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Topic: Balancing Patent Rights and Public Health: The Role of Compulsory Licensing in Improving Access to Essential Medicines in Nigeria

Content

Abstract

The affordability of pharmaceutical products continues to pose serious barrier to healthcare access in many African countries, particularly for low-income populations. In Nigeria, much of the problem stems from the reliance on imported medicines and raw materials, which inflates the cost of treatment. Despite the legal availability of compulsory licensing under both international, regional and national frameworks, its application remains remarkably limited. This study explores the reasons behind the under-utilisation of compulsory licensing provisions as a tool to enhance access to essential medicines. Focusing on Nigeria, the research sets out four main objectives: To examine the procedure of acquiring compulsory licences of patent rights in Nigeria; to determine if compulsory licensing of patent rights can be a means for persons in Nigeria to have easy access to pharmaceutical products; to analyse the reasons for the under-utilisation of compulsory licensing provisions of patent rights in Nigeria; and to recommend a strategy or strategies to address the issue of balancing public health and patent right. This paper employs a mixed-method approach, the study draws on both primary data gathered through interviews, questionnaires and secondary legal and policy sources. A formal application was made to the Nigerian Patents Registrar to confirm the number of applications for compulsory licence that has been filed in the past twenty years, the subject matter of each application and if they were granted. The analysis also considers the relevant provisions of national patent laws, TRIPS Agreement, and the African Continental Free Trade Area (AfCFTA) framework. The findings aim to contribute to the broader discourse on balancing public health and patent right, access to medicine, intellectual property rights, and sustainable healthcare solutions in Nigeria

CHAPTER 1 INTRODUCTION

1.1 Introduction

This chapter introduces the whole research and serves as a footprint. A detailed background to the research is stated and it succinctly addresses the problem being researched upon.

The objectives, limitations, delimitations and significance of the study are clearly addressed in this chapter.

1.2 Background to the study

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition (World Health Organisation, 1948).

The right to health for all people means that everyone should have access to the health services they need, when and where they need them, without suffering financial hardship. No one should get sick and die just because they are poor, or because they cannot access the health services they need. (Ghebreyesus, 2017).

The right to health includes the right to easy accessibility of pharmaceutical products and other health services. In Nigeria, the provision of the constitution which is close to conferring right to health on citizens is the right to life provided in section 33.

One of the principal aim of every business which include pharmaceutical companies, is to make good profit from what they manufacture and or sell. Before getting pharmaceutical products to the market, several expenses would have been incurred from the research and development stage to preclinical research to clinical research to manufacturing and then, labelling. All of these aforementioned stages would normally consume a fortune and as such, the business owner wants to recoup the money invested and make profit. This

makes the business owner want to protect his product by all means from exploitation and as such, approaches the government for protection. The protection of the product's formula from exploitation is referred to as patent and its labelling, trademark.

A patent right is more like a social contract wherein an inventor approaches the government to protect his invention so that another person will not commercially exploit it, the government grants the inventor protection for a specific period of time (often twenty years) while the inventor in exchange for that, discloses the step by step procedure of arriving at his invention so much so that anyone skilled in the industry of such invention can independently recreate the invention with the disclosure as a guide (Sanya, 2021).

In situations such as national emergency, there may be a breach to the above when the government will permit a third party other than the patent holder from manufacturing the product of the patent holder without seeking the consent of the patent holder. This is referred to as compulsory licensing.

1.3 Statement of the Problem

According to a news report published by (Adaramola Z., & Shuaibu, F., 2021), the Nigerian National Office for Technology Acquisition and Promotion (NOTAP) stated that more than 90% of the technology relied upon by the Nigerian state is imported.

The Director General of the office had stated that no nation that is serious about development will fold its hands and allow a continuous importation of technology.

The issue of importation is not restricted to technology in Nigeria. The pharmaceutical industry is not left behind as 70% of drugs used in Nigeria are imported into the country. (Nwogu, 2018)

It is trite that if a country imports more than exports, the country will definitely run at deficit and as such, asides investing heavily in research and

development, compulsory licensing of the imported and patented technology and drugs is to be determined by this paper whether it could aid easy access to medicines.

To evidence the problem, the cholera epidemic will be cited. The number of people who have died as a result of cholera in Nigeria in 2021 is now more than the number of COVID-19 related deaths reported so far.

The cholera death toll in the country hit 3,208 from a total number of 88,704 suspected cases recorded from the beginning of the year till October 3, 2021.

While the number of confirmed COVID-19 cases in the country is 209,546, the COVID-19 related death reported is 2,838, according to figures from the Nigeria Centre for Disease Control. (Adejoro, 2021)

The cholera drugs and even vaccines are produced overseas. Factors such as poverty have reduced the access to these drugs and or vaccines to prevent the disease in Nigeria. It is observed that indigenous pharmaceutical companies prefer to import these drugs when in fact and according to the Patent and Designs Act 1971, they can simply apply for compulsory license of the drugs and vaccines to make it easily accessible and reduce death. The problem is the rationale behind the option to import which makes the drugs inadequate and expensive.

On the other hand, pharmaceutical companies are generally not happy about the compulsory license provision. Their rationale is that it discourages them from investing in new drugs and a undermines their intellectual property right. This paper also seeks to proffer a balance between the public health and patent right in this regard.

1.4 Research Objectives

This research paper intends;

i. To examine the procedure of acquiring compulsory licences of patent rights in Nigeria.
ii. To determine if compulsory licensing of patent rights can be a means for persons in Nigeria to have easy access to pharmaceutical products.
iii. To analyse the reasons for the under-utilisation of compulsory licensing provisions of patent rights in Nigeria.
iv. To recommend a strategy or strategies to address the issue of balancing public health and patent right.

