



A Review of the Nigerian System of Intellectual Property

A Case Study
Under NABDA/CAS-IP NPI Collaboration Project

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Executive Summary

Intellectual Property (IP) in Nigeria can be traced back to the colonial era when the English Trademark Ordinance was introduced into the colonies even before the amalgamation of the then British Northern Nigeria and Southern Nigeria Protectorates to form what is today called Nigeria in 1914. Intellectual Property is administered in Nigeria under two main set ups- industrial property, which deals with trademarks, patents and industrial designs as well as copyright. The system of Trademark registration is governed by the Trademarks Act 1965 found in Cap 436 Laws of the Federation of Nigeria(LFN)1990. Patents and Designs registration on the other hand are governed by the Patents and Designs Act 1970, to be found in Cap 344, Laws of the Federation of Nigeria 1990. The Trademarks, Patents and Designs Laws are currently administered by the Commercial Law Department, Trademarks, Patents and Designs Registry, of the Federal Ministry of Commerce and Industry. Copyright on the other hand is protected in Nigeria by the Copyright Act and the Nigerian Copyright Commission (NCC), an agency under the supervision of the Federal Ministry of Justice, NCC is charged with the primary responsibility for all copyright matters.

National and International developments have necessitated reforms in the intellectual property system of different countries of the world. The World Trade Organization's TRIPS (Trade Related Aspect of Intellectual Property Right) Agreement of 1994, obliges members to provide intellectual property protection in its laws. TRIPS established minimum standards for the availability, scope, and use of seven forms of intellectual property: copyright, trademarks, geographical indications, industrial designs, patents including (Plant Variety Protection, PVP), layout designs for integrated circuits and undisclosed information (trade secrets). On living organisms, WTO allows countries to patent microorganisms but requires countries to use a *sui generis*(ie other, different) system to protect new plant and animal varieties or by the application of the two types of protection. As a WTO member, Nigeria is under obligation to reform its intellectual property laws in this direction though in line with AU Model Law which disapproves the patent of any life form. The mandatory requirement for amending the laws was January 1, 2000 while the time frame set for implementation was 2005 subject to extension.

Recently in Nigeria (2006), there had been recommendations and steps taken for the different Intellectual Property schedules to be placed under one umbrella institutional framework for effective administration and management. To this extent there was a proposal to establish Nigerian Intellectual Property Organization (NIPO) by the Ministry of Science & Technology and NOTAP, to bring all the agencies under one umbrella similar to the WIPO system and ensure an effective and balanced development of the IP system in the country. The quest for a paradigm shift in the framework led to a move to secure the approval by the then President Olusegun Obasanjo of the Intellectual Property Commission of Nigeria (IPCON) under the aegis of the Federal Ministry of Justice, thus bringing the Nigerian Copyright Commission and the Registry of Trademark, Patents and Design together under one umbrella organization to be hosted by the Federal Ministry of Justice with the view that IP is a judicial matter.

A draft national IP bill seeking to conform to WTO was prepared by a committee with members drawn from the stakeholder institution. The draft bill includes Plant Breeders Rights, Animal Breeders Rights and Farmers Rights. But there is the need to re-examine the proposed draft bill and the umbrella IP body it is seeking to create in view of experiences in other countries of the world and the expectations from the reform. This will enable Nigeria to benefit from the gains associated with the WTO's TRIPS including associated increased investments and trade in agriculture and biotechnology. There is also the possibility of sanctions from the WTO if Nigeria continues to delay the reform process.

The National Office for Technology Acquisition and Promotion (NOTAP), an agency under the aegis of the Federal Ministry of Science and Technology, established by Decree No. 70 of 1979 also plays important role in Intellectual Property and Technology Transfer (TT) Management in Nigeria. It does this by assisting researchers to patent their inventions free of charge, patent documentation, establishment of technology transfer offices in the universities and research institutes, awareness creation to increase the culture of patent in the country and assisting in licensing and commercialization. Records available at NOTAP shows that for the period 1998-2007(10years) the non-conventional (local) patents filed at the Trademarks, Patent and Designs Registry was 566 representing 11.7% of the total applications filed, while the conventional (foreign) patents filed was 4,257 representing 88.3% of the total patents filed. For patents granted, non-conventional (local) has

318 applications granted representing 11.7% of the total granted, while the conventional (foreign) has 2,398 representing 88.3% of the total number of patents granted.

