequently, the existence of TRIPS flexibilities does not always guarantee their effective practical use. Another important development within the TRIPS framework is Article 31bis, which was introduced to address the challenges faced by countries with limited pharmaceutical manufacturing capacity.[25] Many developing countries lack the technical infrastructure needed to produce medicines domestically, even where compulsory licences are legally available. Article 31bis therefore allows countries with manufacturing capacity to produce and export generic medicines under compulsory licences to countries that cannot manufacture such medicines themselves. Although this amendment represented an important attempt to improve access to medicines, critics argue that the system remains procedurally complex and has not been used extensively in practice. This has led some scholars to question whether the international intellectual property framework adequately addresses the practical realities faced by developing countries.

The importance of public health protections within the international intellectual property system was further emphasised by the adoption of the Doha Declaration on the TRIPS Agreement and Public Health in 2001. The declaration was adopted at a time when many developing countries were facing severe public health crises, particularly the rapid spread of HIV/AIDS, tuberculosis, and malaria.[26] These health emergencies raised serious concerns that strict intellectual property rules were preventing developing countries from obtaining affordable medicines. The Doha

[23] TRIPS Agreement, art 31.
[24] TRIPS Agreement, art 31(b).
[25] TRIPS Agreement, art 31bis.
[26] Doha Declaration on the TRIPS Agreement and Public Health (n 3).

Declaration therefore clarified the relationship between intellectual property protection and public health by affirming that the TRIPS Agreement should be interpreted and implemented in a manner that supports the protection of public health and promotes access to medicines for all.[27] Importantly, the Doha Declaration reaffirmed the right of WTO member states to utilise TRIPS flexibilities, including compulsory licensing and parallel importation, in order to protect public health. The Declaration represented a significant political acknowledgment that intellectual property protection should not operate in a manner that undermines access to essential medicines. Nevertheless, despite this important clarification, substantial inequalities continue to exist between developed and developing countries in their ability to effectively utilise these safeguards. Many developing countries continue to face institutional weaknesses, financial constraints, regulatory limitations, and dependence on imported pharmaceutical products, all of which reduce the practical effectiveness of TRIPS flexibilities.

The interpretation of TRIPS provisions has also been influenced by decisions from the WTO dispute settlement system. One notable example is the case of *Canada – Patent Protection of Pharmaceutical Products*, in which a WTO dispute settlement panel examined Canada's regulatory review exception.[28] This exception allowed generic manufacturers to use patented inventions for the purpose of conducting tests and obtaining regulatory approval before the patent expired. The WTO panel concluded that such limited exceptions could be compatible with TRIPS provided that they do not unreasonably interfere with the normal exploitation of the patent. The decision demonstrated that carefully designed limitations on patent rights may be permissible where they serve legitimate public policy objectives, including the promotion of generic competition and access to medicines.

For developing countries like Nigeria, the TRIPS Agreement and the Doha Declaration provide an important legal foundation for incorporating public health safeguards into domestic patent laws. These international instruments allow governments to respond to public health needs while still respecting the broader framework of intellectual property protection. However, the effectiveness of these safeguards ultimately depends not only on their formal legal recognition but also on the institutional, political, and economic capacity of states to implement them in practice. The continuing gap between legal possibility and practical implementation therefore remains one of the central challenges in balancing pharmaceutical patent protection with access to medicines in developing countries.

1.4 Patent Protection and Access to Medicines Under Nigerian Law

Nigeria's patent system is primarily governed by the Patents and Designs Act, which provides the legal framework for protecting inventions within the country.[29] The Act reflects Nigeria's effort to comply with international intellectual property obligations while also

[27] ibid para 4.
[28] *Canada – Patent Protection of Pharmaceutical Products* (2000) WT/DS114/R (WTO Panel Report).
[29] Patents and Designs Act Cap P2 Laws of the Federation of Nigeria 2004.

maintaining certain mechanisms designed to safeguard public interest and promote technological development. Like many developing countries, Nigeria has attempted to balance the protection of intellectual property rights with the need to ensure that essential medicines remain accessible and affordable to its population. However, although the Nigerian legal framework formally recognises public health safeguards, significant gaps continue to exist between the law on paper and its practical implementation.

