Access to Medicines: the Colonial Impacts on Patent law of Nigeria

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Abstract
This article explores the colonial impact on the patent law of Nigeria. The colonial and historical past of the country and the introduction of patent law were not based on the justifications for patent law, but for the beneficial interest of the colonial masters which was the sustenance of the raw material needs of the industrial West. This lopsided objective heralded Nigerian independence, leading to inconsistency in policy articulation, formulation and implementation, and remains a factor that continues to affect the public health sector. In this respect, and in the context of fighting against HIV/AIDS, malaria, tuberculosis and other communicable diseases, inventing and developing pharmaceutical products is both necessary and indispensible. However, an understanding of the colonial impact would place greater burden on reassessing the internal problems and reforming the patent legislation. It advocates that the Nigeria Intellectual Property Commission (NIPCOM) Bill needs to be reappraised as a reform option that would shed the burden of patent law imposition and enhance access to drugs and health care in Nigeria.

Key Words: Access to medicines, colonial law, patent law, public health, NIPCOM Bill, Nigeria, Paris Convention, TRIPS Agreement.

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Introduction
The impact of colonisation on the development of patent law continues to influence access to drugs and health care in developing countries including Nigeria. This flows from the mandatory provision of the Paris Convention which allowed the patent laws of the colonial masters to regulate the issue of patents in the various colonies. This consolidated the imposition of patent law on the colonies and enhanced the beneficial interest of the industrial nations to the detriment of the colonies including Nigeria. In this respect, Nigeria was pressured to adopt a patent law system at a time when there was a total absence of invention or industrial activity. In effect, the patent law system failed to spur inventions, innovations, research and development and the Nigerian societal growth remained “directionless.” This resulted in inordinate policy articulation, formulation and implementation and exacerbates the public health care and related matters in a country endowed with enormous human and natural resources.

The contentions of this article asserts that the introduction of patent law in Nigeria has neither delivered the benefits of the patent system, nor improved drug development, production or distribution to improve access to essential medicines. It is set out in three parts, the first part outlines the development of patent law and how colonization influenced the patent law development in Nigeria. In addition, this part reviews the use of colonial and national development plans to negate the development of an efficient patent law system, with its attendant impact on access to medicines and health care in Nigeria. It is argued that these development plans were meant to sustain the raw material base of the industries of the West without any genuine effort at technology transfer to the colonies. The effect of this has contributed to the inconsistency in patent and health care policies affecting the pharmaceutical sector in Nigeria. Part two analyses the pharmaceutical sector in Nigeria and other issues that impact on access to drugs and healthcare. The final part concludes the article.

Evolution of patent law
Patent law is the branch of intellectual property law that protects inventions in products and processes and gives the inventors the exclusive right to the use of the inventions for a limited period usually 20 years from the time of filing the
applications. In this respect, patenting are allowed in ALMOST all fields of technology and incorporated in the laws of most countries.\(^1\)

The development of patent law evolved through the internationalisation with the formation of the Paris Union.\(^2\) During this period, Britain annexed the colony of Lagos in 1861, the Protectorate of Northern Nigeria in 1900 and the Protectorate of Southern Nigeria in 1900 (together constituting the present day Nigeria). This followed the abolition of slave trade in 1807\(^3\) and the expansion of trade in agriculture from Africa to Europe.\(^4\) The legal system and administration introduced in Nigeria was that of the United Kingdom’s colonial authorities, which included the patent law ordinances and proclamations made applicable by the Foreign Jurisdiction Act 1845 and its subsequent amendments.\(^5\) These have in no small way influenced patent law system in Nigeria.\(^6\)

The handing down of English patent laws was part of the standardized approach (or a template approach) of extension of administration to the colonies. This standardized approach for patent law can be criticised both as unnecessary – as there were no inventions or industrial activities in Nigeria at the time of this extension – and also because these laws were carefully crafted to favour inventors and promote their inventions. By so favouring inventors, they favoured the industrialised Britain not Nigeria, a nation still focusing on peasant farming based on the use of rudimentary tools. Moreover, even at Nigeria independence, the imposition of foreign laws removed from the country the status of a sovereign and independent state which should “order its international and domestic affairs.”\(^7\) This

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\(^1\) See TRIPS Agreement, Article 27(1) (2).
\(^3\) Abolition of Slavery Act, March 25 1807.
\(^5\) While the Foreign Jurisdiction Acts allowed for the exercise of jurisdiction in foreign countries and gave the power to extend, without any exceptions, adaptation, or modifications. The Colonial Laws Validity Act of 1865 extended to any colony an Act of Parliament when it was made applicable to such colony by express words or necessary intendment of any Act of Parliament. This Act removes doubts as to the validity of Colonial laws; it provided the legal authority for the extension of the British enacted laws to be applicable in the colonies.
manifest as tension within the polity in the case of *Rhone Poulence*\(^8\) resulting in the enactment of the Patents Rights (Limitation) Decree in 1968.