Also considering the challenges and the objectives of establishing the Agricultural Research Council of Nigeria (ARCN), the Council has plans of setting up a central IP management body to be housed in its Legal Unit to coordinate intellectual property issues in the agricultural research institutes. This is because the council is aware that the public goods investments policy in agriculture is facing a bleak future for a number of reasons principal amongst which are: Increased emphasis on market mechanisms facing public funded organizations to respond to broad economic opportunities, and changes brought about by the introduction of intellectual property rights (IPR). The National Council on Science and Technology (NCST) and the newly formed Nigerian. Research and Development Coordinating Council (NRDCC) are important organs through which S&T policy issues affecting R&D such as Intellectual Property can be harmonized for the growth of R&D in Nigeria.

A few recommendations have been offered. A study need to be carried out to determine which model of IP office the country should adopt- an umbrella body or a decentralized system of having the different IP registries in different ministries. This will enable the country overcome the present impasse in creating an umbrella agency. Irrespective of the outcome of the exercise, one clear observation under the new dispensation is that Plant Varieties Protection (PVP), Animal Breeders Rights, Farmers Rights and microorganisms are *sui generis* (unique, different), technological patents going by the WTO and extended by the AU Model Law which does not allow the patent of any life form. This implies that they are not to be administered within the existing IP frameworks is the trend in most other countries, and these are usually located within the technology system of the country for a balanced development.

It is thus recommended that the National Crop Varieties and Livestock Breeds Registration and Release Committee Decree 33 of 1987 be amended to include Plant Variety Protection (PVP), Animal Breeders Rights, and Farmers Rights. The Committee is currently administered by the National Centre for Genetic Resources and Biotechnology (NACGRAB). Another recommendation is to enact a National Biotechnology Law. This will give a legal backing to the establishment of the National Biotechnology Development Agency (NABDA), regulate research on microorganisms in terms of IP, and regulate biotechnology research with respect to benefit sharing on biopharmaceuticals and nutraceuticals from bioresources. Alternatively, two separate laws on new plant varieties protection and to provide for a *sui generis* system for new microorganisms respectively should be enacted. Also the lessons offered by the licensing of NICOSAN- a drug developed by the National Institute of Pharmaceutical Research and Development (NIPRD) through a lead from traditional knowledge but licensed to Xechem International, an American company, could be useful in the exploitation of our rich genetic resources for disease control and wealth creation if harnessed.

Acronyms

AARD	Agency for Agricultural Research and Development
AU-STRC	African Union Scientific, Technical and Research Commission
ARCN	Agricultural Research Council of Nigeria
AU	Africa Union
BRELA	Business Registration and Licensing Agency
CAS-IP	Central Advisory Service on Intellectual Property
CHOP	Children's Hospital, Philadelphia
CPB	Cartagena Protocol on Biosafety
CGIAR	Consultative Group on International Agricultural Research
CBD	Convention on Biological Diversity
CIPRO	Companies and Intellectual Property Registration Office
DTI	Department of Trade and Industry
EMBRAPA	Brazil Agency for Agricultural Research, and Development
FMST	Federal Ministry of Science & Technology
FDA	Food and Drug Administration
FGN	Federal Government of Nigeria
GI	Geographical Indications
ICANN	Internet Corporation for Assigned Names and Numbers
ICT	Information and Communication Technology
IP	Intellectual Property
IPCON	Intellectual Property Commission of Nigeria
IPR	Intellectual Property Right
IPS	Intellectual Property System
IPTTO	Property and Technology Transfer Offices
LFN	Laws of the Federation of Nigeria
MARDI	Malaysia Agricultural Research and Development Institute
NABDA	National Biotechnology Development Agency
NAFDAC	National Agency for Food and Drug Administration and Control
NASRDA	National Space Research and Development Agency
NARI	National Agricultural Research Institutes
NARS	Nigeria Agricultural Research System
NCC	Nigerian Copyright Commission
NCST	National Council of Science and Technology
NCST	Nigerian Council on Science and Technology
NGO	Non-Governmental Organizations
NHLBI-SCDR Lab	National, Heart Lung and Blood Institute, Sickle Cell Disease Reference Laboratory
NICTIB	National Information and Communication Technology Infrastructure Backbone
NIGCOMSAT	Nigeria Communication Satellite
NIPO	Nigeria Intellectual Property Organization
NIPRD	National Institute of Pharmaceutical Research and Development
NITDA	National Information Technology Development Agency
NJAES	New Jersey Agricultural Experiment Station
NNMDA	Nigeria Natural Medicine Development Agency(NNMDA).
NOIP	National Office of Industrial Property.
NOTAP	National Office for Technology Acquisition and Promotion
NPI	National Partners Initiative
NRDCC	National Research and Development Coordinating Council