Under section 1(1) of the Patents and Designs Act, an invention qualifies for patent protection if it is new, involves an inventive step, and is capable of industrial application.[30] These requirements closely mirror the patentability standards established under Article 27 of the TRIPS Agreement. By adopting similar criteria, Nigeria ensures that its patent regime aligns with international intellectual property standards. Once a patent is granted, the patent holder enjoys several exclusive rights. Section 6(1) of the Patents and Designs Act gives the patentee the legal authority to prevent other persons from making, importing, selling, or using the patented product without authorisation.[31] These rights are important because they allow inventors to benefit commercially from their innovations. In the pharmaceutical sector, such protection helps encourage investment in research and development by ensuring that companies can recover the resources spent on developing new medicines.

The Act also specifies the duration of patent protection. According to section 7(1), a patent remains valid for twenty years from the date the patent application is filed.[32] This duration corresponds with the minimum patent term required under the TRIPS Agreement, thereby ensuring that Nigeria meets its international obligations regarding patent protection. Nevertheless, while compliance with international standards may encourage foreign investment and international cooperation, strong patent protection may also contribute to higher medicine prices where affordable generic alternatives are unavailable. In a country such as Nigeria, where many citizens finance healthcare through out-of-pocket expenditure, the economic impact of pharmaceutical patent protection can directly affect access to life-saving medicines.

Although the Act provides strong legal protection for patent holders, it also includes mechanisms aimed at preventing the misuse of patent rights and protecting public interest. One of the most important of these mechanisms is the system of compulsory licensing, which is provided under section 11 of the Patents and Designs Act and further explained in the First Schedule to the Act.[33] Compulsory licensing allows the government or authorised third parties to use a patented invention without the permission of the patent owner under certain conditions. For instance, paragraph 1 of the First Schedule allows a compulsory licence to be granted when the patented invention is not being worked in Nigeria or where the demand for the patented product is not being adequately

[30] Patents and Designs Act 2004, s 1(1
[31] Patents and Designs Act 2004, s 6(1).
[32] Patents and Designs Act 2004, s 7(1).
[33] Patents and Designs Act 2004, s 11; First Schedule.

met.[34] The purpose of this provision is to prevent patent owners from merely holding exclusive rights without ensuring that the invention benefits the public.

The Act also allows compulsory licences to be issued where patent rights are being used in an anti-competitive manner or where the patented invention is required for the development of another important technological invention.[35] Such provisions reflect the broader policy objective of promoting technological progress while preventing the abuse of patent monopolies. However, despite the existence of these legal safeguards, Nigeria has not effectively utilised pharmaceutical compulsory licensing in practice. Unlike countries such as India, Brazil, and Thailand, which have relied on compulsory licensing mechanisms to improve access to medicines during public health emergencies, Nigeria has rarely operationalised these provisions within the pharmaceutical sector. This implementation gap represents one of the most significant weaknesses in Nigeria's patent system.

Several factors contribute to this limited practical utilisation of compulsory licensing in Nigeria. One major challenge is the country's heavy dependence on imported pharmaceutical products. Even where compulsory licences are legally available, Nigeria's domestic pharmaceutical manufacturing capacity remains relatively weak compared to countries such as India. As a result, the ability to locally manufacture generic versions of patented medicines remains limited. In addition, the effective use of compulsory licensing often requires strong institutional coordination between government agencies, regulatory bodies, and domestic manufacturers, a level of coordination that has not always been fully developed within Nigeria's healthcare and intellectual property systems.