1.5 Research Questions

The above objectives will be properly addressed by answering the following research questions;

i. To what extent do people know the procedure for acquiring a compulsory licence of patent in Nigeria?
ii. Can compulsory licensing of patent rights be a means for persons in Nigeria to have easy access to pharmaceutical products in Nigeria?
iii. What is the rationale for under-utilisation of compulsory licensing provisions of patent rights in Nigeria?
iv. What are the strategies that will address the issue of balancing public health and patent right in Nigeria?

1.6 Significance of the Study

This study is important to the Nigerian society as it assesses the compulsory licensing regime on patent rights in Nigeria and proffers recommendations or solutions to the incessant importation of pharmaceutical products into the country which already has an adverse effect on the country's economy.

1.7 Delimitation of the Study

The research focuses on compulsory licensing of patent rights in Nigeria. Due to the short period within which this research is to be conducted, it will be restricted to the patents registry, thirty-six pharmaceutical companies in Lagos

and Oyo States, Nigeria, officials of the ministry of trade and industry and the judiciary.

1.8 Limitation of the Study

The research is limited to compulsory licensing of patent rights. The research does not cover other areas on compulsory licensing such as copyright.

CHAPTER 2 THEORETICAL FRAMEWORK AND REVIEW OF RELATED LITERATURE

2.1 Introduction

There are several theories on intellectual property. The theories include; natural, incentive/reward, economic/utilitarian, personhood and more recently development theory. This paper intends to focus on the incentive/reward and development theories stating their school of thoughts and juxtaposing same with compulsory licensing.

This chapter moves further to review literature of jurists who have posited on the utility and or benefit of compulsory licensing, non-benefit and the supposed reason compulsory licensing has not been utilised in Nigeria.

2.2 Theoretical Framework

2.2.1 Development Theory

The theory is a new and or emerging theoretical framework in intellectual property. The most influential proponent of this theory is the American economic historian; Rostow, W.

This school of thought according to (Oyewunmi, 2015) posits that intellectual property ought not to be restricted to the good or benefit of the intellectual property right owners alone but extended to the society or public at large.

The theory as it relates to intellectual property takes its root from the several positions taken especially by the World Intellectual Property Organisation on its development agenda.

Higher and higher levels of intellectual property protection inherent in any harmonisation exercise that takes no account of the circumstances of each country, are extremely detrimental to developing countries. Intellectual property rights have to be viewed not as a self-contained and distinct domain rather as an effective policy instrument for wide-ranging socio-economic and technological development. The primary objective of this instrument is to

maximise public welfare. A WIPO Development agenda would obviously need to take into account any possible negative impact on the users of intellectual property, on consumers at large, or on public policy in general, and not just the promotion of the interest of intellectual property owners. It is vital to inject this balance and equity into the various WIPO bodies. (Oyewunmi, 2015, p. 14)

2.2.2 Incentive/Reward Theory

The reward theory is based on the underlying belief that society has a moral obligation to compensate and reward inventors and creators of intellectual works. It thus perceives the conferment of intellectual property rights as a just reward owed and given in return for the exercise of the creative faculties and attendants services to the society.

2.3 Relevance of the Theoretical Frameworks to the Study

The Development theory and the Incentive/Reward theory are both critically relevant to this study as they provide the foundational frameworks for examining the interplay between patent rights and public health, particularly in the context of access to essential medicines in Nigeria.

The Development theory underscores the importance of intellectual property as a tool for achieving broader socio-economic and technological development. It supports the idea that intellectual property protection should serve not only the interests of rights holders but also the public good. This perspective is highly relevant to the study, as it justifies the use of mechanisms such as compulsory licensing to promote public health outcomes. In a country like Nigeria, where access to affordable medicines remains a significant challenge, the Development theory provides a policy and ethical basis for interpreting patent laws in a way that prioritizes public welfare over private commercial interests.

On the other hand, the Incentive/Reward theory explains the rationale behind the grant of exclusive rights to inventors. It highlights the role of intellectual property in encouraging innovation by ensuring that creators are adequately rewarded for their efforts and investments. This theory is relevant to the study as it acknowledges the legitimacy of patent protection in the pharmaceutical industry, but also implies that such protection must be balanced with societal needs, especially when the public's access to life-saving medicines is at stake.

Together, these theories provide a balanced lens through which the study explores the legal, ethical, and policy dimensions of compulsory licensing as a mechanism for reconciling patent rights with the urgent public health needs in Nigeria.

2.4 Exclusivity of Patent rights and the concept of Compulsory licence

A patent does not give a positive right to its proprietor to use the invention but rather only confers the right to exclude others from using the invention for a limited period of time. (Parmar & Ahmed, 2012)

In Nigeria, the grant of patent comes with certain rights conferred on the patentee in respect of the invention, as defined by the claims. These rights are as stated in section 6 (1) of the Patents and Designs Act, which provides that a patent confers upon the patentee the right to preclude any of the following acts:

i. Where the patent has been granted in respect of a product, the act of making, importing, selling or using the product, or stocking it for the purpose of sale or use; and
ii. Where the patent has been granted in respect of a process, the act of applying the process or doing, in respect of a product obtained directly by means of the process, any of the acts mentioned in paragraph (i) above.

