**International Journal of Law**
**ISSN: 2455-2194; Impact Factor: RJIF 5.12**
**Received: 27-04-2020; Accepted: 28-05-2020; Published: 03-06-2020**
**www.lawjournals.org**
**Volume 6; Issue 3; 2020; Page No. 178-183**

# Compulsory licensing of pharmceutical drugs: A tool for achieving balance between healthcare and patent rights

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**Abstract**
Good health and wellbeing as Sustainable Development Goal 3 of the World Health Organization can only be achieved through availability, access and affordability of healthcare. Pharmaceutical drugs are very important in healthcare delivery and most times, new drugs are patented by the inventors of the drugs to give them exclusive control of its sales and pricing. Therefore, there is often the challenge of protecting the patent rights of the inventors of drugs against the desire of government to provide healthcare by making the drugs available at an affordable price. This paper presented compulsory licence as a veritable tool by the government to achieving the balance between the patent right of the inventors of drugs and the desire to achieve healthcare. Particularly, in addition to the Nigerian legislation, this paper considered the roles of international instruments such as Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and Declaration on TRIPS Agreement and Public Health (Doha Declaration), extracting the contribution of each of them, in the provision of healthcare through compulsory licensing of drugs.

**Keywords:** compulsory licensing, healthcare

## 1. Introduction
Every government has the obligation to ensure access to healthcare to its citizens through provision of pharmaceutical drugs. Availability of pharmaceutical drugs play a significant social role in that they are an integral part of the realization of a fundamental human right - the right to health and life [1]. That is why drugs could be classified as essential goods, to emphasize that they have to be accessible for all persons. The concept of accessibility is very important. It means that policies pursued must aim to make drugs available for all who wish to have them, and at affordable prices [2]. Consequently, there is need for government intervention and ability to control availability, access and distribution of drugs so that drugs may be available and affordable for healthcare. Although these pharmaceutical drugs are essential for both universal health coverage and meeting the sustainable development goals, a number of developing countries lack both the manufacturing capability to develop new drugs as well as the negotiating power to buy them at affordable prices. As innovations of medicines are owned by companies, it is important to recognize that improving access to them is intertwined with international trade laws and intellectual property rights, particularly patents law.
Invented drugs which is an essential in healthcare is protectable as patent under various laws of different nations. The high cost of research leading to the development and production of drugs for cure of ailments makes it imperative that the efforts be rewarded with protection of the right over the invention. Therefore, the protection of drug invention as patent comes as a reward for the research and the expense of the inventor or the pharmaceutical company as the case may be in the production of the drugs. Put simply, patent protection of invented drugs seek to reward hard work as it protects against the proliferation of the invention thereby affording the inventor the opportunity to make maximum return on the invention with the period of the patent protection.
To address the issue of balance between the rights conferred by patent and access to pharmaceutical drugs/healthcare, World Trade Organisation adopted TRIPS Agreement in 1995 and consequently in 2001, members of the World Trade Organization (WTO) signed in Doha the Declaration of the TRIPS Agreement and Public Health [3], which emphasized issues related to public health. The TRIPS Agreement and Doha Declaration, for the first time provided a strong negotiating tool to developing countries by allowing them to issue compulsory licensing of pharmaceuticals drugs.
With the powers conferred on the government by national laws, TRIPS Agreement and Doha Declaration, the government in effective utilization of the power has been placed in a position to control access and availability of drugs and by extension exercising control of its healthcare system through compulsory licensing of drugs.

## 2. Nature of Patent as Intellectual Property Right
A Patent is a grant made by the relevant government authorities within a country to protect new inventions or improvements thereon that are considered to have improved the way(s) the earlier inventions were made or used [4]. In simple terms, a patent is simply a form of market monopoly granted to inventors as an incentive to invent or innovate. Because the monopoly granted is usually for a specific period, the period is usually taken as allowing the patentee the opportunity to reap the fruits of his labour before the patent expires and falls into the public domain for free exploitation thereafter. In this respect, it is also a condition for granting patents that, apart from being useful, the process for making the product must be described in detail

so that the product or process could be precisely replicated by other people with the relevant know-how at the expiration of the duration of the patent. A patented invention can be either an actual product or a new process for making a product.