The enactment of the Patents Rights (Limitation) Decree (the first domestic legislation) in Nigeria came when there was no national technology planning in place.\(^9\) However, the influence of international developments in the area of patent law is informing with the Lisbon Amendment of the Paris Convention passed in 1958 (i.e. close to Nigeria’s independence). Nigeria acceded to this Amendment of the Paris Convention in 1963. By 1964, the administrative organ of the Paris Convention developed the United International Bureaux for the Protection of Intellectual Property (BIRPI) Model Law;\(^10\) the emphasis for the Model Law was on invention for developing countries. The Model Law was developed in response to the pressure from industrialized nations on developing and least-developed countries to join the “community of nations” in the Union; which was an attempt to view international patenting through the eyes of these countries.\(^11\)

The administrative framework set up to implement the Convention followed the resolution at Stockholm,\(^12\) where the World Intellectual Property Organisation (WIPO) was established, coming into force in 1970. The WIPO is a specialized agency of the United Nations (UN) but continues the function and responsibilities of the United International Bureaux for the Protection of Intellectual Property (BIRPI) as an independent inter-governmental organisation.\(^13\) An important sphere of WIPO activities concerns assistance to developing countries through “development cooperation”. The main objectives of the WIPO development cooperation programme are geared towards assisting “developing countries in the establishment

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\(^10\) BIRPI was founded in 1893.


or modernization of intellectual property systems suited to their development goals.\textsuperscript{14} This was actualized through facilitating the creation or improvement of national or regional legislation (with international minimum standards and principles) and its enforcement. The evidence of the policy was, first to facilitate the development of indigenous technology and the acquisition of foreign patented technology; second to facilitate the management and exploitation of intellectual property rights at local levels; third to facilitate the exchange of experience and information in patents; and finally to promote the exchange of experience and information among legislatures and the judiciary in the formulation, enforcement and protection of intellectual property rights.\textsuperscript{15}

Although the major international patent effect on developing countries on inventions came through “the BIRPI Model Law drafted for developing countries and forwarded to 69 developing countries in 1964,”\textsuperscript{16} the present Nigerian patent law took much of its relevance from the Model Law.\textsuperscript{17} In fact, developing countries, including Nigeria believed that the Model Law was an opportunity for them to gain access to patented foreign technology, increasing competitiveness in trade and locating technological information for their countries.\textsuperscript{18} It is in this respect that Nigeria (and most other developing countries) modelled the Patents and Designs Decree of 1970 according to BIRPI Model Law.\textsuperscript{19} This law still regulates the patents

\textsuperscript{14} Sipa-Adjah G. Yankey, \textit{International Patents and Technology Transfer to less Developed Countries}. (Grower Publishing Co., Avebury 1997) at 211.


\textsuperscript{17} Lesser, William ‘An overview of Intellectual Property Systems in World Bank Discussion Papers in Strengthening Protection of Intellectual Property in Developing Countries: A Survey of the Literature [WDP-112]’, <http://www.wds.worldbank.org/servlet/WDContentServer.pdf>, accessed 28/05/2008. William Lesser observed that the BIRPI was a response to the pressure from the industrial countries on the less-developed countries to join the ‘community of nations’ in the Union; it was an attempt to view international patenting through the eyes of the less-developed countries. Also, that this resulted in a working agreement with the United Nations and several of its subsidiary bodies under various resolutions in assisting the transfer of technology to developing countries noted in the Report of the Secretary-General of the United Nations, ‘Progressive Development of the Law of International Trade’, (1966).


law and its administration in Nigeria to date, but achieving the essence of the policy behind the patent system still remains elusive in the face of public health crisis in Nigeria.

The failure of the patent objective in Nigeria may be traced to the Paris Convention, which from inception was contentious on the status, rights and obligations of the colonies and protectorates. As observed, the Paris Convention:

... did not create substantive law for member states; further, they [Union Members] also did not impose new law on member states. Rather, they reflected, to a large extent, a consensus reached among the states which was legitimated by the existence of a similar system within their respective domestic countries.20

In this respect, the Washington Conference, Article 16bis was adopted to regulate the application of the Convention to the colonies, possessions, and other subject territories (and this provision remained unchanged even after the Lisbon revision). Article 16bis provides:

The contracting countries shall, at any time, have the right to accede to the present Convention on behalf of all or part of their colonies, possessions, dependent territories and protectorates.

They may, for this purpose, make either a general declaration of adhesion that includes all their colonies, possessions, dependencies and protectorates, or expressily indicate only those which are included, or which are excluded...

The contracting countries may, in the same way, denounce the Convention on behalf of all their colonies, possessions, dependent territories and protectorates, or on behalf of some of them.