The carrying out of any of the above listed acts, by way of manufacturing or otherwise producing the patented product or a product obtained through use of a patented process, importing it from another country, distributing it by way

of trade or commerce or stocking it for purpose of sale are all prohibited unless carried out with the consent or authority of the patentee. (Oyewunmi, 2015)

It should be further noted that unlike copyright which protects individual expressions even of the same idea, patents confer broader protection almost akin to monopoly rights. This is because the rights conferred on the patentee, subject to certain exceptions, extend to the use or exploitation of the invention by anybody, including even an inventor who independently carried out inventive effort to produce an identical invention. In determining the limits of the patentee's rights, recourse is to be made to the claims as the scope of the protection conferred is determined by the claims. Once the act of a third party falls within the scope of the claims, this provides a basis for an infringement action. (Oyewunmi, 2015)

The principles above are illustrated in the case of Agborofo v. Grain Haulage and Transport Limited (1997-2003) 4 Intellectual Property Law Reports (I.P.L.R) 139 where the court stated that it was not necessary for infringement that there should have been actual copying of the patentee's device or the patent specification. If the alleged infringement was substantially what was claimed by the inventor in his claims, although, arrived at quite independently, there would be infringement. The court held that on this principle that even if the defendant independently and without the knowledge of the existence of the plaintiff's invention, manufactured a plastic boiler whose boiling mechanism consisted of a component which was perforated, mounted on a stainless steel and functioned as an out of defendant would still be liable to the plaintiff for the infringement of his patent because those were the key components of the plaintiff's invention which were covered by his claims. (Oyewunmi, 2015)

2.5 Literature review

Literature will be reviewed regarding the position of authors which posits that compulsory licence is beneficial to the society and can aid development while on the other hand, literature will be reviewed on the otherwise position of authors.

2.5.1 The Advantages and or utility of compulsory licence

i. Rapid technical progress through dependent patents:

There is barely any invention that something related has not been done in the past in that same industry. Most of the inventions are a step forward of the state of the art and some an improvement of a subsisting patent.

In this instance, the new inventor (which covers part of a subsisting patent) who owns the improved invention will have to seek a licence from the owner of the earlier patent. Both parties (the earlier inventor and the improved patent holder) are both at crossroads because they need each other. The rationale for this is that; the improved inventor cannot proceed to work on his invention unless the earlier inventor come to terms with him while on the other hand, the earlier inventor cannot proceed to use the improved invention unless he obtains the licence of the improved work from the new inventor. The set of persons who are at the receiving end is the public especially where the improved invention is beneficial.

The law on compulsory licensing of patents will come into play here as if both parties have been unable to come to terms, both of them may be subjected to the compulsory licence provision in the interest of the public.

When the parties are forced to agree as to terms which are usually a cross licence or based on royalties, the public enjoys the improved invention and another entity can still later on improve on the improved invention which is all still in the interest of the public. The aforementioned is the rationale that led to the reasoning of (Abbas, 2013) where the author stated that the use of compulsory licensing for patents will help in generating rapid technical progress.

Sometimes, delay in development of important technology is caused due to deadlocks between the improver and the original patentee. For instance, "holdup problems" occurred in the Wright Brothers and Marconi cases. Similarly, the broad Edison lamp patent slowed down progress in the incandescent lighting field. Compulsory licensing can be used as an effective tool to resolve these deadlocks by pressurising the original patentee to come to the terms of an agreement with the improver. It can therefore help in generating rapid technical progress. (Abbas, 2013)

Relating this to Nigeria, the researcher is of the position that the brilliant minds in the country (Nigeria) that are interested in innovating especially those from the eastern part, can enjoy the provision of compulsory licensing by improving on previous patents that are subsisting while they apply for licence from the patent holders and in the instance they do not reach an agreement, they can apply to the court for such.

It is pertinent to note that the Patents and Designs Act, 1971 in Nigeria makes provision for compulsory patent in circumstances of dependent patents. This is provided for in section 2, part 1 of the first schedule to the Act.

ii. **Its use in the pharmaceutical industry to improve access to drugs at affordable prices:**

Jurists have been of the position that the proper use of compulsory licence of patent can improve the access to drugs at affordable prices especially in developing countries.

Although some jurists have countered this position stating that the compulsory licence of drugs will amount to production of counterfeited drugs. The counter position will be fully discussed in subsequent paragraphs under the non-beneficial arguments of compulsory licence of patents.

The granting of patent rights motivates monopolistic pricing. A patent holder who dominates the market is expected to cut output and raise prices, a profit increasing move, which reduces both consumer and social welfare. Furthermore, the desire to retain monopoly profits and corporate goals of research may induce the patent holder to refrain from reaching an agreement on authorising licences voluntarily. For this reason, it is necessary to have access to compulsory licences to promote production and distribution of cheaper generic medicines in poor countries.

On one hand, the main benefit of compulsory licences is that they introduce the dynamic effects of competition. Hence, by exerting competitive pressure on the originator firm's prices, compulsory licences may increase the affordability and accessibility of essential medicines. (Niesporek, 2015)

Nigeria imports 70% of its pharmaceutical drugs and active pharmaceutical ingredients from mostly China and India. (Maina, 2020). Naturally, prices of imported products are on the high side which limits its access to the rich and middle class members of the Nigerian society. The grant of compulsory licence to local pharmaceutical companies in Nigeria will improve access to drugs in the country and the price.

A study conducted by (Urias & Ramani, 2020) reveals that the use of compulsory licence for patents has led to access to drugs and reduced price of the drugs. This will be discussed below.

The authors (Urias and Ramani, 2020) in their journal article gave several examples (such as India and Ecuador) of where the utility of compulsory licence of patent led to decrease in price of drugs.

i. In 2012, India granted compulsory licensing to local companies to make Sorafenib which is a drug for cancer treatment. This grant of compulsory licence led to reduction of the price variation at 96.86% of the drugs.
ii. Also in 2012, Ecuador granted compulsory licence to its local companies to make Abacavir 600 mg and Lamivudine 300 mg meant for Human immunodeficiency virus HIV and Acquired immunodeficiency syndrome

AID. This led to the price variation to 74.98% of the price of the aforementioned drugs.