Section 1(1) Patents and Designs Act [5] and Article 25 TRIPS Agreement provides for patentability of inventions. For ease of reference, the provisions are reproduced below:

**Section 1(1) Patents and Designs Act**

*(1) Subject to this section, an invention is patentable-*

*(a) if it is new, results from inventive activity and is capable of industrial application; or*

*(b) if it constitutes an improvement upon a patented invention and also is new, results from inventive activity and is capable of industrial application.*

**Article 25**

*Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.*

*Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*

Flowing from the above explained nature of patent, a patentable pharmaceutical drug must satisfy the following conditions:

a. It must be new: This means that the pharmaceutical drug or the process in making the drug must not have been known or disclosed to the public before the date of application for the patent. The rationale for the strict requirement of newness is to avoid situation where right to a product which is already in public use is given exclusively to a person with the attendant consequences of granting the person exclusive control of the use of the product [6]. Section 1(2) of PDA provides that an invention is new if it does not form part of the state of the art [7]. The wide definition of "new" in determining whether or not an invention is patentable is limited by some exceptions in the Act [8]. An invention will still be regarded as new if it has been displayed or exhibited in an official or officially recognized international exhibition [9]. Also, an invention shall not be deemed to have been made available to the public where the disclosure is confidentially made by inventor or someone deriving title through him in confidence to third parties.
b. Inventive activity: Inventive activity deals with the existent of the variance between the state of technology available to the public and the addition made by the invention. It is the gap in technological advancement filled by the invention. S. 1(2) of PDA provides that an invention results from inventive activity if it does not obviously follow from the state of the art [10] The test for ascertaining inventive activity is an objective teat which is achieved by comparing the invention and the existing technology [11].
c. Capable of Industrial Application: An invention will be patentable if amongst other conditions mentioned above, it is practically applicable. S. 1(2) provides that an invention is capable of industrial application if it can be manufactured or used in any kind of industry, including agriculture. It must be useful or industrially applicable. In other words, it must have utility in the way and for the purpose claimed by the patentee.

In general, an invention which will qualify for patent may be completely new invention or improvement on an existing patented invention [12]. Therefore, in a case where there is invention and production of drugs to further the process of an existing medical breakthrough, the invention is capable of protection by the inventor. The improvement must not be mere minor but must be such to render the product or process better or more efficient than it was before [13]. PDA provides that the improvement must satisfy all the requirement of newness, inventive activity and capability of industrial application.

**3. Pharmaceutical Invention as Patentable Invention**

The provisions of PDA is clear that only inventions are patentable. It must therefore be established that that the product of the prospective patentee meet the requirement of invention as provided by the PDA. Unfortunately, PDA does not define the term 'invention' for the purposes of granting a patent. Therefore, there may be question on whether pharmaceutical drugs produced after research qualifies as invention to be capable of patent protection.

Given the general meaning of invention as explained above, it is beyond doubt that the production of new pharmaceutical drugs qualifies as invention and accordingly regarded as patentable. The Oxford Advanced Learner's Dictionary defines an 'invention' as 'a thing or an idea that has been invented,' or 'PDA of inventing something.' It must be said that for our present purposes, the Advanced Learners' Dictionary define the term 'invent' as meaning 'to produce or design something that has not existed before.' This does not fully capture the essence of 'invention' in the context of granting of patents, because patents can be granted over something that has been produced before but later engineered to be applied in a different way in a manner that qualifies as an inventive process. Therefore, an attempt to precisely define an 'invention' is unhelpful for the present purposes. This was the stance taken by the Court in *Crossley Radio Corporation v. Canadian General Electric Co Ltd (1936) D.L.R. 508*, in stating that:

*'It would be idle to attempt a comprehensive definition. In certain cases, the decision must necessarily be the result of nicety. It is a question of fact and degree…depending upon practical considerations to a large extent rather than upon legal interpretation* [4]

Also, the TRIPS Agreement does not provide for the meaning of invention. However, by Article 27 of the TRIPS Agreement, patents shall be available for any inventions, whether products or processes, in all fields of technology. The TRIPS Agreement requires patent protection to be available for any invention in any field of technology in all World Trade Organisation (WTO) [15] member states. There is no discrimination between types of products - pharmaceutical or other for patentability [16] In fact, the provision is essentially aimed at pharmaceutical products, for which certain developing countries, as well as developed countries, had refused to grant patents. Some countries, unable to invest in development of pharmaceutical drugs,

were before the TRIPS Agreement, excluding pharmaceuticals from patentability so as to allow the possibility for copies of patented drugs to be produced locally or imported - from other countries which also do not respect pharmaceutical patents - without the authorization of the company that invented the drug [17].