NSS	National Seed Service.
NUC	National Universities Commission
OFAR	On Farm Adaptive Research
PBR	Plant Breeders Rights
PCT	Patent Cooperation Treaty
PDC	Patent Information and Documentation Centre
PIC	Prior Informed Consent
PROMETRA	International Association for the Promotion of Traditional Medicine
PVP	Plant Variety Protection,
R&D	Research and Development
RI	Research Institute
SACRO	South African Companies Registration Office
SAPTO	South African Patents & Trade Marks Office
SCD	Sickle Cell Disease
SHESTCO	Sheda Science and Technology Complex
S&T	Science and Technology
TMKP	Traditional Medicine Knowledge and Practice
TRIPS	Trade Related Aspect of Intellectual Property Right
TT	Technology Transfer
TTO	Technology Transfer Offices
UNIDO	United Nations Industrial Organization.
UPOV	Union for the Protection of Plant Varieties
VCU	Virginia Commonwealth University
WHO	World Health Organization
WIPO	World Intellectual Property Organization

1. Introduction

1.1 Background of the Study

Intellectual property protection in Nigeria can be traced back to the colonial era, when the English Trademarks Ordinance was introduced into the colonies, even before the amalgamation of northern and southern protectorates to form what is now called Nigeria, in 1914. Intellectual Property is administered in Nigeria under two main set ups. Intellectual Property is administered in Nigeria under two main set ups- Industrial property, which deals with trademarks, patents and industrial designs as well as copyright

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Copyright on the other hand is protected in Nigeria by the Copyright Act. One of the most salutary provisions of the Act is the establishment of a body charged with the responsibility of implementing and enforcing the law. Section 30 of the Act established the Nigerian Copyright Commission (NCC). An agency under the supervision of the Federal Ministry of Justice, NCC is charged with the primary responsibility for all copyright matters.

National and International developments have necessitated reforms in the intellectual property system of different countries of the world. The World Trade Organization's TRIPS (Trade Related Aspect of Intellectual Property Right Agreement of 1994, obliges members to provide intellectual Property protection in its laws. TRIPS established minimum standards for the availability, scope, and use of seven forms of intellectual property: copyright, trademarks, geographical indications, industrial designs, patents, layout designs for integrated circuits and undisclosed information (trade secrets). As a WTO member, Nigeria is under obligation to reform its intellectual property laws in this direction. WTO TRIPS has however provision for *sui generis* (unique, standalone) IP systems for which the AU Model Law endorsed by all African Heads of State, has given guidelines to African countries.

National Biotechnology Development Agency (an agency in the Federal Ministry of Science and Technology) is participating in the National Partners Initiative(NPI), a programme of the Central Advisory Service on Intellectual Property(CAS-IP) of the Consultative Group on International Agricultural Research(CGIAR) which is based in Rome, Italy. The aim of the NPI is developing an international network of intellectual Property (IP) experts involved in issues relating to management of IP in agriculture. CAS-IP NPI is doing this because it believes that IP management should be about ensuring that research outputs are accessible for use to benefit those who need them most- resource poor farmers. CAS-IP aims to enable access to, and the use of CGIAR products for the benefit of the poor through effective IP and technology transfer management. Twelve countries are participating in the NPI: Burkina Faso, India, Indonesia, Kenya, Malaysia, Nigeria, Peru, Philippines, Tanzania, and Thailand.

The review of Nigeria's IP policies, with a view to making recommendations for reform towards agricultural development in line with the objectives of the CAS-IP NPI and using the TRIPS and AU Model Law tools is a major objective of this paper. Issues discussed include Nigeria IP laws, and the framework for administration, the Copyright Notification System of the National Copyright Commission (NCC), the experience of the National Office for Technology Acquisition and Promotion (NOTAP) in promoting IP and TT and the role of the R & D system in promoting IP. The case study of NICOSAN - a drug for the management of Sickle Cell Disease as a licensed Nigerian patent was also discussed.

1.2 Objectives of the Study

The study seeks to review the Nigerian system of Intellectual Property and Technology Transfer management viewed against the country's obligations as a WTO and AU member. It makes recommendations that will guide our policy makers as they try to reform our IP system to meet our

national aspirations and as well conform with international standards. It tries to recommend legal and administrative framework needed for the reform. It is also hoped that Nigeria's experiences in IP management when it is shared will offer a few lessons to other NPI participating countries either by avoiding Nigeria's mistakes or in following Nigeria's footsteps where it can make any positive contribution.