Another author who is of the same position with the earlier authors and whose work has been reviewed above is Muhammad Zaheer Abbas, who in the journal paper (Abbas, 2013) stated that compulsory licensing of pharmaceutical patents sometimes becomes inevitable to save lives of the populace by ensuring accessibility of drugs at affordable prices; it can be used to break up monopolies and cartels, which are some of the abuses of patent rights. (Abbas, 2013)

Going forward, authors have also posited that compulsory licence of patents could be used as a tool to threaten pharmaceutical companies to reduce the price of their drugs which will lead to access to drugs for the lower class in the society. This position was held by Urias & Ramani (2020) in their article where they stated that the utility of compulsory licensing threats as a tool to reduce drug prices in negotiations with patent holders is widely acknowledged. However, the effectiveness of the actual granting of compulsory licences on drug affordability is usually assumed rather than substantiated by real evidence. To provide further insight, this systematic review gathered and studied data on price changes brought about through the issuance of compulsory licensing. Our evidence strongly suggests that compulsory licensing is indeed an effective mechanism to achieve price reductions of patented medicines". (Urias & Ramani, 2020)

2.5.2 Disadvantages of compulsory licensing of patent rights

i. It discourages investment in research and development:

The rationale for intellectual property rights (especially patent and copyright) is that a creator's work is protected for a specific period of time wherein during that time of protection, the creator enjoys exclusivity of exploring the work so that he can recoup the funds and compensation for time spent in creating the work.

Particularly, a patent right is more like a social contract wherein an inventor approaches the government to protect his invention so that another person will not commercially exploit it, the government grants the inventor protection for a specific period of time (often twenty years) while the inventor in exchange for that, discloses the step by step procedure of arriving at his invention so much so that anyone skilled in the industry of such invention can independently recreate the invention with the disclosure as a guide (Sanya, 2021).

Against this background which is more of a contract between the government and the creator, the creator invests his funds and time into making a work with the hope to recoup during the years of exclusivity. A creator whose work is compulsorily licensed will naturally feel cheated that the contract between himself and government is being breached and might not even be able to recoup his funds injected into the research and development as the beneficiary of the compulsory licence will make similar work and will be in the same market as the initial creator. This will not encourage subsequent creatives to create a work.

The above is the position of (Agarwal, Reddy, & Balaram, 2020) where the authors posited that by granting compulsory licence, the incentive to create is killed and as such the society suffers more. A person who is granted compulsory licence reaps the benefits of a product without any contribution to its research, invention and development. (Agarwal, Reddy & Balaram, 2020)

However, this researcher is of the opinion that that even though compulsory licensing might be an incentive-killer, creators can recoup their funds through sales in developed countries.

ii. It leads to counterfeit products which has adverse effect on the consumers and or public:

Several authors have posited that compulsory licensing of an invention or a work does not in the real sense transfer technology or know-how. It only grants the

licensee the right to access the claims (if patent) and the right to adapt or translate or reproduce (if copyright).

A Compulsory licence only grants the permission to produce the protected product and does not in any way guarantee transfer of technology or know-how. This means that the licensee might face difficulty or it might even be impossible for him to produce and sell the same quality product at a price lower than the price at which the originator was selling them. The application which is filed for granting Compulsory license, must contain the description as to how the product may be manufactured, however this need not be the most efficient process. At times, such processes are protected through 'know-how' or 'trade secrets' instead of patents, or even by a separate patent owned by another company. (Bagri & Tiwari, 2017)

CHAPTER 3 LEGAL FRAMEWORK

3.1 International Legal Framework

3.1.1 Paris Convention

Article 5A(2) of the Paris Convention lays the foundation for the legal framework on compulsory licence.

The article gives members of the union the right to enact legislative measures for the grant of compulsory licence in order to prevent the abuse exclusivity right conferred by patent. The provision particularly gives an instance of when an inventor patents an invention but refuses to mass produce and make it useful to the society.

3.1.2 Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)

In order to compliment the Paris convention and balance the interest of a patent holder and public health, the World Trade Organisation in Article 31 of TRIPS set the standard.

By this provision, where the law of a nation permits compulsory licencing, the following must be respected:

i. The grant of such is to be determined on case to case basis.
ii. There have been efforts by the Applicant to obtain the licence voluntarily on reasonable commercial terms but same was refused. This requirement may be waived in instances of national emergency or other extreme urgency or in cases of public non-commercial use. In cases of national emergency or other extreme urgency, the patent holder is to be notified as soon as reasonably practicable.
iii. The scope is limited for the purpose for which it is granted, non-exclusive and non-assignable.

iv. It can only be granted in respect of the domestic market of the member nation granting the licence.

v. The patent holder shall be paid adequate remuneration in the circumstance of each case, taking into account economic value.

vi. The decision granting compulsory licence and remuneration to be granted to the patent holder shall be subject to judicial review.

3.1.3 Doha Declaration

Developing countries had raised concerns regarding their limitations on compulsory licence of pharmaceutical products as it related to Article 31 of TRIPS as they did not have the manufacturing infrastructure to produce locally thereby making access to essential medicines tough.

As a result of this, the World Trade Organization (WTO) issued the Doha Declaration on the TRIPS Agreement and Public Health in November 2001. This Declaration marked a significant reaffirmation of the rights of WTO member states to prioritize public health over private patent rights, particularly in the area of pharmaceuticals.

It reinforced the view that patent protection should not become a barrier to access to affordable medicines, particularly in developing and least-developed countries grappling with public health crises such as HIV/AIDS, tuberculosis, malaria, and other epidemics.

The key contributions of the Doha Declaration are:

i. Affirmation of Public Health Priority

The Declaration clearly states that:

> "The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health."

