Nigeria being a member of the World Trade Organisation (WTO) since 1\textsuperscript{st} January 1995 is a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights (‘TRIPS Agreement’). The statutory framework in Nigeria regulating the implementation of the TRIPS Agreement, patent rights and access to medicines is the Patents and Designs Act.\textsuperscript{3} In 2008 a Bill\textsuperscript{4} was proposed to consolidate the administration and management of intellectual property rights within a single institutional framework. Although this Bill is yet to be adopted, it indicates the overall approach, which should be implemented in the imminent reform of the intellectual property framework in Nigeria.\textsuperscript{5}

3:1 \textbf{A review of Parallel Importation in Nigeria:}

The Patents and Designs Act 1990 adopts the domestic or territorial exhaustion of rights principle\textsuperscript{6} by specifying that the patentees’ rights are exhausted when the products

\textsuperscript{1} This paper is the second part to the series on the Effects of Parallel Importation in Nigeria.
\textsuperscript{2} Yetunde Okojie LL.M (UCL), BL (Nig. Law Sch.) LL.B. (U.I). Associate at SPA Ajibade & Co, [Legal Practitioners, Arbitrators and Notaries Public].
\textsuperscript{6} For more on domestic and territorial principles of exhaustion of rights, see Part 1 of the series on \url{http://www.spaajibade.com/resources/wp-content/uploads/2016/03/Website-article-on-Parallel-Importation-and-the-Exhaustion-of-Rights-Principle-under-the-1.pdf}
covered by the patent are lawfully sold in Nigeria.\(^7\) Notwithstanding, Section 6(3)(b) of the Patents and Designs Act also offers an exemption to the exhaustion of rights of a patentee where the patentee “makes provision for a special application of the product”. By virtue of this special application exception, the patentee’s rights are reserved despite their exhaustion. This provision restricts and complicates the exhaustion of rights principle in Nigeria as it fails to clarify what would amount to a special application.

This restrictive approach towards exhaustion adopted by the Patents and Designs Act 1990 seems unnecessary as the TRIPS Agreement and the Doha Declaration allows WTO Members the freedom of choice and flexibility in terms of the exhaustion regime to be adopted at the national level, as discussed in the first part of this paper.\(^8\)

On the other hand, the IP Bill 2008 has adopted an international exhaustion regime for patent rights. Consequently, Article 112(3)(f) of the proposed Bill provides that rights afforded to a patent will not cover “an act done in respect of a product covered by the patent after the product has been lawfully sold in any country”. This provision is much clearer than what is contained in the current Patent and Designs Act and if implemented, parallel importation of patented products in Nigeria would be permitted upon an initial sale of the product any place in the world.

3:2 A review of Compulsory Licensing in Nigeria:

Nigerian legislations governing intellectual property have come a long way from what was in operation prior to 1970, when the United Kingdom Patent Ordinance 1925\(^9\) was enforced in Nigeria. An amendment in the Law came as a result of the decision of the High Court of Lagos State in the case of Rhone Poulenc and Anor v Lodeka Pharmacy.\(^10\) In this case, the defendant supplied the Ministry of Health with pharmaceuticals protected by a patent held by the plaintiff. After the first supply, the Ministry of Health ordered for a second supply of pharmaceuticals and the defendants imported the second supply without reference to the plaintiff.

The plaintiff subsequently brought an action for infringement and the defendant sought to rely on Section 46(1) of the Patent Act 1949,\(^11\) which provided that “any government department or any person authorized in writing by a government department may make, use and exercise any patented invention for the service of the crown”. However, the High Court held that the content of Section 46 of the Patent Act 1949 did not extend to

---

\(^7\) Section 6(3)(b) of the “Patents and Designs Act 1990”.


\(^9\) No. 6 of 1925.

\(^10\) (1965) LLR 9.