Another mechanism available under Nigerian law is the concept of government use of patented inventions. Under this system, the government may authorise the use of a patented invention for public purposes, including healthcare services and national development projects. Although the patent holder's consent is not required in such circumstances, the law requires that appropriate compensation be paid to the patent owner. This approach is consistent with Article 31 of the TRIPS Agreement, which allows governments to use patented inventions where necessary in the public interest. Government-use provisions may therefore provide an important legal tool during national health emergencies where access to essential medicines becomes urgent. However, the practical effectiveness of such measures still depends heavily on administrative capacity, funding, and regulatory efficiency.

Nigeria has also adopted policies aimed at improving access to essential medicines, particularly because the country relies heavily on imported pharmaceutical products. Legal tools such as compulsory licensing and parallel importation may help address this challenge by reducing the cost of medicines and increasing market access to generic alternatives. However, the use of these measures has often been limited by institutional challenges, regulatory complexities, inadequate

[34] Patents and Designs Act 2004, First Schedule para 1.
[35] Patents and Designs Act 2004, First Schedule paras 2–5.

technical expertise, and concerns regarding compliance with international trade obligations. In some instances, governments in developing countries may also hesitate to utilise TRIPS flexibilities due to fears of diplomatic pressure, trade retaliation, or reduced foreign investment from multinational pharmaceutical corporations and developed countries.

In addition, Nigeria's regulatory environment continues to face several structural difficulties that affect access to medicines. Regulatory agencies such as the National Agency for Food and Drug Administration and Control (NAFDAC) play an important role in ensuring the safety and quality of medicines, yet they often operate under financial and administrative constraints. Weak infrastructure, delays in regulatory approvals, limited research funding, and the prevalence of counterfeit pharmaceutical products further complicate efforts to strengthen domestic pharmaceutical production and improve access to affordable medicines. These practical realities demonstrate that the challenge of balancing patent protection with public health extends beyond legal doctrine into broader institutional and socioeconomic conditions.

Despite these challenges, Nigeria's patent system still provides a legal framework within which intellectual property protection can coexist with public health goals. The existence of compulsory licensing provisions, government-use mechanisms, and parallel importation safeguards demonstrates that Nigerian law formally recognises the importance of balancing innovation incentives with access to medicines. Nevertheless, the effectiveness of these safeguards ultimately depends on Nigeria's ability to strengthen institutional capacity, improve domestic pharmaceutical manufacturing, and develop clearer procedures for implementing TRIPS flexibilities in practice.

1.5 Balancing Patent Rights with Access to Medicines in Nigeria

Balancing pharmaceutical patent protection with the need for affordable medicines remains a major challenge, particularly for developing countries such as Nigeria. Patent protection is important because it encourages pharmaceutical companies to invest in research and innovation. However, when patent rights are too strong or rigidly enforced, they may limit access to life-saving medicines for populations with limited financial resources. The challenge therefore lies not in choosing between innovation and public health, but in developing a legal and policy framework capable of protecting both interests simultaneously.

One important mechanism available to Nigeria is compulsory licensing. This allows the government to authorise the use of a patented invention without the consent of the patent holder under certain conditions. The *Patents and Designs Act* permits compulsory licences where a patented invention is not being sufficiently exploited in Nigeria or where the supply of the product does not adequately meet public demand.[36] This mechanism aligns with Article 31 of the TRIPS Agreement, which allows governments to intervene in the public interest while still requiring that patent holders receive appropriate compensation.[37] Compulsory licensing is particularly important

[36] Patents and Designs Act Cap P2 Laws of the Federation of Nigeria 2004, First Schedule para 1.
[37] Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299 (TRIPS Agreement) art 31.

during public health emergencies where patented medicines remain unaffordable or inaccessible to large sections of the population.