This reaffirmed that WTO members have the sovereign right to use TRIPS flexibilities including compulsory licensing and parallel importation to ensure access to medicines.

ii. Freedom to Determine Grounds for Compulsory Licensing

Doha confirmed that countries can freely determine the grounds on which compulsory licences are granted. This means a country may issue such a licence for any legitimate reason, including high pricing, supply shortages, or unmet medical needs, without requiring justification to the WTO or patent holders.

iii. Right to Define "National Emergency"

The Declaration recognizes that each member has the autonomy to define what constitutes a national emergency or extreme urgency. Importantly, it explicitly mentions public health crises like HIV/AIDS as examples of such emergencies.

iv. Addressing the Export Restriction Problem (Paragraph 6 Solution)

Article 31(f) of TRIPS limits compulsory licenses to predominantly domestic supply, posing a major hurdle for countries without pharmaceutical manufacturing capacity. To resolve this, Paragraph 6 of the Doha Declaration acknowledged this challenge and led to the creation of a mechanism allowing exports of generic medicines under compulsory licences to countries in need.

This solution was later formalized in Article 31bis of TRIPS, enabling countries with manufacturing capacity to produce and export medicines to those lacking such capabilities, under specific safeguards.

3.2 National Legal Framework

Examination of Compulsory licensing under the Patent and Design Act, 1971

Section 11 of the Patents and Designs Act refers to the first schedule of the same Act to cover the provisions of compulsory licensing.

As earlier stated and in accordance with Part I, of the first schedule of the Patents and Designs Act, a compulsory licence can be granted upon an application made to Court. The court that is vested with jurisdiction to entertain such application according to section 32 of the Act (Interpretation section) is the Federal High Court of Nigeria.

An application for compulsory licence can be made after the expiration of four years from the filing of a patent application or three years after the grant of the patent application, whichever period last expires. The provision expressly states the grounds upon which such application could be made. Which are;

(a) that the patented invention, being capable of being worked in Nigeria, has not been so worked

(b) that the existing degree of working of the patented invention in Nigeria does not meet on reasonable terms the demand for the product

(c) that the working of the patented invention in Nigeria is being hindered or prevented by the importation of the patented article

(d) that by reason of the refusal of the patentee to grant licences on reasonable terms, the establishment or development of industrial or commercial activities in Nigeria is unfairly and substantially prejudiced.

Asides the grounds stated above, the Act in sections 2 and 3, first schedule, makes provision for compulsory licence in situations of dependent patents. The section states that if an invention protected by a patent in Nigeria cannot be worked without infringing rights derived from a patent granted on an earlier application or benefiting from an earlier foreign priority, a compulsory licence may be granted to the patentee of the later patent to the extent necessary for the working of his invention if the invention;

(a) serves industrial purposes different from those served by the invention which is the subject of the earlier patent; or

(b) constitutes substantial technical progress in relation to that last-mentioned invention.

The section went further to state that if the two inventions mentioned above serve the same industrial purpose, a compulsory licence may be granted under that paragraph only on condition that a compulsory licence shall also be granted in respect of the later patent to the patentee of the earlier patent, if he so requests.

Going forward, section 5 of the first schedule states that an application for compulsory licence can only be granted by a court after the applicant had earlier approached the patentee for a voluntary licence but they were unable to agree on reasonable terms and within reasonable time. The provision states that a compulsory licence shall not be granted unless the applicant-

(a) satisfies the court that he has asked the patentee for a contractual licence but has been unable to obtain such a licence on reasonable terms and within a reasonable time; and

(b) offers guarantees satisfactory to the court to work the relevant invention sufficiently to remedy the deficiencies (or to satisfy the requirements) which gave rise to his application.

The unclear or ambiguous word in the above quoted section here is the word "reasonable terms' ' and "reasonable time.

This in the researcher's opinion should not be much of an issue when in fact the application is to be filed before a court. A court is meant to exercise its discretionary powers to address this. Moreover, application for compulsory licence is based on case to case basis with different facts. Hence, the Act cannot state a flat time lag that will be a reasonable time or term.

Sections 8, 9, 10 and 11 of the first schedule to the Act stipulates the guidelines for the court and what the patentee can do to vary or cancel the compulsory licence granted by the court.

Section 8 states that upon hearing of an application for compulsory licence, the court must first decide whether a compulsory licence may be granted and shall then if it decides in favour of the grant and the parties cannot agree on the terms, proceed to fix the terms (including adequate royalties having regard to the extent to which the relevant invention is to be worked) which shall be deemed to constitute a valid contract between the parties.

Section 9 states that upon application of the patentee, the court may cancel a compulsory licence if;

1. the licensee fails to comply with the terms of the licence; or
2. the conditions which justified the grant of the licence have ceased to exist, so however that in that latter case a reasonable time shall be given to the licensee to cease working the relevant invention if an immediate cessation would cause him to suffer substantial damage.

Section 10 states that upon the application of the patentee or licensee, the court may vary the terms of a compulsory licence if new facts justify the variation, and in particular (without prejudice to the generality of the foregoing) if the patentee has granted contractual licences on more favourable terms.

Section 11 states that where the court grants, cancels or varies the terms of a compulsory licence, the proper officer of the court shall inform the registrar, who shall register the grant, cancellation or variation without fee and the grant, cancellation or variation shall have no effect as against third parties until it has been registered.

The seemingly provision that might appear unclear or contradictory is section 13 to the first schedule where it is stated that the Minister can grant compulsory licence before the time earlier stated in section 1. The provision states;

"13. The Minister by order in the Federal Gazette may provide that, for certain patented products and processes (or for certain categories thereof) declared by the order to be of vital importance for the defence or the economy of Nigeria or for public health, compulsory licences may be granted before the expiration of the period mentioned in paragraph I above and may permit importation".