In accordance with this article, Great Britain acceded on behalf of Canada21 and the Irish Free State22, but did not accede on behalf of Nigeria/West African colonial territories. 23 Rather, the British Parliament asserted its full legislative and

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21 September 1 1923
22 December 4 1925
23 Nigeria however acceded to the Paris Convention in September 1963 and during this period the wave of independence was sweeping across the West African sub-region.
administrative authority over the colonies and protectorates\textsuperscript{24} and passed the Gold Coast (now Ghana) Patent Ordinance 1899\textsuperscript{25} modelled on the British Patents, Designs and Trade Marks Act 1883.\textsuperscript{26} This Ordinance was replicated for the rest of the colonies in accordance with the resolutions of the Paris Convention. The replication in the colonies became the foundation of patent legislation in Nigeria as the colonial office sent copies of the legislation to the colony of Lagos, the Southern and Northern protectorate Nigeria (now constituting the present day Nigeria\textsuperscript{27}) with the specific instruction to pass a similar ordinance.\textsuperscript{28} The Governor of the Lagos Colony stated that the Patent Ordinance of Lagos Colony was "based on the imperial statute and Gold Coast Ordinance dealing with the matter."\textsuperscript{29} The possible reason for this imposition was that Britain was pre-occupied with the establishment of administrative powers and control of the region for economic reasons.\textsuperscript{30} Part of this included the amalgamation of Nigeria and the need to maximise revenue through custom duties in the export of raw materials (mainly oil palm kernel, groundnut, cocoa, rubber, cotton and beniseed).\textsuperscript{31} This also influenced the idea of the Colonial and Welfare Development Act, enacted in furtherance of the economic benefits of the imperialist rule.\textsuperscript{32}

Reflecting on the rationale for the enactment of patent legislation for the colonies, in the case of Ghana, the significant factor was the protection of the imperialist interest in the gold mining industry. Patent protection was provided for the machinery necessary for the exploitation of gold and other mineral resources.

\textsuperscript{24} Sir Henry Jenkyns, 'British Rule and Jurisdiction Beyond the Seas', \textit{Harvard Law Review}, Vol.16/No. 5 (1902) at 384.
\textsuperscript{25} Gold Coast (now Ghana), Patent Ordinance 1899, No. 1 of 1899.
\textsuperscript{26} See the Board of Trade’s letter dated 16 May 1898 in C.O. 96 Gold Coast 1898, Vol. xx, 329 cited in Yankey 1987: 100.
\textsuperscript{27} This extension resulted in the enactment of the Patents Ordinance No. 17 of 1900 for the Lagos Colony; the Patents Proclamation Ordinance No. 27 of 1900 for Southern protectorate Nigeria, amended by the Patents Amendment Ordinance No. 19 of 1901; and the Patents Proclamation Ordinance No. 12 of 1902 for Northern Protectorate Nigeria.
\textsuperscript{28} See C.O. 96 Gold Coast 1899, in Yankey 1987: 104.
\textsuperscript{31} E. T. Penrose, \textit{The Economics of the International Patent System} (Johns Hopkins Press, Baltimore 1951) at 53.
This was obviously for the benefit of the colonial masters as there were hardly any industry or research institutions that would have benefited from patent protection from inventions at that time.\textsuperscript{33} However, the replication of this Ordinance in Nigeria and other British West African colonies and protectorates raises questions concerning the justification for this extension. Since the satisfaction of the administrative objective of the colonial authorities was paramount, the patent legislation was not meant to spur inventiveness, research and development, innovation and the transfer of technology, which would have enhanced access to medicines. Therefore, satisfying functional administrative structures would amount to satisfying the beneficial interest of the constituting authority (The British Crown) in sustaining the raw material base of the colonial masters.

These colonies and protectorates did not actively participate in the new formulation, nor were they taken into account when the international formulation was put in place.\textsuperscript{34} Thus, while the participants at the conference were quick to accept that uniform legislation was “impossible in a world of national states with different interests, different legal structures and different economic histories, aspirations and ideologies.”\textsuperscript{35} Nevertheless, the movers of the Paris Convention were equally quick to bind the destinies, aspirations and ideologies of the colonial territories to their colonial masters, without their participation.\textsuperscript{36} Thus the decision to enact a patent system for the colonies and protectorates did not consider the importance of such a system to the socio-economic situation in these colonies.

The imposition of European institutions, norms, and systems - including the patent system - on the cultural, economic, and legal landscape, was an expansion of the colonial enterprise,\textsuperscript{37} and had nothing to do with stimulating indigenous


\textsuperscript{34} E. T. Penrose, \textit{The Economics of the International Patent System} (Johns Hopkins Press, Baltimore 1951) at 53.

\textsuperscript{35} E. T. Penrose, \textit{The Economics of the International Patent System} (Johns Hopkins Press, Baltimore 1951) at 53.