\(^11\) The Act of 1949 is a United Kingdom Act and this 1949 Act has been repealed by a Patents Act of 1977 in the UK. The 1977 Act has also been amended severally, the last being in October 2014.
the defendants. Furthermore, the high court stated that the patent regime in operation in Nigeria did not confer on the Nigerian government the same rights given to the British Crown under the "Registration of United Kingdom Patent Ordinance 1925", which was at the time applicable to Nigeria.  

This decision was understood by the Nigerian government as an affront to its sovereignty and consequently the government passed the Patent Rights (Limitation) Act, which granted the government and its agencies similar powers and rights as those possessed by the United Kingdom government under Section 46 of the Patent Act 1949. The Patent Rights (Limitation) Act 1968 was promulgated to enable the Nigerian government make use of certain inventions by third parties. The Limitation Act also made provision on how to use these inventions in emergencies. Even though Nigeria passed the Patent Limitation Act of 1968, the Patent Ordinance was still in force and an applicant for a patent still had to apply for registration in the United Kingdom before re-registering in Nigeria. This position was inconsistent with a sovereign status, and it was one of the reasons that led to the promulgation of the Patents and Designs Act of 1970 after Nigeria attained independence.

3.3 Compulsory License under the Patent and Designs Act 1990:

Section 11 of the Patents and Designs Act postulates that the first schedule of the Act shall have effect regarding compulsory licenses. Paragraph 1 of the First Schedule of the Patents and Designs Act 1990 also states that "any time after the expiration of four years after the filing of a patent application or three years after the grant, whichever period last expires, a person may apply to the court for the grant of a compulsory licence…" The schedule goes further to provide four main grounds upon which a compulsory license could be granted. These 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; and"

---


13 No. 8 of 1968.


16 Olusegun Oyedepo, supra, (n. 14)
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.”

Furthermore, Paragraph 13 of the First Schedule empowers the Minister by order of the Gazette\(^\text{17}\) to grant compulsory licenses, for patented inventions that are of crucial importance for the “defense or the economy of Nigeria or for public health”. Paragraph 13 in addition provides that compulsory licenses on these grounds may be permitted within the period stipulated in paragraph one and may also authorize importation.

Once a court hears a claim for the issuance of a compulsory license, the parties are allowed to agree upon the terms of such an arrangement. If they cannot agree, the court would then fix the terms, which includes the payment of adequate royalties taking into account “the extent to which the relevant invention is to be worked”.\(^\text{18}\) Under the Patent and Designs Act 1990 the grant of compulsory license to any government agency is not automatic; the court must consider the application and decide whether the application is meritorious before granting it.

### 3.4 Compulsory license under the Proposed IP Bill:

Similarly, the IP Bill 2008 makes provisions for the grant of compulsory licenses in its First Schedule. Notably, it expands the grounds laid down in the Patent and Designs Act, upon which such licenses may be granted. The Bill in addition to the non-working or insufficiency of working and refusal to deal grounds provided for in the Patent and Designs Act, has included anti-competitive, public interest and national emergency grounds.\(^\text{19}\) Furthermore, Paragraph 1(c) of the First Schedule explicitly stipulates that a compulsory license might be allowed to facilitate public health and nutrition and ensure that medicine is available to everyone.

### 3.5 Compulsory License under TRIPS:

One of the aims of the TRIPS Agreement was to ensure minimum standards between all trading systems that are members of GATT (The General Agreement on Tariffs and Trade)\(^\text{20}\) within the WTO. These minimum standards were especially targeted at the developing countries in an attempt to ensure that they make substantial changes to their

---

\(^{17}\) In Nigeria the appropriate Minister is the Minister of Trade and Tourism.