The shortcoming in the aforementioned provisions is that the Act made specific mention of the word "application" but did not specify the exact type of application. It is pertinent to note that to commence an action in a federal high court in Nigeria, this can be done by either filing a writ of summons, originating summons, originating motion or petition.

Order 53 rule 1(2) of the Federal High Court (civil procedure) rules, 2019 provides that applications such as this must be commenced by an originating motion which same must be served on the patent registrar.

From the foregoing, the researcher does not find any provision of the Act that is cumbersome or rigorous. The procedure and grounds for the application is well spelt out in the first schedule to the Act.

However, a subsidiary legislation known as the Patent Rules, 1971 has stylishly established that an application for compulsory licence of patent can be filed to the Registrar of Patents Registry. Rule 36 of the Patent Rules states;

"An application for the grant of a compulsory licence under Part I of the First Schedule to the Act shall be made on Form 7. Such application shall be accompanied by an unstamped copy thereof and a statement in duplicate setting out fully the nature of the applicant's interest and the facts upon which he bases his case. Copies of the application and the statement of the case shall be transmitted by the registrar to the patentee".

This is a sharp distinction from what is provided for by the Patents and Designs Act, 1971. The Act only provides for the situation where a court can and the Minister can grant compulsory licence.

CHAPTER 4 METHODOLOGY, DATA PRESENTATION, ANALYSIS AND INTERPRETATION

4.1 Methodology

4.1.1 The Research Design

The mixed research method was adopted in this research. More specifically, the action research design is adopted. This was done by administering questionnaires and conducting interviews with judicial officers, managing directors of pharmaceutical companies and officials of the Ministry of Trade, Industry and Commerce. Going forward, the researcher made an application to the patents registry and federal high courts in Lagos and Ibadan requesting for applications of compulsory licence that was made to their office within the year 2002 till 2022 and details of any that was granted.

4.1.2 Population and Sampling Techniques

This paper focuses its population on the Judiciary (Court officials), patents registry and manufacturing pharmaceutical companies.

Nigeria has 115 manufacturing pharmaceutical companies (Pharmapproach.com, 2021) but this research will focus on thirty-six of these companies which are based in Lagos and Oyo States, Nigeria because Lagos state is known as the commercial hub of the country while Ibadan which is the capital of Oyo state is the largest city in West Africa. The primary data is obtained directly from the patents registry while the secondary data is obtained from journal publications and online articles on the subject of this paper. The probability sampling technique is adopted in this research.

4.1.3 Data Collection Instruments

To conduct this research, the researcher made use of questionnaires, a set of interview guide, and two sets of formal applications addressed to the Patents registry and Federal High Court through the Court officials. The applications made to the Federal High Courts and patents registry were to request for data on compulsory licence that was made to their office.

4.3 Data Presentation and Analysis

Interview guide, questionnaires and formal applications served as the instrument used in data collection. Out of forty pharmaceutical companies in Ibadan, Oyo State and Lagos State that were approached, thirty-six were receptive to participate in the research by answering questions posed to them by the researcher.

The data are presented and analysed using tables, figures and narratives to answer the questions posed in this research.

i. **To what extent do people know the procedure for acquiring a compulsory licence of patent in Nigeria?**

From the perspective of Court officials, they both agreed that they are aware of the compulsory licences of patent rights in Nigeria. When asked in what situation can a patent by a third party be used without consent, one of them indicated that;

In a situation where licence is granted to a third party to use a patented product or a product awaiting patent, and such approval is without the consent of the patentee.

The other Court official stated three situations;

In response to a national health emergency within the country concerned or overseas. To prevent the abuse of a patent by the inventor or patentee. Where International law allows the use of such patent as long as it is not prejudicial to the legitimate interests of the patent owner.

From the perspective of officials of the Ministry of Trade, Industry and Commerce, one of them stated that when the government grants compulsory licences to the third party, education and private purposes. Another official

answer is that patent rights can be used without consent when its use is for education, private use and or compulsory licence.

From the above, officials of the Ministry of Trade, Industry and Commerce gave further grounds for utilising patent rights by third parties without consent. One common response was the application for compulsory licence. Also, it was observed that a patent can be utilised without the consent of the patentee for educational and private purposes.

Further, when asked regarding the process of applying for compulsory licensing, both Court officials indicated being aware and knowledgeable about the procedure of filing for a compulsory licence. One of the Court officials simply referred the researcher to parts I & II of the patents and design act (LFN 2004).

As regards the awareness of compulsory licence provisions in Patents and Designs, one of the Court officials stated that section 11 and the first schedule to the patent and design act provide for the grant of compulsory licence of a patent in deserving cases.

The above shows that there is legislation that states the condition and procedure for filing an application for compulsory licensing. Also, one of the officials in the Ministry of Trade, Industry and Commerce stated that compulsory licence can be made by an application.

Table 1: Pharmaceutical companies perspective on awareness of compulsory licence of patents

S/N	QUESTIONS	RESPONSE	FREQUENCY	PERCENTAGE (%)
1	Are you aware of the instance where a patent right can be	No Yes	30 6	83.3 16.7

	used by third parties without the consent of the owner?			
2	**In what situations, if any?**	**When the owner rejects** **National emergency** **No response**	**3** **1** **2**	**50** **16.7** **33.3**
3	**Are you aware of compulsory licensing? What is involved in the process?**	**No** **Yes**	**30** **6**	**83.3** **16.7**
4	**Are you aware of compulsory licence provision in the patents and design act?**	**No**	**36**	**100**
5	**Have you ever tried to apply for a compulsory licence of patent right?**	**No** **No response**	**34** **2**	**94.4** **5.6**
	Total		**36**	**100**

Table 1 presents results on Pharmaceutical company's perspectives on the awareness of the procedure of acquiring compulsory licence of patents. It is shown that almost all of the respondents 30 (83.3%) indicated that they are not aware of instances where a patent right can be used by third parties without the consent of the owner, while the other 6 (16.7%) signified that they are aware of instances where a patent right can be used by third parties without the consent of the owner.