## 4. Compulsory Licence of Patent under PDA and TRIPS Agreement

Compulsory licence in patent occurs where a right for the exploitation of a patent is given to another other than the patentee, thereby allowing a third party to exploit the patent, subject to the conditions provided in the grant of the licence and the law. A compulsory license is a non-voluntary authorization imposed by a government or a court between the patent holder and a third party, by which the latter is allowed to use the patented invention without the patent owner's consent [18]. In clear terms, compulsory licence is given without the consent or against the will of the right holder of the patent. Compulsory licence is clearly expropriate and on the face of it offends S. 6 of PDA which confers on the patentee the exclusive right to the control of the patent.

In Nigeria, section 11 PDA provides for the grant of a compulsory licence with respect a patent. The First Schedule stipulates the procedure, conditions and other terms for grant of compulsory licence. The title for the First Schedule PDA reads, "Compulsory Licences and Use of Patents for Service of Government Agencies". Specifically, Part 1 of the First Schedule provides for compulsory licence will be granted to a person who makes an application to Court and fulfils certain conditions. Part II of the First Schedule provides for the use of compulsory licences by government agencies.

Under TRIPS Agreement, a country's laws may allow the state or the court to issue a compulsory license, which permits either the government, an individual or a company to use a drug (i.e. produce or import a generic drug) without the authorization of the patent owner. Compulsory licenses are usually granted on grounds of general interest such as public health, economic development, national defence and the absence of working (i.e. when the holder is not exploiting its patent) [19]. The TRIPS Agreement does not limit the grounds on which government or courts may issue compulsory licences.

But there are restrictions on the use of compulsory licenses:

a. Usually there must be an effort to negotiate a voluntary license with the patent owner on reasonable commercial terms within a reasonable period of time. Importantly however, this attempt at negotiation with the patent holder is not required if the drug is to be used for public non-commercial use, if there is a national emergency or other situation of extreme urgency, or if a legal process has determined that the patent owner has engaged in anti-competitive practices.
b. If a compulsory license is issued, the patent owner is entitled to be paid adequate remuneration (e.g. either a symbolic fee acknowledging the inventor or a proper royalty in lieu of financial compensation for lost sales). The competent authority may also decide that the license should be granted free of charge. The TRIPS Agreement does not say how adequate remuneration should be determined. However, where the compulsory licence is issued based on Part II, Second Schedule of the Act, there will be no obligation to pay royalty to the patent holder [20].
c. Furthermore, the license must be used predominantly for supplying the domestic market in the country issuing the license (unless the license is issued to remedy anti-competitive practices by the patent owner). This presents a likely barrier to accessing affordable drugs: many developing countries don't have the ability to produce their own generic drugs and would need to import them from other countries that do. But those countries that do have a generic drug industry are not permitted under TRIPS Agreement to issue a compulsory license authorizing someone to make a patent-protected drug primarily for export to other countries.
d. Compulsory licence is non-exclusive [21] and does not entitle the licensee to grant further licence [22].

There has been exercise of compulsory licence by nations of the world, many of which are with respect to anti-retroviral drugs for the management of HIV/AIDS. For instance, in 1997 South Africa effected an amendment to its health regulations to allow for compulsory licences to be granted for AIDS drugs and for local pharmaceutical companies to make cheap and affordable generic versions of those drugs [23].

## 5. Compulsory Licensing of Patented Pharmaceutical Drugs as Access to Healthcare

The provision of healthcare is one of the fundamental objectives of government as it inseparable from the right to life. An affordable access to pharmaceutical drugs is required for sustained healthcare of a nation. Therefore, there was concern that the patent rules will restrict access to pharmaceutical drugs as the patentees will have exclusive control of its availability in the market. A drug that is patented can only be made, used, imported/exported or sold by the patent holder. According to the World Health Organization's Action Programme on Essential Drugs, a drug that is patented is usually marketed under a proprietary or brand name reserved exclusively to its owner, i.e. the individual or firm granted a patent on that invention. The concern is more with the developing countries in their efforts to control diseases of public health importance, such as HIV, tuberculosis and malaria. The provisions on compulsory licence may rightly be regarded as a lawful key, equipping the government to control availability of pharmaceutical drugs, including its pricing for affordability of the people. Pharmaceutical drug prices are often well above production costs [24]. As much as regulation of pharmaceutical drugs sounds good, indiscriminate exercise of power of compulsory licence could bring apathy to development of new drugs as the incentive for funding of discovery and development of new pharmaceutical drugs will be eroded.