1.3 Materials and Methods

To achieve the objectives of the study all available documents on the Nigerian system of intellectual property were reviewed. This was intended to review operations in the IP institutions. Some documents relating to Nigeria's S & T policies as well as biotechnology policy were also reviewed. The institutions from which documents were reviewed include -Trademarks, Patents and Designs Registry, Nigerian Copyright Commission(NCC), Xechem Pharmaceuticals Ltd, Federal Ministry of Science and Technology, Federal Ministry of Commerce and Industry, Agricultural Research Council of Nigeria (ARCN), Sheda Science and Technology Complex, National Office for Technology Acquisition and Promotion(NOTAP), National Biotechnology Development Agency(NBDA), Nigeria Natural Medicine Development Agency (NNMDA) and National Centre for Genetic Resources and Biotechnology(NACGRAB).

This study coincided with another study on the Compendium on Intellectual Property in the developing countries conducted by CAS-IP's NPI. Questionnaires administered on the Nigerian system of IP for that purpose were also useful for this study. Interview from some officials of the major stakeholders of the system were also conducted including officials of National Agency for food and Drug Administration and Control (NAFDAC) and National Institute Pharmaceutical Research and Development. Websites of some relevant institutions were also visited including Africa Union (AU), WIPO, UPOV, Xechem International Inc. and Rutgers State University, New Jersey, USA.

2. Intellectual Property Laws and Administrative Framework In Nigeria

2.1 IP administration in Nigeria

Intellectual property protection in Nigeria can be traced back to the colonial era, when the English trademarks ordinance was introduced into the colonies, even before the amalgamation of northern and southern protectorates to form what is now called Nigeria, in 1914. Intellectual Property is administered in Nigeria under two main set ups.

i. Industrial property, which deals with trademarks, patents and industrial designs.

The system of Trademark registration is governed by the Trademarks Act 1965 found in Cap 436 Laws of the Federation of Nigeria 1990. Patents and Designs registration on the other hand are governed by the Patents and Designs Act 1970, to be found in Cap 344, Laws of the Federation of Nigeria (LFN) 1990. The Trademarks, Patents and Designs Laws are currently administered by the Commercial Law Department, Trademarks, Patents and Designs Registry, of the Federal Ministry of Commerce and Industry¹.

The country has no legislation for Geographical Indications (GI). GI is administered as part of Trademarks under Section 43(1) of the Trademarks Act CAP 436(Certification Trademarks), Laws of the Federation of Nigeria (LFN) 1990.

¹ Yauri Shafiu Adamu (Senior Asst. Registrar Trademarks, Patents and Designs Registry; Federal Ministry of Commerce and Industry, Old Secretariat, Area 1, Garki, Abuja) The System Of Intellectual Property Law And The Registration Framework In Nigeria: a paper contribution.

² See <http://www.nigerianlaws.com>

A major drawback in the registry is inadequate funding which has not enabled it to re-tool sufficiently to meet international standard especially in the area of database management. This calls for a review of the status of the registry with a view to giving it some degree of autonomy.

i. Copyright

Copyright on the other hand is protected in Nigeria by the Copyright Act³. Nigeria is a member of the Berne Union⁴. Consequently, Nigeria is bound by the formality-free principle of copyright protection. Copyright protection in Nigeria is thus granted by the law automatically. Under the Nigerian Copyright law, beyond satisfying the basic requirement of originality and fixation in tangible medium from which it could be perceived or communicated, every copyright work is protected upon their creation with the import that copyright protection is automatic. There is no requirement of copyright registration under the Copyright Act. However, owing to the need to satisfy the constant yearning of right owners for a framework for establishing evidence of existence of works, especially unpublished materials, and pursuant to its statutory mandate to maintain a data bank of all authors and their works, the Nigerian Copyright Commission has introduced the Copyright Notification scheme, which allows authors of copyright works to notify the Commission of the creation and or existence of works, and all other information relating to the work.

One of the most salutary provisions of the Act is the establishment of a body charged with the responsibility of implementing and enforcing the law. Section 30 of the Act established the Nigerian Copyright Commission (NCC). An agency of the Federal Ministry of Justice (earlier created under the Federal Ministry of Information), NCC is charged with the primary responsibility for all copyright matters. With the 1992 and 1999 amendments, the powers of the Commission have been expanded to cover enforcement of the law. Consequently, the Commission can appoint copyright inspectors who are empowered to conduct investigation and prosecute copyright infringement cases⁵. The inspectors have powers analogous to the powers of a police officer. The Commission is also empowered to make regulations prescribing conditions necessary for engaging in business involving the production, distribution or public exhibition of copyright works.⁶ This power has served as a powerful tool in initiating some important rights management schemes, which are aimed at creating a favorable environment for the exercise of rights by authors and right owners⁷.