\textsuperscript{36} At the Washington Revision Conference in 1911, the members of the Union still went ahead to amplify the conferment of the right to regulate the application of the Convention provisions on the colonial masters.

innovation. There was no technological policy framework at that time; indeed, there
was a near total technological vacuum in the colony and protectorate that
subsequently became Nigeria. This is evident from the report of the Comptroller-
General of Patents, Designs, and Trade Marks of United Kingdom which states that
from 1884 to 1899 the applications for patents shows that the entire West African
British colonies put together received only seven patents applications in totality.38
Suffice to mention that none of the applicants was from Nigeria.

Despite the paucity of patent applications in this region, the British Crown
exercised its powers by conferring on the colonies’ administrative authorities,
legislative powers vested with varying degrees of imperial control.39 In January 1
1914, the colony of Lagos and the Protectorate of Southern Nigeria merged with the
Protectorate of Northern Nigeria to form the Colony and Protectorate of Nigeria, in
furtherance of administrative convenience. This amalgamation resulted in the repeal
of the Patents Ordinance for Lagos and the Patents Proclamation Ordinances for
Northern and Southern Nigeria, their place was taken by the Patents Ordinance
1916,40 which applied to the whole of Nigeria. The Patent Ordinance of 1916 was
replaced by the Registration of United Kingdom Patents Ordinance of 1925.41 In part
the replacement of this ordinance was necessitated by the amalgamation,42 bringing
together all the laws regulating patents in the colony and the protectorates of Nigeria.
However, it was also necessitated by the lack of local technical knowledge of the
patent system, made obvious in the report on the draft Patent Ordinance of 1916 by
the Attorney-General of Nigeria.43

The Ordinance of 1925 provides for the registration in Nigeria of patents
granted in the United Kingdom provided the application for registration was made

38 See “the Seventeenth Report of the Comptroller-General for the year 1899” Ordered by the House
of Commons 8 May 1900. Printed for Her Majesty’s Stationary Office by Eyre and Spottiswoode
[Electronic version] accessed on 24/04/2008 from
<http://parlipapers.chadwyck.co.uk/imageserver/pageimage.cgi?RECORD=19>; See also Appendix
3, 4, and 5 below for the patent applications.
39-60 at 40.
40 The Patent Ordinance, No. 30 1916, was already in force in other British Colonies of Uganda,
Sierra Leone and Hong Kong before it’s promulgation in Nigeria on 13 July 1916.
41 Registration of United Kingdom Patents Ordinance No. 6 of 1925.
42 Sipa-Adjah G. Yankey, International Patents and Technology Transfer to less Developed
Countries. (Grower Publishing Co., Avebury 1997) at 121.
within three years from the date of the issue of the patent. The rights conferred in Nigeria dated from the date of the grant of the patent in the United Kingdom and remained in force so long as the patent was in force in the United Kingdom. The 1925 ordinances contained provisions for the application for a patent grant, the examination of a patent application, terms of a patent, what constituted abuses of patent monopoly and the measures for checking the abuses. However, the impact of colonial laws on the patents law and its administration in Nigeria lasted beyond the colonisation period up to the enactment of patent law under independence. In Nigeria, the combined effect of the international developments in the area of patent law, and the colonial laws that were handed down by Great Britain influenced the patent law and its administration.

These imposed laws - the 1925 ordinance and the United Kingdom Patents Act of 1949 - became the subject of judicial scrutiny in Nigeria and shows the tension in the country with respect to the application of foreign laws. In *Rhone Poulence* the first claimant took out a United Kingdom Patent No. 716207 in 1951 “in respect of improvement in or the new phenthiazine derivatives.” They subsequently registered it in Nigeria in 1957 under the 1925 UK Patent Ordinance as Patent No. 367 under the exclusive licence of the second claimant, a subsidiary of the first claimant. The second claimant engaged in the selling and distribution of the chemical product chlorpromazine under the name “Largactil,” which had very wide sales and a good reputation throughout Nigeria. In 1964, following a supply order from the Federal Ministry of Health, the defendant, an indigenous pharmaceutical company, supplied a large quantity of Largactil and also received additional supply order for the same drug. It was also alleged that the defendant displayed the same drugs on its stand at an exhibition of pharmaceutical industries at the Federal Palace Hotel, Lagos in April 1964.

The claimants commenced this action to restrain the infringement of their rights and in the meantime applied for an interim injunction to restrain further breaches pending the determination of the action. The defendant acknowledged the patent right of the claimants, but contended that it was no infringement to supply to

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45 Phenthiazine derivatives are chemical substances derived directly or indirectly from the substance phenthiazine and the compound known as chlorpromazine hydrochloride which was the subject matter of the suit.
the Federal Ministry of Health for the use by the public. The defendant relied on s.46 (1) of the United Kingdom Patents Act 1949 which provided that:

Notwithstanding anything in this Act, any Government department, and any person authorised in writing by a Government department, may make, use and exercise any patented invention for the service of the Crown in accordance with the …provisions of this section.