\(^{20}\) GATT covers, among other things, international trade in goods, the Council of the Trade in Goods, which is made up of representatives of all WTO members, is responsible for the workings of the GATT Agreement. For more see Matsushita et al, *The World Trade Organization: Law, Practice and Policy* (2\(^{nd}\) edition Oxford International Law Library, 2006), p.702.
laws.\textsuperscript{21} To achieve this, the TRIPS Agreement made several provisions and it appears that the most controversial are Articles 27 and 31, which are the provisions relating to compulsory licensing.\textsuperscript{22}

Article 27 of the TRIPS Agreement explicitly provides that there will be no bias “as to the place of invention, the field of technology and whether products are imported or not”. This provision would obviate the requirement that a patent must be worked in Nigeria in order for it to enjoy the monopoly right granted under the patent.\textsuperscript{23} This provision is therefore in conflict with the requirement prescribed in the First Schedule of the Patents and Designs Act 1990 that a compulsory license may be permitted over a patented invention which has not been operated in Nigeria. In Nigeria, the working of a patent has always been seen as the main justification for granting state monopoly to a patent and although the provision may appear to be burdensome to owners of patented inventions in technologically advanced countries, it is doubtful whether a total removal of the ‘working’ provision would benefit a developing country like Nigeria.\textsuperscript{24}

Article 31 of the TRIPS Agreement states that “where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:” Article 31 of TRIPS Agreement goes further to list certain onerous conditions\textsuperscript{25} before the patent could be used without the owner’s approval, thus making the utilization of the compulsory licensing scheme imprecise. Furthermore, Article 31(b) of the TRIPS Agreement requires the intended user to make an effort to acquire authorization from the patent holder on commercial terms that are reasonable. However, Article 31(b) of the TRIPS Agreement also provides an opportunity for the Member to waive the requirement in extreme emergencies or in situations of public and non-commercial uses.

It has been suggested that licensing of patented technology from a developed country to a developing country would be prohibitively expensive and sometimes burdensome and that developing countries like Nigeria are better off taking advantage of the opportunity for compulsory licensing provided under Article 31 of the TRIPS Agreement.\textsuperscript{26}

\begin{flushright}
\textsuperscript{22} Ibid. p.104
\textsuperscript{23} Ibid.
\textsuperscript{24} Ibid.
\textsuperscript{25} These conditions are listed in Article 31(a)-(i) of the TRIPS Agreement.
\end{flushright}
3.6 The Nigerian Healthcare Industry:

Initially, government and academic institutions funded scientific research and such research in the sciences was considered humanitarian or charitable. Consequently, the findings of researchers were made available to all. Also, the scientific community prior to 1980 frowned upon the privatization or commercialization of findings. More recently, with the increasing cost of producing new drugs and the need to invest in research to facilitate development in disease prevention and drug improvement, the researcher mostly relies upon the intervention of corporate bodies in funding research.

Although these corporate bodies provide huge investments into medical research and facilitate drug development, they in turn expect profitable returns on their huge investments. One means through which a balance of R&D and profitability could be attained would be a provision protecting intellectual property rights in stipulated pharmaceutical products using the patent rights system.

According to the WHO, in 2009 Nigeria’s healthcare system ranked an abysmal 187th out of 191 members of the WHO. Furthermore, there is a growing trend of severe and life threatening ailments plaguing the Nigerian population currently. These ailments include non-contagious and contagious illnesses such as hypertension, cancer, diabetes and more recently EBOLA and Lassa fever, are offering enormous growth prospects for the pharmaceutical companies. The growth opportunities for pharmaceutical companies are gradually progressing from customary pharmaceutical markets (Europe and Latin America) controlled by conglomerates like Sanofi-Aventis, Novartis, Pfizer and GSK and are now expanding their global footprint into Africa.
The IMS Health Market Prognosis Report\(^{35}\) (“the Report”) shows that pharmaceutical expenditure in Africa by 2016 is anticipated to reach US$30 Billion. That Report indicates that:

“[T]his value is driven by a 10.6% compound annual growth rate (CAGR) through 2016, second only to Asia Pacific (12.5%) and in line with Latin America (10.5%) during this period.”\(^{36}\) Furthermore, the report shows that “(W)hile continuing to struggle with infectious and parasitic illnesses, Africa is expected to experience the largest increase in death rates from cardiovascular (CV) disease, cancer, respiratory disease and diabetes, over the next ten years, resulting in greater demand for healthcare services and appropriate medicines. The combination of economic strength and an expanding middle class is already driving a demand for medicines across Africa.”\(^{37}\)