The unfortunate byline is the low patronage of the scheme by authors and copyright owners. Between 2005 when the scheme was introduced in its present form and June 2008, the NCC received 995 applications only⁸.

³ Cap 68 Laws of the Federation of Nigeria 1990 as amended by Copyright (Amendment) Decree No.98 of 1992, and Copyright (Amendment) Decree No.42 of 1999. The Copyright Act was promulgated in 1988 as Copyright Decree No. 43 of 1988.

⁴Nigeria became a member of Berne Union in 1993.

⁵ See Section 32A of the Act

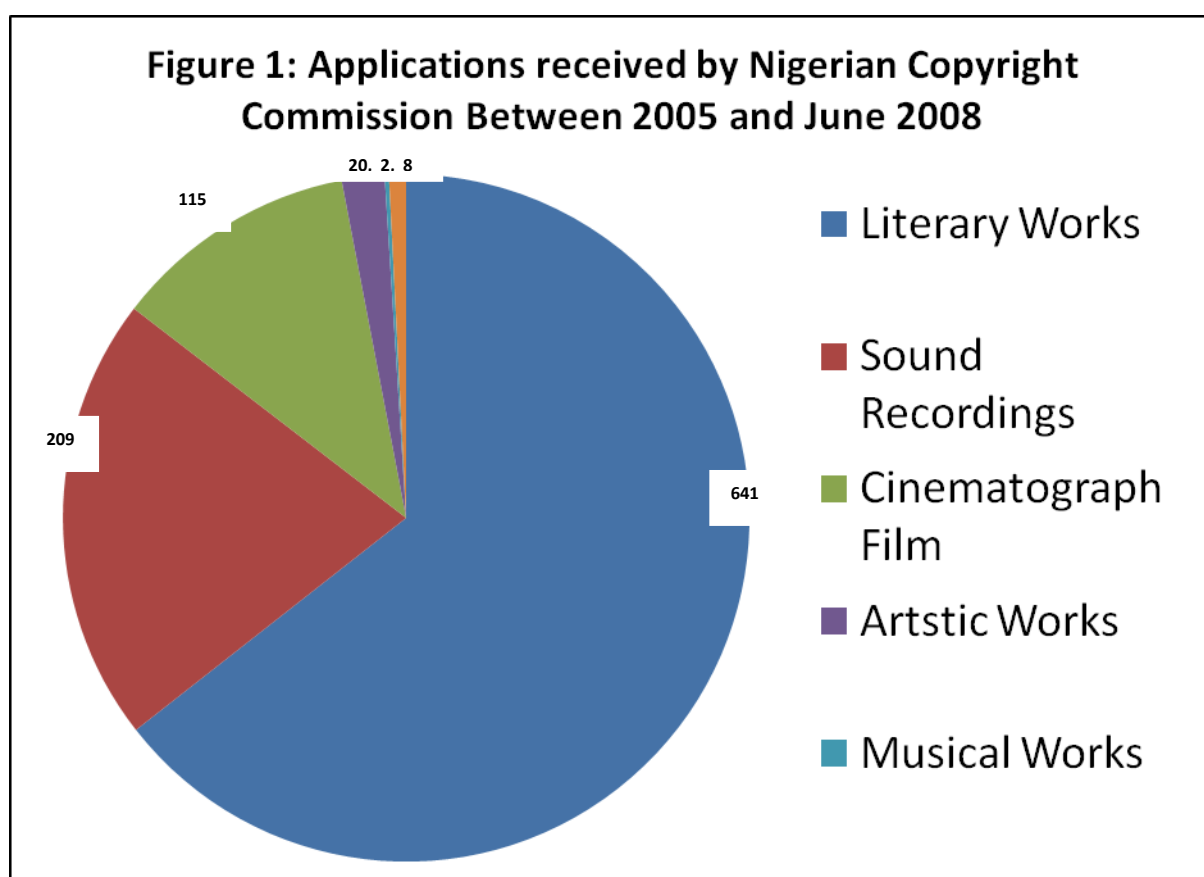
⁶ Section 37 (4) of the Copyright Act.