Ikpeazu J. held that the UK Patent Act 1949 did not apply in “its totality or as such to Nigeria.” He maintained that the only significant effect the 1949 Act had in Nigeria was in respect of the rights and privileges that ensued from the issuance of a certificate of registration after the registration of a United Kingdom patent in Nigeria as provided by s. 6 of 1925 ordinance. But that this “did not mean that the whole Act applied.” Further, His Lordship held that s. 46(1) of the 1949 Act was an express power which the Act specifically confers on a government department which could operate in diminution of the patentee’s rights. For this limitation to operate in the country, the Nigerian legislature had to make an express provision in favour of a government department to enable them to authorise non-patentees or non-licensees to supply patented product. Since the Nigerian legislature had not made such provision the conclusion according to Ikpeazu J. was that “the legislature did not intend the power to exist.” Consequently, an injunction was issued against the defendant.

This decision in the Rhone-Poulence led to the promulgation of the Patents (Limitation) Decree of 1968, passed by the military leadership in power. This decree was saved and continued to be in force by the provision of Part 1 of Schedule 1 of the Patents and Designs Decree 1970. The provision in s. 15 made clear the intentions of the Decree. It states that:

Notwithstanding anything in this Act, where a Minister is satisfied that it is in the public interest so to do, he may authorise any person to purchase, make, exercise, or vend any

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46 The decision noted that s. 46 (1) was relied upon and considered in the case of Pfizer Corporation v. Ministry of Health (1965) 1 All ER, but Ikpeazu J. was not swayed by the judgment in that case simply because an appeal to the House of Lords was pending. Interestingly, the Nigerian court accepted that ‘according to the Act, a patent has the same effect against the Crown as it has against a subject, except for the protection the Crown derives from the Crown Proceeding Act 1947 and from section 46 (1) of the Patent Act.’ The House of Lords has upheld the decision which allowed any government department to authorise the use of a patent under section 46 (1) at 450.

47 Patents (Limitation) Decree No. 8 of 1968.
such article or invention for the service of a government agency in the Federal Republic.

The 1968 Decree affected drug importation and supply by exempting government from infringement of a patent right with respect to the articles concerned or the liability to pay compensation or royalty to a patentee or any person deriving title from him. The power may be exercised in the prosecution of any civil war in which the Federal Republic may be engaged and the supply and maintenance of essential services, and the promotion and protection of the economy. Furthermore, it made the application of the UK Patents Act and amendments thereof in Nigeria subject only to the modifications introduced by the Decree. This law therefore received the United Kingdom Patents Act of 1949 and the 1925 Ordinance as the statutory law regulating the patent law system and its administration into the Nigerian legal system until the coming of the Patents and Designs Decree of 1970.

During the operation of the 1925 Ordinance, the colonial masters resorted to the colonial development plans for the protection of their industrial interest and raw material needs through harnessing the agricultural potentials of Nigeria. This had effect on the emergent independent government in Nigeria with the subsequent national development plans failing to redress the need to harness the patent law potential or articulate policies for the healthcare in Nigeria. The expectation of Nigeria had been that a development plan should facilitate the management and exploitation of intellectual property rights, promote exchange of experience in the formulation, enforcement and access to patented technology. Though this was not the case, the plans itself were slow to be implemented, the policy behind them was

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48 Patents (Limitation) Decree s. 1 (3) of 1968.
49 Patents (Limitation) Decree s. 3 (2) of 1968.
50 Patents (Limitation) Decree s. 3 (1) of 1968.
51 Patents (Limitation) Decree s. 5 (2) of 1968.
52 Colonial Development Act 1929 was passed by the British Parliament, providing for grants of up to £1,000,000 annually “for the purpose of aiding and developing agriculture and industry” in the colonies “and thereby promoting commerce with or for industries in the United Kingdom”. This was followed by the Colonial Development and Welfare Act 1940 which made provision for the British government to contribute financially to the economic and social advancement of the colonies. The 1940 Act heralded the Colonial Development Plans of 1945-1955 and 1955-1960, which led Nigeria from colonial rule to independence.
not useful to the colonies. Hence the plans themselves were not strong framework for development, particularly with regard to patents and public health.

The Select Committee of the British House of Commons criticized them given that “the plan does not propound a complete strategy of development; it was merely an aggregate of proposals for spending money.”\(^{54}\) Evidently, these plans were unsatisfactory and became a manifestation of failures as the initial plan (1929 and 1940) died on the drawing board because of lack of strategy. While the implementation of the later plans (1945 and 1955) under social welfare approach did not address the patent law issues that should have enhanced development through invention. Invariably, whilst the colonial masters were interested in the development of agricultural production for their industries, the resultant effect was the failure to encourage inventions even in the rudimentary industry in Nigeria.