Several countries have successfully used compulsory licensing to improve access to medicines. A notable example is India's decision to grant a compulsory licence to Natco Pharma for the production of a generic version of Bayer's cancer drug Sorafenib. In *Bayer Corporation v Union of India*, the Indian courts upheld the licence because the drug was priced far beyond what most patients could afford.[38] The decision demonstrated that TRIPS flexibilities can be used to address urgent public health needs while remaining consistent with international intellectual property law. However, the Indian experience also highlights an important distinction between countries that possess strong domestic pharmaceutical industries and countries that remain heavily dependent on imported medicines. India's ability to operationalise compulsory licensing was supported by its substantial generic pharmaceutical manufacturing capacity and its relatively developed patent litigation framework. Nigeria, by contrast, has not developed comparable industrial or institutional capacity, making the practical use of compulsory licensing considerably more difficult.

This difference illustrates one of the central problems affecting access to medicines in Nigeria. Although Nigerian law formally recognises compulsory licensing, there is limited evidence of its effective use within the pharmaceutical sector. The reasons for this include weak domestic manufacturing capacity, regulatory inefficiencies, inadequate institutional coordination, limited technical expertise, and concerns about the economic consequences of challenging multinational pharmaceutical companies. In addition, because Nigeria imports a significant proportion of its medicines, compulsory licensing alone may not sufficiently address medicine shortages unless accompanied by broader industrial and regulatory reforms.

Another useful strategy is parallel importation, which allows a country to import patented medicines from markets where they are sold at lower prices. The TRIPS Agreement leaves the issue of exhaustion of intellectual property rights to the domestic laws of member states.[39] By allowing parallel importation, governments can take advantage of price differences across countries and obtain medicines at more affordable costs. For developing countries such as Nigeria, this mechanism may help reduce the cost of essential medicines where domestic manufacturing capacity remains limited. However, parallel importation also requires strong regulatory oversight to ensure the quality, safety, and authenticity of imported pharmaceutical products. In countries where counterfeit medicines remain a significant problem, weak regulatory systems may reduce the effectiveness of this approach.

Voluntary licensing provides another important mechanism for balancing patent protection with public health needs. Under voluntary licensing arrangements, patent holders permit generic manufacturers to produce and sell patented medicines in certain markets, often in exchange for royalties. This approach allows pharmaceutical companies to maintain intellectual property

[38] *Bayer Corporation v Union of India* (2014) 6 SCC 190 (Supreme Court of India).
[39] TRIPS Agreement (n 26) art 6.

protection while expanding access to medicines in low- and middle-income countries. Initiatives such as the Medicines Patent Pool have supported such agreements by facilitating generic production of treatments for diseases such as HIV/AIDS, Hepatitis C, and Tuberculosis.[40] Voluntary licensing may therefore reduce tensions between patent enforcement and healthcare access by encouraging cooperation between multinational pharmaceutical companies and generic manufacturers.

Nevertheless, voluntary licensing also has important limitations. Because such arrangements depend largely on the willingness of patent holders, access to medicines may still remain subject to commercial interests rather than public health priorities. Pharmaceutical companies may restrict the geographic scope of licences, impose production limitations, or exclude certain middle-income countries from licensing arrangements altogether. As a result, voluntary licensing may not always provide a reliable long-term solution for countries seeking broader pharmaceutical independence and sustainable healthcare access.

Finally, encouraging generic competition after patent expiration remains one of the most effective ways of reducing medicine prices. Once patents expire, generic manufacturers may enter the market and offer more affordable alternatives. The experience of the United States under the Hatch-Waxman Act demonstrates how regulatory frameworks can support the timely introduction of generics while still preserving incentives for pharmaceutical innovation.[41] Increased generic competition generally leads to lower medicine prices, thereby improving access for patients and healthcare systems. However, in Nigeria, the benefits of generic competition are often limited by weak domestic manufacturing capacity, dependence on imported pharmaceutical ingredients, inadequate financing, and regulatory delays affecting local pharmaceutical producers.