⁷ Adewopo Adebambo; Framework for Copyright Registration: a Case Study of the Copyright Notification Scheme of the Nigerian Copyright Commission(NCC) , A paper submitted by the Director General, Nigerian Copyright Commission to the National Biotechnology Development Agency as part of the Case Study on the System of IP in Nigeria.

⁸ Data obtained from the Copyright Notification desk at NCC. Out of the 995 applications, literary works had 641, sound recordings 209, cinematograph film 115, artistic works 20, musical works 2, transfer of rights 8.

Table 1: Applications received by Nigerian Copyright Commission Between 2005 and June 2008

TYPE OF COPYRIGHT	NO. OF APPLICATIONS
LITERARY WORKS	641
SOUND RECORDINGS	209
CINEMATOGRAPH FILM	115
ARTISTIC WORKS	20
MUSICAL WORKS	2
TRANSFER OF RIGHTS	8
TOTAL	995



This does not reflect the robust capacity of the creative industries today in Nigeria. For instance the Nigerian film industry often called Nollywood is ranked as one of the most vibrant in the world. The often cited reason for this low patronage is low level of awareness among authors. While such may

hold true for some authors, especially the uneducated ones, we cannot say the same of the more enlightened sections of the creative industries. On a positive note however, the Copyright Notification is already beginning to prove its utility in cases of disputes. In a number of court cases, parties have been known to rely on the Copyright Notification Certificate to advance their claims. More so, some producers of works and prospective licensees now insist on documentary evidence of copyright ownership before accepting works for reproduction or signing any user license. The National Film and Video Censors Board has also prescribed as a condition for accepting a film for censorship and classification, the possession of a Copyright Notification Certificate issued by the NCC. These developments will hopefully strengthen the legal and administrative initiatives towards entrenching an effective rights management regime in the copyright industries.

2.2 International IP Conventions relevant to Nigeria

The above IP laws are designed and tailored substantially along with international treaties and conventions on intellectual property. The following are international IP conventions that Nigeria has endorsed.

- i. The Universal Declaration of human rights (Article 27), which includes, the right to benefit from the protection of authorship of any scientific, literary, or artistic production.
 - ii. The Paris Convention for the Protection of Industrial Property of 1883 was the first international agreement on the protection of intellectual property rights. It deals with only industrial property as other forms of Intellectual Property Rights (IPR) were considered non-industrial in nature. The convention conveys protection of trademarks, patents and industrial designs.
 - iii. The Berne Convention of 1886 covers literary and artistic works. Nigeria became a member of the Berne Union in 1993.
 - iv. The Rome convention of 1961 provides protection to producers of phonograms and broadcasting organization.
 - v. The PCT, Patent Cooperation Treaty facilitate patent filing in different PCT member states, using a streamlined procedure.
- Some important International IP Conventions that Nigeria has not endorsed include the following:
 - i. Madrid System for the International Registration of Marks. The Madrid Protocol was adopted in June 1989 and entered into force in 1995. The protocol is one of two treaties comprising the Madrid System for international Registration of Trademarks. The first treaty, the 1891 Madrid Agreement provides for the registration of trademarks in several countries through the filing of one international trademark registration with WIPO.
 - ii. Union for the Protection of Plant Varieties (UPOV) which will be discussed here later.

2.3 World Trade Organization's TRIPS and related Issues.

2.3.1. World Trade Organization's TRIPS

The World Trade Organization's TRIPS (Trade Related Aspects of Intellectual Property Rights)⁹ Agreement of 1994 obliges members to provide IP protection in their laws. TRIPS establish minimum standards for the availability, scope, and use of seven forms of intellectual property: copyright, trademarks, geographical indications, industrial designs, patents (including Plant Variety Protection i.e. Plant Breeders Right), layout designs for integrated circuits and undisclosed information (trade secrets). TRIPS spelt out permissible limitations and exceptions in order to balance the interests of IP with interests in other areas, such as public health and economic development.

TRIPS is unique among other IPR accords because membership in the WTO is a "package deal" meaning that WTO members are not free to pick and choose among agreements. They are

⁹ <http://www.wto.org>

subject to all the WTO's multilateral agreements. However, it allowed countries to exclude from protection "plants and animals other than microorganisms". It does require that countries provide for protection of plant varieties either by patents or by an effective *sui generis* (literally meaning *of its own kind/genus* or unique in its characteristics¹⁰ or stand alone¹¹) system e.g. PVP or by applying both systems. The adoption of the Agreement also covered enforcement objectives that members are required to comply with and also provides for transitional period for compliance by members. The mandatory requirement for amending the laws was January 1, 2000 while the time frame set for implementation was 2005.