There has been legislative intervention in ensuring access to pharmaceutical drugs at both national and international level through compulsory licence. Compulsory licensing allows the use of a patented invention without the owner's consent, with the aim of improving access to essential drugs [25]. The power of compulsory licences is most obvious when government use them effectively. However, compulsory licences also have power when governments warn patent owners that they will use them if necessary. At the national

level, PDA clearly provided for compulsory licence in S. 11 and First Schedule. The World Trade Organization (WTO) was at the forefront at the international level with the adoption of TRIPS Agreement which introduced globalization on access to drugs. In 2001, WTO members drew up the Doha Declaration to clarify ambiguities between the need for governments to apply the principles of public health and the terms of the TRIPS Agreement. In particular, concerns had been growing that patent rules might restrict access to affordable medicines for populations in developing countries in their efforts to control diseases of public health importance, such as HIV, tuberculosis and malaria.

Even though compulsory licensing is permitted in national laws and by international instruments, it has not been used that often by countries. Of course, for the option to invoke compulsory licensing to matter, compulsory licensing need not actually be used: the threat to issue a compulsory license can affect the behavior of patentees to the advantage the society by making the patentees flexible on their pricing and terms of negotiating licences with third parties that wish to make the drugs available. In fact, the mere existence of the option of compulsory licence controls availability and pricing, thereby making it unnecessary to exercise the compulsory licence.

## 6. TRIPS Agreement/DOHA Declaration and Provision of Healthcare through Compulsory Licensing

The TRIPS agreement was introduced in 1995 and sets out the minimum standards for intellectual property regulation in World Trade Organization (WTO) member countries [26]. Before introduction of the agreement, countries could offer intellectual property rights as they saw fit. Some countries offered none at all, and many countries excluded medicines [27]. In these countries, companies were allowed to produce generic equivalents (copies) of medicines that were protected by patents in other countries.

In Article 7 of the TRIPS Agreement, the objective of TRIPS Agreement was clearly stated to balance the monopoly rights created by patent. Specifically, TRIPS Agreement seeks to promote technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. In essence, while it seeks to encourage invention through patent rights, it also recognizes the need to balance same with

a. The conduciveness of the social and economic welfare
b. Rights and obligations

The social and economic welfare will rightly be interpreted to include access to healthcare through availability of pharmaceutical drugs. Where pharmaceutical drugs are not available or affordable despite being in existence, the welfare position cannot be said to have been achieved. Also, every citizen has right to life and same is threatened by patent rights as it creates monopoly and control of pharmaceutical drugs by only the patentee. Non-access to drugs or healthcare when required to sustain life could be argued vigorously to mean a denial of right to the life. The TRIPS Agreement was made to ensure a balance between intellectual property rights (in this case, patent rights) and other important interests like healthcare.

The TRIPS Agreement also sets out some basic principles that should guide how it gets interpreted [28]. It says that, in shaping their own laws, countries "may take measures necessary to protect public health [29]. It also recognizes that countries may need to take "appropriate measures" to prevent the "abuse" of patent rights by patent-holders or to prevent practices which "unreasonably" restrain trade or negatively affect the international transfer of technology. These measures, however, must be "consistent" with the provisions of TRIPS. These provisions in TRIPS support the argument that countries are entitled to flexibility in how they meet their obligations to protect patent rights.

The TRIPS agreement obliged all WTO member states to provide a minimum level of intellectual property rights. However, it did not create a worldwide system. Instead, it set out international norms for national intellectual property protection systems. Each WTO member state is supposed to create its own system but may work with others to create regional systems. A patent on a drug granted by one country's patent office gives the company the right to prevent the production, sale, and importation of generic equivalents in that country.

Article 31 (f) of the TRIPS Agreement stipulates that a compulsory licence must be issued predominantly for the supply of the domestic market of the member granting the licence. Consequently, many countries without a significant pharmaceutical sector have not been able to take advantage of the compulsory licensing provisions of TRIPS. Although Members may issue compulsory licences for importation, they are restricted to importing goods from countries where pharmaceuticals are not patented, or where their term of protection has expired. As the sources for generic production of newer lifesaving drugs increasingly run out, resolving this problem became of extreme importance to members' efforts to secure access to affordable medicines to address public health needs.