Moreover, according to the last National Census conducted in Nigeria, the Nigerian Population of about 140 Million is possibly the largest domestic market in Africa.\(^{38}\)

3:7 Options available to Nigeria:

Over the years, Nigeria’s pharmaceutical spending has risen by 16 percent compound annual growth rate (CAGR), nonetheless the high rates of effective pharmaceutical ingredients in Africa makes it impossible for most local enterprises to compete with Asian producers.\(^{39}\) With an increased number of Asian producers in Africa, the value of drugs being imported from India and China is twofold the market price, making it too expensive for the masses to have access to essential medicine.

It has been suggested that there are some options available to Nigeria to improve accessibility of Nigerians to medicines; two of these are compulsory licensing and parallel importation.\(^{40}\)

\(^{35}\) IMS health is a leading provider of information, services and technology from the healthcare industry around the world.


\(^{37}\) Ibid p. 3.

\(^{38}\) Ibid p.3.

\(^{39}\) Ibid.

Compulsory licensing as an Option

Paragraph 5 of the Doha Declaration recognizes compulsory licensing as a lawful and practical choice, which the Nigerian government can use to increase the supply of pharmaceuticals within the country. The Doha Declaration recognizes that public health calamities can be characterized as imminent national need or other situations of maximum emergency, which gives the government of developing countries the liberty to decide how and under what circumstances such licenses may be granted. Compulsory licensing is not restricted to only locally produced pharmaceuticals, it could also be applied to imported pharmaceuticals on a long-term or short-term basis.

It should be considered that in the long run the drugs might be less expensive if they are indigenously manufactured rather than transported across borders. However, the success of compulsory licensing is dependent upon adequate technical competence. In Nigeria, presently, only a limited number of local pharmaceutical firms possess the abilities to produce essential medicines for Nigeria, as only 30 percent of the essential medicines in Nigeria are produced locally. Considering this, it is essential that the Nigerian government look into authorizing more compulsory licenses in favour of local pharmaceutical companies with the capacity to manufacture essential drugs for the Nigerian populace.

Parallel Importation as an Option

Like other manufacturing industries, in the pharmaceutical sector a system of differential pricing operates globally. Price differentiation is a strategy available to companies with monopolistic power allowing them to increase quantities sold without decreasing overall prices. As long as a company can segment the markets so that products targeted for one market, say the cheaper brand, do not leak into another market, the strategy becomes viable. Arguably, it benefits consumers because products which otherwise would not be sold at a lower price can reach them through market segmentation. Consequently, the costs of the similar medicine may vary in countries at the same time.

---

41 Ibid p.188.
44 Ibid p.189.
According to Correa, “The patent system is designed to enable patent holders to set prices higher than those that would be obtained in the competitive market.”45 When a patent holder enjoys a monopoly over the drugs with respect to particular diseases with no alternative remedial options, the patent on the drug becomes an important factor in price determination for that drug.46

Thus, the parallel importation of patented drugs from a state where the drugs are less expensive would allow the importing country to purchase the drugs at lower price compared to if the drugs were imported directly. This contradicts the principle of market segmentation on which price discrimination functions.

The proposed Nigerian IP Bill 2008 (if and when implemented) would provide the opportunity for parallel importation based on its recommendation that the country adopts the international exhaustion doctrine. Parallel importation of drugs into the Nigerian market apart from enabling the drugs to be imported at a cheaper rate would also provide the importers with higher negotiating leverage with local and multinational manufacturers to accept lower prices.47 If the Nigerian government resorts to this option it must strengthen the administrative capacity for effective implementation by ensuring that the process for procuring licenses is transparent and manageable.48

For further information on this article and area of law please contact Yetunde Okojie at S. P. A. Ajibade & Co. by telephone (+234 1 460 5091), fax (+234 1 4605092) mobile (+234 8078.9.1721) or email (ykojie@spaajibade.com)

www.spaajibade.com

48 Ibid.