The concerns of developing countries that TRIPS will not adequately compensate them as sources of genetic resources while they lack the capacity to compete in technologies that will generate patents is noteworthy. Indigenous communities also believe that all life forms and life creating processes are sacred and should not be subject to proprietary ownership. There are therefore calls for review of aspects of TRIPS. This has prompted the AU to develop a Model Law to guide member countries to develop national laws on some of the contentious areas.

One major drawback of TRIPS is that it did not set definite guidelines nor was any mechanism put in place to assist countries in the reform of their laws. Implementation of the reform was left at the mercy of national bureaucrats who may be tempted to influence the process to the advantage of their institutions.

2.3.2 TRIPS and Biotechnology Inventions

Under Article 27, TRIPS obliges patents for both processes and products, to be granted in all fields of technology. Article 27.3 (b), however allows the exclusion of plants and animals and essentially biological processes for their production from patent grant but obliges the protection of microorganisms and microbiological or non-biological processes for their production. In this regard issues like microbes, genes, gene sequences, genetic engineering and bioinformatics become very relevant as they are important processes of biotechnological inventions which are often carried out through genetic modification. However, there are a lot of microbiological discoveries that does not involve genetic modification.

Another key concern of IP and biotechnology is the patenting of research tools or the grant of overly broad patents that could potentially block useful research¹². TRIPS provide a way out under Article 30 on exceptions to patent rights and Article 31 on other use without the authorization of the patentee. Article 30 allows limited exclusions to the rights conferred by the patent "provided that such exceptions do not unreasonably conflict with a normal exploitation of a patent and do not unreasonably prejudice the legitimate interests of the patent owner". Significantly under this provision interests of third parties such as non commercial users of patented product and process for research and experimental purposes would be permitted¹³.

2.3.3. Union for the Protection of Plant Varieties (UPOV)

The purpose of this Convention *Union pour la Protection des Obtentions Végétales* (UPOV) or the International Union for the Protection of New Varieties of Plants signed in 1961 with its latest amendment in 1991 is to ensure that the members of the Union acknowledges the achievement of breeders of new plants by granting to them an intellectual property right on the basis of a set of clearly defined principles. Plant Variety Protection is a patent required under TRIPS but on a *sui generis* basis. Nigeria has no Plant Variety Protection Act. It is worthy of note that many UPOV member countries have reported increases in plant breeding activities with direct effect on their agricultural industries.

¹⁰ Dictionary.com "Word of the day" [2001-06-14 \[1\]](http://en.wikipedia.org/wiki/Sui_generis) accessed [2007-10-14](http://en.wikipedia.org/wiki/Sui_generis). In http://en.wikipedia.org/wiki/Sui_generis

¹¹ http://en.wikipedia.org/wiki/Plant_breeders'_right

¹² Watal, J (2000) Intellectual Property and Biotechnology: trade interests of developing countries. Int. J. Biotechnology, Vol. 2, Nos 1/2/3, 2000.

¹³ Ibid

United Kingdom combined the Plant Variety Protection and the Seed Act and enacted the Plant Variety and Seeds Act 1964 (UK).¹⁴ The US on its part passed the Plant Variety Protection Act 1970 (US). This legislation provided protection to developers of novel, sexually reproduced plants. However, the United States originally acceded to the UPOV Convention on the basis of the Plant Patent Act of 1930 that provided for the patent of only asexually reproduced plants and did not bring the PVP Act into compliance with UPOV requirements until 1984 when the Commissioner of Plant Variety Protection promulgated rules to do so. Since the 1980s, the US Patent Office has granted patents on plants, including plant varieties: this provides a second way of protecting plant varieties in the USA. The landmark Supreme Court decision of *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), suggested the possibility of securing utility patents on plants previously thought eligible solely for protection under the PVP Act. Two decades later, in the 2001 decision of *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001), the Court conclusively held that sexually reproduced plants eligible for protection under the PVPA are also eligible for utility patents. Like USA, Australia passed the Plant Variety Protection Act 1987 and the Plant Breeders Rights Act 1994. Australian patent law also permits the patenting of plant varieties. In total, 65 countries have signed the UPOV Convention and adopted plant breeders' rights legislation consistent with the requirements of the convention.