Also, the national development plans failed to address the issue of patents in spurring inventiveness, research and development and technology transfer. This national development plan was criticized for not relating to definite national objectives of economic growth and for the fact that Nigerians were not involved in its formulation.\(^{55}\) Even the Patents Rights (Limitation) Decree did not show any understanding of the difference in the level of industrialisation nor the costly and cumbersome procedures of obtaining a Nigerian patent or the need to encourage indigenous inventive activity. It is the same effect that prompted the enactment of the Patents and Designs Decree 1970.\(^{56}\) This Act governs the patent law system and administration in Nigeria,\(^{57}\) and marked the end of the colonial era of the patent history of Nigeria.

The present law raises the question as to the efficiency of the patent system in stimulating inventiveness, encouraging research and development, enhancing technology transfer, increasing technology base and improving the production capabilities in Nigeria. If these expectations were actualised, pharmaceutical production and access to drugs and health care would have been the obvious rather


\(^{56}\) Patents and Designs Decree No. 60 of 1970 (now Patents and Designs Act, published under chapter 344, laws of the Federation of Nigeria 1990). PLS CITE THE LAWS OF NIGERIA 2004

\(^{57}\) Prior to this promulgation, the patent law of Nigeria continued to depend on the Registration of United Kingdom Patents Ordinance 1925 and the United Kingdom Patents Act 1949.
than the exception. However, the health sector has not leveraged on the existing patent system, and health condition of the population is an indication of ineffective patent system in the country. This is made obvious by the incidence of HIV/AIDS, malaria pandemic, tuberculosis and other communicable diseases. There is need to tackle the health problems through a patent system that will enhance access to essential life saving medicines. Certainly the need to reposition the patent law system would enhance the vibrancy of the pharmaceutical sector.

**The Pharmaceutical Industry Issues**

The colonial impact on the Nigerian pharmaceutical sector can be observed in the five stages in its evolution. The first phase, the *pre 1957 era* dominated by foreign multinationals involved in the business of distribution of imported drugs, there was no local participation in the drug business. This goes to support the fact that inventions and patenting was entirely a foreign business that was alien to the colonies.

The second phase, from 1957 to 1980, saw the expansion of foreign participation, with production plants now established in Nigeria. The production plants were set up during the operation of the Registration of United Kingdom Patents Ordinance 1925 as the statutory law for patents. Again these production plants were not used as a means of producing cheaper drugs, but were still involved in profit maximisation and evidence of the market mechanism response geared towards actualising the shareholders profits with the monopoly and technological power. After the enactment of the Patents and Designs Act 1970, two more production plants were setup by SmithKline Beecham (1973) and May and Baker

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60. The foreign companies that operated during this period include Beecham, May and Baker, Pfizer, Glaxo and J. L. Morrison.

61. The companies with production plants included Glaxo (1958), Pfizer (1962), Sterling (1963), Wellcome (1967), PZ (1968), and Pharchem (1968).

(1977). Participation in the drug sector remained a foreign interest, necessitating the enactment of the Nigerian Enterprises Promotion Decree of 1972 which was subsequently amended and renamed the Indigenization Policy 1977. This policy obliged foreign businesses in specified sectors to transfer their ownership wholly or in part to private Nigerian investors and businessmen. It aimed at increasing local participation without eliminating foreign investment. The Indigenization Policy of 1977 forced most of the multinational companies to sell 60% of their shares to Nigerian investors, it increased government participation in some business, in it pursuit of the goals of “egalitarianism, spatially balanced distribution of economic activities, spatially balanced spread of beneficiaries of equity shares, and ownership and control of businesses”, and the pharmaceutical sector was affected.

The Indigenization Policy heralded the third phase lasting from 1980-1982 and local production increased from 5% to 20% and the economy witnessed positive signs of growth, with the likely catalyst seen to be the Indigenization Policy and not the Patents and Designs Act. The fourth phase from 1983-1986 witnessed the degeneration of what was a growing economy with the nation becoming an import dependent for its drug needs, while abandoning the drug production plants that were set up. A further support to the negative impact of colonisation on development of the nation and the impact became the genesis of fake, counterfeit and substandard drugs in Nigeria. The course of development of the pharmaceutical industry was now

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64 Michael Adejugbe, 'The Myths and Realities of Nigeria's Business Indigenization', Development and Change (1984) 15 (4), 577-92, according to Adejugbe ‘Schedule One industries were expanded and reserved exclusively to Nigerian citizens or associations; foreign companies could engage in Schedule Two industries provided 60 per cent equity share had been sold to Nigerian citizens and in Schedule Three provided 40 per cent equity had been sold to Nigerians. Superimposed on this was the rider that a company could operate virtually in any economic sphere provided 60 per cent equity had been sold to Nigerians and that such a company operated in ten (out of nineteen) of the states of Nigeria.’ At that time the county had a nineteen state structure. See also Chibuzo S. A. Ogbuagu, ‘The Nigerian Indigenization Policy: Nationalism or Pragmatism?’ (1982) <http://afraf.oxfordjournal.org/cgi/reprint/82/327/241.pdf>, accessed June 21, 2010.

altered and the business of drug manufacturing was negated. This was made worst by the enactment of the “infamous” Import License Decree which allowed for unrestricted import of all goods, including drugs, abandoning drug manufacture with an over dependence on oil as the major income earner.