For Nigeria, improving the effectiveness of these strategies will require broader institutional and structural reforms. Regulatory institutions such as the National Agency for Food and Drug Administration and Control (NAFDAC) must be strengthened to improve drug regulation, quality control, and approval processes. Nigeria must also invest more heavily in domestic pharmaceutical manufacturing capacity in order to reduce reliance on imported medicines and improve long-term healthcare security. In addition, clearer administrative procedures for implementing compulsory licensing and other TRIPS flexibilities would improve legal certainty and allow Nigeria to respond more effectively during public health emergencies. Without such reforms, the existence of public health safeguards within Nigerian law may continue to remain largely symbolic rather than practically effective.

[40] Ellen ‘t Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* (Health Action International 2016) 142.
[41] Drug Price Competition and Patent Term Restoration Act 1984 (Hatch-Waxman Act) 98 Stat 1585.

1.6 Conclusion

This section presents the key findings of the study. The findings are derived from the doctrinal, comparative and policy analysis undertaken in Sections 2 to 5 and are structured directly around the central problem and research questions identified in the introduction: the tension between respecting international pharmaceutical patent obligations strongly shaped by U.S. innovation interests and ensuring affordable access to essential medicines in Nigeria.

1. Nigeria's patent regime formally complies with TRIPS but does not yet achieve an effective balance between innovation incentives and access to medicines: The study finds that the Patents and Designs Act (sections 1(1), 6(1) and 7(1)) mirrors TRIPS standards on patentability and the 20-year patent term and therefore satisfies Nigeria's WTO obligations. However, the core balancing problem remains unresolved in practice. While the Act provides strong exclusive rights for patentees important for attracting foreign investment and respecting U.S. and other innovation-driven interests it offers no differentiated pharmaceutical/access-sensitive framework to mitigate the well-documented effect of such exclusivity on medicine prices in a market where most healthcare expenditure is out-of-pocket. The formal legal balance is therefore tilted toward protection, with insufficient operational counterweights for access.

2. TRIPS flexibilities are formally domesticated but remain practically ineffective in Nigeria: In relation to the second research question, the study finds that compulsory licensing (section 11 and First Schedule), government use, and the deference to national exhaustion for parallel importation (consistent with TRIPS arts. 31, 31bis and 6, as clarified by the Doha Declaration) are present on paper. Yet there is limited evidence of their successful invocation for pharmaceuticals in Nigeria. This contrasts with active use in India, Brazil and Thailand. The gap confirms the problem flagged in the introduction: the mere existence of safeguards does not translate into access. Procedural ambiguity unclear grounds, application process, and royalty/adequate remuneration determination and absence of streamlined administrative guidelines render the flexibilities largely symbolic.

3. The practical barriers to compulsory licensing and related mechanisms are primarily institutional, industrial and regulatory rather than strictly legal: Addressing the third research question, the study identifies a cluster of interrelated barriers that explain non-use. First, weak domestic pharmaceutical manufacturing capacity and heavy dependence on imported finished products and active pharmaceutical ingredients (APIs) mean that even if a compulsory license were granted, local capacity to work the invention at scale is limited unlike India's generic industrial base demonstrated in *Bayer Corporation v Union of India*. Second, fragmented institutional coordination among the Patent Registry, Federal Ministry of Health, Federal Ministry of Industry, Trade and Investment, and NAFDAC, coupled with limited technical and legal expertise on TRIPS flexibilities, inhibits timely, legally defensible action. Third, regulatory constraints funding deficits, approval delays, weak infrastructure, and the high

prevalence of counterfeit medicines undermine both local production and safe parallel importation. These findings directly answer the query about why safeguards are underutilized.