Widespread criticism of the TRIPS agreement and its consequences for treatment of AIDS led the WTO to adopt a ministerial declaration on public health in Doha, Qatar, in November 2001. The declaration also attempted to deal with a problem highlighted by the international advocacy campaign for access to medicines—namely, the challenge faced by countries lacking domestic pharmaceutical manufacturing capacity. The Doha declaration recognised that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing. Doha Declaration stated expressly the problems addressed by the Doha Declaration. Particularly, Paragraph 1 of the Declaration states thus:

We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

Some developed countries has sought to limit the scope of the Declaration to the HIV/AIDS crisis, however, the mention of certain ailments does not imply that the Declaration is limited to them. It covers any "public health problem", including those that may be derived from diseases that affect the population in developing as well as developed countries, such as asthma or cancer.

Paragraph 6 of the Doha Declaration instructs the Council for TRIPS to find an expeditious solution to the problem faced by countries with insufficient or no adequate

pharmaceutical production capacity in making effective use of the compulsory licensing provisions of the TRIPS Agreement [30]. To this end Doha Declaration in Paragraph 1 clearly recognized the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. Therefore, TRIPS Agreement does not and should not prevent members from taking measures to protect public health [31]. In the light of the above, the Doha Declaration recognizes that each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted [32]. Also, each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency [33]. It recognized WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement and instructed the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002 [34]. It gave a mandate to the TRIPS council to expand the flexibilities, allowing compulsory licences for export. This was initially temporary [35], but recently became a permanent addition to the original TRIPS agreement [36]

Consequently, some countries have taken advantage of the Doha Declaration in importing patented pharmaceutical drugs to their country. For instance, in April 2004, Mozambique Deputy Minister of Industry and Commerce, Salvador Namburete, issue compulsory licence no. 01/MIC/04 on the consideration of the HIV pandemic at Mozambique where about 1.5 million were estimated to be HIV carriers and over 100,000 having fill blown AIDS. The compulsory licence which was for Lamivudine, Stavudine and Nevirapine was granted to Pharco Mocanbique (a company incorporated in Mozambique) to manufacture triple compound under the name Phacovir 30 and Phacovir 40 with a maximum royalty rate of 2% to be paid to the patent owner. In September 21, 2004, Zambian Minister for Commerce, Trade and Industry, Dipak Patel, issued compulsory licence no. CL.01/2004 [37] for Lamivudine, Stavudine and Nevirapine. Relying on S. 40 of Zambian Patent Act and the high rate of death resulting from HIV/AIDS pandemic, a licence was granted to Pharco Ltd, a company incorporated in Zambia, to produce triple compounds under the name Phacovir 30 and Phacovir 40 with a maximum royalty rate of 2.5% to be paid to the patent owner. On 20th April 2004, the Ministry of Health and Social welfare of Switzerland announced the existence of emergency with respect to HIV/AIDS and authorized the importation of drugs for HIV/AIDS, irrespective of existence of patent or other intellectual property rights protection available in Switzerland until such time as it is no longer considered essential to address the public health crisis related to HIV/AIDS in Switzerland at the time.

## 7. Conclusion

Every government of nation has accepted the need to ensure access to pharmaceutical drugs by its citizens. This fact is obvious in the various patent laws of nations, which has made provisions on compulsory licensing of patent. By making provisions on compulsory licensing, the government and courts are empowered to grant licence to third parties who are not owners of patent in drugs, to produce and distribute it, subject to some terms as may be imposed in the licensing. Governments across the world have tried to improve access to drugs sold by engaging in compulsory licensing. Compulsory licensing has obviously become a bargaining tool in the hands of developing countries to improve access to essential drugs which are mainly developed and produced by the developed countries who are advanced in medical research.

At international level, the TRIPS Agreement and Doha Declaration which came subsequently, have created the legal platform for compulsory licensing of drugs at international level, as a means to making access to drugs. The Doha Declaration was not intended to amend the TRIPS Agreement in any substantial manner but it was aimed at clarifying the relationship between the TRIPS Agreement and public health policies of member countries of WTO, and confirm the rights that members have retained under the Agreement, including the area of compulsory licensing. The Doha Declaration is a strong political statement that has made it easier for developing countries to adopt measures necessary to ensure access to healthcare through compulsory licensing, without the fear of being dragged into a battle at the international legal sphere. This was achieved by addressing the real problems of compulsory licensing in area of public health. Although access to medicines was the main preoccupation that led to the Doha Declaration, the Declaration covers not only drugs, but any product, method or technology for healthcare. Thus, the provisions of the Declaration recognizing compulsory licence applies to pharmaceutical products, processes and uses, surgical, therapeutic and diagnostic methods, diagnostic kits as well as medical equipment.

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