Among those who indicated to be aware of instances where a patent right can be used by third parties without the consent of the owner, 50% indicated that when the original patent owner rejects the use, 33.3% gave no response, while the other 16.7% indicated national emergencies calls for use of patent right without the consent of the owner.

Further, it is shown on Table 1 that majority of the pharmaceutical companies which a total number of 30 (83.3%) indicated that they are not aware of compulsory licensing and the process involved, while the other 6 (16.7%) signified that they are aware of compulsory licensing, but not aware of the process involved.

In addition, it is shown that all of the pharmaceutical companies (100%) indicated that they are not aware of compulsory licence provisions in the patents and design act. Finally, an overwhelming proportion of the pharmaceutical companies which is 94.4% indicated that they have never tried to apply for a compulsory licence of patent right.

ii. Can compulsory licensing of patent rights be a means for persons in Nigeria to have easy access to pharmaceutical products in Nigeria?

Among the Court officials, a question was posed by the researcher on their thoughts on compulsory licensing and if it can aid the easy access of Pharmaceutical products in Nigeria.

One of the Court officials, stated that;

It is my view that it can aid ease access of pharmaceutical product in Nigeria in the sense that it may aid fast improvement to medicine. However, this will not be without its side effect to the economy and health as it might open doors for piracy and counterfeiting.

The other court official also said;

Yes, it will encourage accelerated development in the field of pharmacy and medicine. Apart from access, there will be additional advantage of affordability.

From the responses, it is noted that there is unanimous agreement by the Court officials regarding the advantage of having compulsory licensing. It was affirmed that truly, compulsory licensing makes it easy to access Pharmaceutical products in Nigeria. Apart from this, it was also reported that the easy access to the products provides an opportunity to fast improvement of the medical and Pharmacy field in Nigeria. There was an assertion that compulsory licensing makes it possible for the Pharmaceutical industry in Nigeria to develop rapidly, and subsequently makes the drugs affordable by the general populace.

While the advantages were stated, one of the court official equally highlighted some of the disadvantages of compulsory licensing. The first disadvantage was indicated to be the side effect on the economy and the second is the opportunity it provides for piracy and production of counterfeit drugs. The court official explained further that already we have several pirated and counterfeited drugs allegedly from the south-eastern Nigeria, in the instance where compulsory licence is granted, former employees of the licensee would have seen the procedure and might want to replicate the same, leading to counterfeited products.

In response to the same question on compulsory licence aiding easy access to pharmaceutical products, one of the officials of the ministry of trade, industry and commerce, stated that compulsory licence can aid easy access especially where the patent holder lacks the capacity to commercialise the invention that relate to pharmaceutical product.

The other two officials from the same ministry (both Registrars in Patent Office) also agreed in the affirmative that compulsory licences can aid easy access of Pharmaceutical products in Nigeria. It was further opinionated that having a compulsory licence could give an opportunity to commercialise the invention of products in the Pharmaceutical industry. This would subsequently contribute positively to the economy of the nation.

Table 2 presents distribution to pharmaceutical companies as regards their position on compulsory licensing being a tool for easy access to Pharmaceutical products in Nigeria.

Table 2: Compulsory licensing as easy access to Pharmaceutical products

Response	**Frequency**	**Percentage (%)**
No	3	8.3
Yes	21	58.3
Maybe	8	22.2
I think so	4	11.1
Total	**36**	**100**

From Table 2, it is shown that more of the respondents 21 (58.3%) agreed that compulsory licensing would grant easy access to Pharmaceutical products in Nigeria, 8 (22.2%) indicated that compulsory licensing may lead to easy access to Pharmaceutical products, 4 (11.1%) thinks it will grant easy access to Pharmaceutical products, while the other 3 (8.3%) signified that compulsory licensing would not grant easy access to Pharmaceutical products. From the distribution, it is discovered that more than average of the Pharmacists indicated that compulsory licensing ensures easy access to Pharmaceutical products in Nigeria.

The researcher went further to ask the pharmaceutical companies if they have the capacity to manufacture pharmaceutical products in large quantity. The result is as shown in table 3 below;

Table 3: Capacity of pharmaceutical companies to manufacture in large quantity

Response	**Percentage (%)**
No	74.5
Yes	25.5
Total	100

From Table 3, it is shown that a majority of the respondents (74.5%) stated that they do not have the capacity to manufacture pharmaceutical products in large quantity while (25.5%) indicated that they do have the capacity. From the distribution, it is discovered that more than average of the Pharmaceutical

companies stated they do not have the capacity to manufacture in large quantity.

iii. Recommend a strategy or strategies to address the issue of balancing public health and patent right

In answering this, a staff of the Ministry of Trade and Industry answered thus:

I concede that having access to medicines should be a fundamental right which should override every law or any other form of right. I have two suggestions on how to balance public health and patent right. First, the TRIPS flexibilities should be domesticated into the Nigerian law. Second, Patent owners whose pharmaceutical products would be subject of compulsory licence should be paid by the Government. The exact sum that the patent owner ought to make should be paid to the Patent owner by the Government just as we have in fuel and electricity subsidy.

4.4 Application(s) for compulsory licence in 2002 - 2022 in Nigeria

It is pertinent to state again that compulsory licence can only be applied to and granted by either the Minister for Trade, Industry and commerce (acting directly or through the Patent registrar) or the judge of the Federal High Court.