4. Influence of the U.S. innovation model shapes both the opportunity and the constraint for Nigeria: The study finds, consistent with the problem raised in the introduction regarding U.S. influence, that the U.S. system (35 USC §§101, 154; *Diamond v Chakrabarty*; Myriad Genetics; and the Hatch-Waxman Act's balance of patent-term restoration with the ANDA generic pathway) exemplifies how strong exclusivity drives high-risk R&D investment while still institutionalising a credible generic-competition pathway. TRIPS globalised this high-protection model, as discussed in Section 3 (art.27(1)) and confirmed in Canada – Patent Protection of Pharmaceutical Products. For Nigeria, the benefit is a globally incentivised pipeline of new medicines and potential investment/technology-transfer partnerships; the cost is structural pressure to maintain high patent standards without a corresponding Hatch-Waxman-type domestic mechanism to ensure timely generic entry, which amplifies price and access pressures.

5. Access challenges extend beyond patent law and require complementary non-patent mechanisms but those alternatives also have bounded effectiveness in the Nigerian context: The analysis of balancing mechanisms in Section 5 yields a nuanced finding. Parallel importation is legally available and could exploit international price differentials, but its impact is contingent on robust NAFDAC quality assurance, which is currently constrained. Voluntary licensing (including through the Medicines Patent Pool) offers a cooperative, diplomatically less contentious route and has improved access for HIV/AIDS, tuberculosis and hepatitis C elsewhere, yet the study finds it remains discretionary, often geographically restricted, and dependent on patentee commercial strategy, thus unreliable as a sole access strategy. Post-patent generic competition the most sustainable price-reduction mechanism evidenced by the U.S. Hatch-Waxman experience is limited in Nigeria by the same industrial and regulatory deficits noted in Finding 3: weak API capacity, financing gaps, and regulatory delays. The overarching finding is therefore that patent flexibilities alone cannot resolve the access problem identified in the introduction without broader health-system, industrial and governance reforms.

6. TRIPS-compliant, development-sensitive balance is legally feasible but conditional on integrated reform: Overall, the study finds that Nigeria can remain compliant with TRIPS and the Doha Declaration while improving access, as both instruments expressly permit the safeguards analysed. The feasibility of such a balance depends on moving from formal domestication to operationalisation through: (a) legislative clarification of compulsory licensing/government-use procedures, (b) industrial policy to build local production capacity, (c) strengthened regulatory and procurement governance, and (d) strategic use of voluntary and regional (AfCFTA) arrangements. Without this integration, the balancing challenge articulated at the outset will persist despite a TRIPS-consistent statute book.

Pharmaceutical patent protection and access to medicines remain difficult and often competing issues for developing countries such as Nigeria. Patent systems are important because they encourage pharmaceutical innovation by allowing inventors and pharmaceutical companies to recover the substantial financial investments associated with research, development, and regulatory approval of new medicines. Strong intellectual property protection therefore plays a significant role in supporting scientific advancement and the continued development of life-saving drugs. However, the same patent protections that encourage innovation may also contribute to high medicine prices and reduced access to affordable healthcare, particularly in countries where large sections of the population face economic hardship and limited healthcare coverage.

The international legal framework established under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) attempts to balance these competing interests by requiring member states to provide patent protection while also recognising the importance of public health safeguards. Through mechanisms such as compulsory licensing, government use, parallel importation, and voluntary licensing, the TRIPS framework allows developing countries to respond to public health needs without entirely undermining intellectual property rights. The Doha Declaration further reinforced the principle that intellectual property rules should be interpreted in a manner that promotes access to medicines and protects public health.

Nigeria's patent system, particularly under the Patents and Designs Act, formally incorporates many of these public health safeguards. Nevertheless, this study demonstrates that the existence of legal protections alone is insufficient. A major challenge within the Nigerian system is the gap between legal provisions and practical implementation. Although Nigerian law permits compulsory licensing and other TRIPS flexibilities, these mechanisms have rarely been effectively utilised in the pharmaceutical sector. Institutional weaknesses, limited domestic manufacturing capacity, regulatory inefficiencies, technical limitations, and economic dependence on imported medicines continue to reduce the practical effectiveness of these safeguards. The analysis in Sections 4 and 5 shows that balancing pharmaceutical patent protection with public health therefore requires more than legal reform alone; it is closely connected to broader institutional, economic, and developmental conditions.