Since 1987, the present phase in the evolution of drug production – the fifth in this series – is in effect a response to the problem created during the fourth phase, and an attempt to develop a strategic economic and industrial policy plan for Nigeria with the introduction of deregulation and liberalization of the economy. By deregulation, it means “the deliberate informed process of removal or mitigation of restrictions which are obstacles or non-deterministic and tend to reduce efficiency or competitive equities.” It is characterized by privatization and commercialisation of the economy, resulting in neo-liberal free market economy with government selling its shares in major companies while it sets up agencies to regulate, supervise and control private participation. This in fact resulted in 100 percent foreign participation in any sector subject to government approval. Part of this policy brought about the introduction of the Enterprise Promotion Act 1989 which repealed the Nigerian Enterprise Promotion Decree of 1977.

The government policy programme resulted in the establishment of the National Agency for Food, Drug Administration and Control (NAFDAC) in 1993. The enabling Decree mandates NAFDAC to “regulate and control quality standards for food, drugs, cosmetics, medical devices, chemicals, detergents and packaged water imported, manufactured locally and distributed in Nigeria”. The establishment of NAFDAC and their efficiency in the fight against fake and counterfeit drugs has

71 Decree No. 15 of 1993.
improved the manufacture of pharmaceuticals and also given impetus to indigenous participation in pharmaceutical manufacture.\textsuperscript{72}

An additional redress by the government have involved some policy documents which include the “Vision 2010 report;”\textsuperscript{73} the “National Economic Empowerment and Development Strategy (NEEDS),” which was expected to lapse in 2013, and the “Visioning for 2020” with ITS 7-points agenda.\textsuperscript{74} Though these documents have been abandoned by the government, it is observable that none of these documents mentioned the need for the Patents and Designs Act or any patent legislation for that matter. This in fact makes it evident that every “government in power” sets out its own agenda and discards any existing agenda. The editorial comment of the \textit{Guardian} has identified these development agendas as constraints to national development.\textsuperscript{75} The reality of the change in policy objectives is that the government hides behind the policy framework as a smoke screen with every succeeding government in Nigeria creating an obstacle with their policy framework. This affects most development, policy and administrative issues, including the patent law system and administration, an inconsistency that has become a colonial hangover trailing Nigeria.

In the context of inventions and patenting, patent rights have enormous public health implications for access to drugs and healthcare. These include the neglect in researching and developing drugs for diseases prevalent in developing countries, making the price of existing drugs unaffordable and strengthening pharmaceutical policies and practices that would discourage innovation and domestic generic industries. The neglect has exacerbated the health conditions and is currently manifesting as crisis in healthcare of developing countries, with 95\% of the global total, of people living with HIV, actually live in developing world.\textsuperscript{76}

\textsuperscript{72} For example Emzor, Mopson, Barewa, Geonnasons, Continental, Ashmina, and Afrik as noted in NAFDAC Nigeria (2005).
\textsuperscript{76} The United States President’s Emergency Plan for AIDS Relief on Worldwide HIV & AIDS Statistical Commentary (PEPFAR) (2003)
As the patent system and administration has not received attention in Nigeria and the lack of an effective law on the production of essential drugs or the generic versions of the drugs. The imposition of laws has not laid the foundation for Nigeria pharmaceutical sector to grow and improve upon and this has resulted to inconsistency in policy articulation, formulation and implementation within the health sector. The implication is that the health sector is neglected and this affects access to drugs, high cost of drugs, and poor infrastructural development leading to the prevalence of fake, substandard and counterfeit drugs as the order of the day.

With the present democratisation in Nigeria, overcoming the problems of the health sector may need urgent intervention from within countries. These must emphasis the option of cross-party agreement in policy formulation for an endearing policy implementation independent of the government in power. This will enhance law making process and enable the Nigeria Intellectual Property Commission (NIPCOM) Bill to present a legislative framework that will enhance a workable patent system. The Bill would set the stage for research and development, inventiveness, innovation and transfer of technology or adaptation of new technology. This may involve a broad approach that will consider the peculiarities of the country, its predicaments and historical antecedents in both articulation and implementation of policies. Such intervention would make the TRIPS Agreement effective for access to drugs and health care in Nigeria.