To ascertain whether there has ever been any application and or grant of a compulsory licence of patent right in Nigeria within 2002 - 2022, an application was written to the Ministry of Trade, Industry and Commerce through the Patents Registrar to furnish the data.

According to a staff of the patent registry, in the past twenty years, the only application which was made and granted is contained the Federal Republic of Nigeria official Gazette, No. 18, volume 101 dated the 19th March, 2014 with short title "Use of Patents for service of Government Agencies (Independent National Electoral Commission) Order, 2014.

In exercise of the powers conferred on the Minister of the Federal Republic of Nigeria by Paragraph 15 of Part II of the First Schedule to the Patents and Design Act, CAP P2 LFN 2004, granted the Independent National Electoral Commission or any person authorised by it to use the Patents and Designs of some inventions. A copy of the gazette where the compulsory licence was published is attached to this paper.

On the other hand, from the interview conducted with the Court officials which are in charge of filing and litigation confirmed that there has not been any application of such.

4.5 Findings

The research findings are;

i. Compulsory licence is a means to easily access pharmaceutical products.
ii. Majority of the pharmaceutical companies do not have the capacity to manufacture pharmaceutical products in large quantity.
iii. Majority of pharmaceutical companies in Nigeria are not aware of the compulsory licence provisions.
iv. Compulsory licence of patent rights appears to be a technical area which many professionals find the procedure tedious to engage in.
v. Within 2002 - 2022, only one compulsory licence application was filed and granted in Nigeria.
vi. Compulsory licence can be a strategy to mitigate the importation of pharmaceutical products in Nigeria.

vii. There are practicable strategies to balance public health and patent right.

CHAPTER 5 CONCLUSION AND RECOMMENDATIONS

5.1 CONCLUSION

This research has critically examined the role of compulsory licensing as a mechanism to improve access to pharmaceutical products in Nigeria, with a focus on patent rights, legal frameworks, and the operational capacities of pharmaceutical companies. The study adopted a mixed research methodology, combining qualitative interviews with judicial officers and ministry officials, alongside quantitative data gathered from pharmaceutical companies and official records.

Findings revealed that while compulsory licensing is recognized by judicial and trade officials as a potentially effective tool to enhance access to medicines, awareness and understanding of the procedure among pharmaceutical companies remain low. Most companies surveyed were not aware of the provisions of compulsory licensing in the Nigerian Patents and Designs Act, nor had they attempted to apply for compulsory licenses. This lack of awareness, coupled with limited manufacturing capacity, poses significant challenges to the practical utilization of compulsory licensing as a strategy for local pharmaceutical production and affordable medicine availability.

Furthermore, the study established that only one compulsory licence application was made and granted in Nigeria between 2002 and 2022, underscoring the rarity of its use despite its potential benefits. Judicial officers and ministry officials generally agreed that compulsory licensing could foster faster development and greater affordability in the pharmaceutical sector, yet concerns about economic impacts and risks of piracy and counterfeiting were also noted.

The research concludes that compulsory licensing can be an important instrument for balancing patent rights with public health needs in Nigeria, but its effectiveness is constrained by limited awareness, procedural complexities,

and manufacturing capacity. Therefore, strategic interventions are needed to strengthen the legal, institutional, and industrial frameworks to make compulsory licensing a viable and sustainable option for improving pharmaceutical access.

5.2 RECOMMENDATIONS

The researcher recommends the following:

i. **Awareness**

It is the researcher's recommendation that the Patents and Designs registry and Non-governmental organisations with focus on intellectual property organise sensitization events wherein the major players i.e. pharmaceutical companies will be invited to educate them on the compulsory licence provision.

ii. **Simplification of Procedures**

The government should review and simplify the application and grant process for compulsory licensing to reduce bureaucratic hurdles and technical complexities that may deter applicants.

iii. **Domestication of TRIPS Flexibilities**

Nigeria should fully incorporate and implement the flexibilities allowed under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

iv. **Making available raw materials, loans and constant electricity**

The Nigerian government must make policies through the Small and medium enterprises development agency of Nigeria and the central bank of Nigeria which will make credit facilities available to pharmaceutical companies.

The tax duty on raw materials should be reduced to the nearest minimum to encourage manufacturing pharmaceutical companies to easily access and use the materials for the finished product which they got compulsory licence on.

The state of electricity needs to be improved in Nigeria. The epileptic power supply in Nigeria needs to be finally resurrected and never to die again. In the alternative, they should encourage the use of solar as a means of electricity. If electricity is constant, the companies will no longer spend exorbitant amounts on buying petroleum or diesel to power their generators and at the same time paying for the epileptic power supply.

v. **Investment in research and development**

In 2021, the Nigerian government drafted a National Development Plan which its execution commenced from 2021 till 2025. The National Development Plan does not cover any plan of the Nigerian government to invest in research and development. Obviously, the Nigerian government has no plan to do such.

It is normal that after a compulsory licence is granted and in the process of production of a patented product, the licensee may see a way to improve the product and will decide to make more findings, where there are no funds to research, there might be no development in that area.

It is the researcher's recommendation that the Nigerian government and private companies invest in research in order to mitigate importation of products.

vi. Establishment of a capacity based facility for manufacturing

Pharmaceutical companies should invest in building facilities and purchase machines that can be used in manufacturing pharmaceutical products.

Compensation Mechanism for Patent Holders

- Fair Remuneration: Introduce a compensation or royalty payment system whereby patent holders receive fair remuneration when compulsory licenses are issued, thereby respecting their intellectual property rights while serving public health goals.

5.3 Areas for Further Research

i. The socio-economic impacts of compulsory licensing on pharmaceutical innovation and access.
ii. Comparative studies on compulsory licensing practices and outcomes in other African countries.

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