At the same time, Nigeria must continue to maintain compliance with international intellectual property obligations in order to preserve international trade relationships, encourage foreign investment, and support broader economic cooperation within the global pharmaceutical industry. Ultimately, this study argues that Nigeria can protect public health while still respecting pharmaceutical patent rights and international intellectual property standards. Achieving this balance requires a carefully designed legal and policy framework that makes effective use of TRIPS-compliant safeguards while simultaneously strengthening domestic institutional and industrial capacity. To that end, the following integrated reforms are recommended:

1. **Strengthen the Practical Use of TRIPS Flexibilities:** While Nigerian law recognises compulsory licensing and government use, the procedures for implementation remain unclear

and underutilised. The Patents and Designs Act should be amended to provide clearer administrative guidelines on the circumstances for granting compulsory licences, application procedures, and the methodology for determining adequate compensation to patent holders. Clearer rules would improve legal certainty and enable timely government response during public health emergencies. Institutional capacity must also be developed through coordinated action among the Federal Ministry of Health, Federal Ministry of Industry, Trade and Investment, the Patent Registry, and NAFDAC, including specialised IP units and targeted training programmes to operationalise these flexibilities.

2. **Invest in Domestic Pharmaceutical Manufacturing Capacity:** Nigeria's heavy dependence on imported finished products and active pharmaceutical ingredients (APIs) weakens the utility of compulsory licensing. Strengthening local production would improve medicine security, reduce import dependence, and make TRIPS flexibilities practically meaningful. This requires tax incentives, research grants, infrastructure support, low-interest financing, and public-private partnerships for pharmaceutical research and manufacturing, as well as stronger collaboration between universities, research institutes, and industry to promote local innovation and technology transfer.

3. **Expand Voluntary Licensing and Strategic Partnerships:** Voluntary licensing, including through mechanisms such as the Medicines Patent Pool, can expand access to treatments for HIV/AIDS, tuberculosis, malaria, and Hepatitis C while respecting patent rights. Nigeria should proactively negotiate such agreements to ensure not only lower-cost supply but also long-term technology transfer and local manufacturing development. Regional cooperation through the African Continental Free Trade Area (AfCFTA) should be leveraged to expand pharmaceutical markets, reduce production costs, improve bargaining power with multinational companies, and develop shared manufacturing and regulatory infrastructure.

4. **Strengthen Regulatory Institutions and Market Governance:** The National Agency for Food and Drug Administration and Control (NAFDAC) must be strengthened with adequate funding, infrastructure, and streamlined approval processes to ensure safety, quality, and efficacy and to build public confidence in locally manufactured generics. Complementary reforms should improve transparency in medicine pricing and public procurement, strengthen competition policy to prevent anti-competitive practices and evergreening-related delays to generic entry, and enhance surveillance against counterfeit medicines, which otherwise undermines parallel importation and generic competition strategies.

5. **Adopt an Integrated Intellectual Property and Public Health Policy:** Access to medicines cannot be solved by patent law reform in isolation. Intellectual property policy should be designed alongside public health financing, industrial development, and infrastructure strategies. An integrated approach will better position Nigeria to preserve incentives for pharmaceutical innovation important to U.S. and other foreign partners and to global R&D while ensuring that essential medicines remain accessible and affordable. Intellectual property

protection and public health need not exist as opposing objectives. Through clearer compulsory licensing procedures, stronger regulatory institutions, increased domestic pharmaceutical production, regional cooperation, and strategic use of voluntary licensing, Nigeria can move towards a system that both supports pharmaceutical innovation and improves access to essential medicines within a fair, TRIPS-compliant and development-sensitive legal framework.