**Conclusion**

This article has observed that the origin and history of patent law in general was initially concerned with the protection of the beneficial interest of the industrial nations. This was enhanced by the mandatory provisions of the Paris Union that encouraged the British colonial authorities in the imposition of colonial patent ordinances and proclamations to the colonies, including Nigeria. At independence, practical dependence was on the Registration of United Kingdoms Patents Ordinance 1925 for regulating patent law in Nigeria long after independence. In the same vain, the colonial masters introduced the colonial development plans in Nigeria for aiding and developing the raw material base and to promote commerce with or for industries in the United Kingdom. The development plans heralded the national
development plans, a weak system that could not tap on the gains of a patent system nor institute a workable patent system. This weak foundation has impacted on the emergent independent Nigeria resulting in instability, and inconsistency in policy articulation, formulation and implementation.

The cumulative effect of the historical development manifests the protection of the colonial master’s interest in the development of the raw material base on one hand and the protection of their investments and potential investments on the other. This diminished the objective for introducing the patent law system for the promotion of inventions even at the rudimentary level for the colonies. Rather, it enthroned an administrative structure that will secure the raw material base for the industries of the colonial masters. This affected the emergent independent governance structure to align with the thinking of “any government in power.” The effect of the above is that the patent law system and administration did not receive any attention and there was no effort at using the system to enhance research and development, invention, innovation or even technology transfer for the pharmaceutical sector to enhance access to drugs and health care in Nigeria.

A step towards righting the wrong demands legislative action and the Nigerian Intellectual Property Commission (NIPCOM) Bill presents the opportunity for reform. The Bill for the establishment of the Nigerian Intellectual Property Commission was one of the Bills suspended because of the Nigerian general elections. With the general election now concluded, there is every need for the legislature to revisit the Bill for enactment into law. This would allow the use of “several measures accepted by the TRIPS Agreement to ensure that intellectual property protection does not override the rights and health of the developing and least developed countries,” including Nigeria. These measures, [relate to] the public health-related flexibilities, allowed under the TRIPS. The Bill would allow for the following particularly desirable specific reforms.

Firstly, there is no TRIPS specification on patentability criteria; this leaves member countries, including Nigeria with the option of interpreting and applying the criteria in accordance to their national priorities. A good example is the “new use” patent protection which allows known substances to be protected because a new use

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has been found for an existing compound. The Nigerian legislature should use the available policy space and freedom to limit the grant of patents for new uses of known compounds which in effect extend the life of a patent beyond 20 years.

Secondly, the expectation is that generic companies must replicate the full set of test data necessary to obtain approval even where a product is off-patent. Their inability to gain marketing approvals based on the clinical data places the cost burden on production which will be passed on to the consumer. Therefore, the provisions of the US FTAs mandating the regulatory agencies to refuse marketing approval to generic versions of products if a patent thereon is in force except with the consent of the patent owner. This puts the responsibility of patent protection on the regulatory agencies and relieves the courts from their judicial responsibility of determining the rights of the patent owner. Therefore, a regulatory agency like NAFDAC, involved in the safety and marketing standards, would get involved in the validity of patents through registration, which is beyond the statutory mandate that set up this regulatory agency. The reform agenda would be an opportunity to resolve the issue of protection of undisclosed information relating to data exclusivity which would allow the generic manufacturers’ access to data needed for neglected diseases specific to Nigeria. In addition, this would streamline the functions of NAFDAC and the Nigerian patent office in the determination of a patent life.

Thirdly, the exceptions to patent rights provided by the TRIPS Agreement allows for additional policy options for developing and least developed countries to make drugs accessible and affordable. These are measures meant to ensure transfer of technology, dissemination of knowledge and to circumvent anti-competitive actions of the research based pharmaceutical companies. Such measures include compulsory licensing, government use exceptions and parallel importation. These flexibilities are available for member states to resort to and could mitigate the negative impacts of the patent system and sustain the advantages of the system. However, the need for them to gain legislative efficacy is required and this can only be achieved through legislative reform, judicial efficiency, resolution and strengthening of institutional and administrative issues hindering access to health care. In this respect therefore, the newly elected legislature needs to treat the NIPCOM Bill as a priority issue in the legislative agenda for the interest of public health care.
In addition, it is recommended that the Nigerian Government should address the issues of health budgeting, budget implementation, manpower development and above all sustain the fight against corruption. These are Non-TRIPS options which should be reviewed and strengthened for a long term policy plan implementation that enjoys cross-party support independent of changes in Government. Attention must also be given to institutional development, infrastructural development, drug production, procurement, storage and manpower development in Nigeria. Though there has been much rhetoric surrounding the war against corruption in Nigeria, this war should not be used to satisfy the political egos of those in power. Rather it should be sustained to enhance project formulation and implementation so as to achieve efficacy, improve and sustain enhance access to drugs and healthcare in Nigeria.