2.3.5 Convention on Biodiversity

The Convention on Biological Diversity (CBD), which came into effect in 1993, reflects some issues of IP. The CBD which came into effect in 1993 was originally intended to preserve biological diversity, but its objectives also include the implementation of fair and equitable sharing of the benefits arising from the use of genetic resources. With regard to the handling of genetic resources, the CBD stipulates that each country has sovereign rights over its natural resources (Article 15, Paragraph 1), that access to genetic resources requires prior informed consent (PIC) of the contracting state providing the resources (Article 15, Paragraph 5), and that measures shall be taken with the aim of sharing in a fair and equitable way the results of research and development based on genetic resources, and the benefits arising from the commercial and other use of genetic resources, with the contracting state providing the genetic resources (Article 15, Paragraph 7).

The link between IPR and CBD originated from the concept of 'bioprospecting' (in contrast to other forms of prospecting such as oil prospecting). In searching for new chemical entities or useful characteristics, some research based industries have found it profitable to screen natural resources such as soil samples, marine waters, insects, tropical plants and genes in developing countries. Some feel that, as compared to the conventional system of screening millions of synthesized chemicals, bioprospecting especially if further based on traditional knowledge, may even cut costs of pharmaceutical R&D. The link to IPRs arises from the fact that in many instances, the bioprospecting or their licenses are granted patent right over these products without any acknowledgement of the contribution of countries/regions of origin or of indigenous communities/individuals. Developing countries like Nigeria are demanding that when profits are reaped through bioprospecting, benefits and technologies developed should be shared with the original suppliers of genetic resources or traditional knowledge. This forms part of the objectives of the African Model Law in the aspect dealing with Community Rights. The recent licensing of the patent of NICOSAN-a drug for the management of Sickle Cell disease by an American Company is a good example. Originally discovered through indigenous knowledge the drug was developed in Nigeria by NIPRD using tropical herbs. The case study of NICOSAN is presented at a latter part of this study. The formation of drug based biotechnology companies in many countries of the world is on the basis of research results from genetic resources (bioresources) as illustrated with NICOSAN.

¹⁴http://en.wikipedia.org/wiki/Plant_breeders'_right

As of January 2007, 190 countries have become parties to the Convention. The CBD recognizes the sovereign right of countries over their genetic resources. However, it does not provide any specific mechanisms of benefit sharing, so in actuality, although there are cases where benefit sharing has taken place as expected, for the most part there has continued to be conflict between developing countries like Nigeria as the holders of genetic resources and developed countries as the users of those resources.

2.3.4. African Model Legislation - for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources.

The African Model Legislation (also called the African Model Law) which took effect in 2000 deals with access to biological resources, benefit sharing and the right of breeders and farmers over their knowledge and resources.

The law crafted under the *sui generis* option is intended to guide member countries to enact their Plant Variety Act/Plant Breeders Right, Animal Breeders Right and Farmers Rights in line with WTO TRIPS. It also includes guidelines on benefit sharing for individuals and local communities for genetic resources as provided by the Convention on Biodiversity (CBD) as well as guidelines on the patent of life forms which it does not approve on the ground that life is sacred and should not be subject to property ownership like patent. The implication of no patent for all life forms could be that only a *sui generis* system and not the existing IP mechanisms could be employed to patent all living organisms including microorganisms. A few African countries have already enacted the PBR such as Kenya. South Africa has operated PBR for over 15 years as at 2008. Also Tanzania more recently enacted the PBR. All African Heads of State have signed AU Model Law but only very few have reviewed their IP laws in line with it.

2.4. U.S. Supreme Court judgment on the patenting of micro-organisms (1980)

The United States Supreme Court judgment that permits the patenting of microorganisms is instructive to us in Nigeria particularly in respect of biotechnology. Tagged *Diamond v Chakrabarty* (1980), the judgment is based on the law that provides for the issuance of a patent to a person who invents or discovers "any" new and useful "manufacture" or "composition of matter." The respondent in 1972 filed a patent application relating to his invention of a human-made, genetically engineered bacterium of the genus *Pseudomonas* capable of breaking down crude oil (thus used for bioremediation of oil polluted soils), a property which is possessed by no naturally occurring bacteria to that level of efficiency. A patent examiner's rejection of the patent application's claims for the new bacteria was affirmed by their Patent Office Board of Appeals on the ground that living things are not patentable subject matter under that section of the law. The Court of Customs and Patent Appeals reversed the judgment, concluding that the fact that micro-organisms are alive is without legal significance for purposes of the patent law. This appeal court judgment was upheld by US Supreme court and forms the basis for patenting microorganisms in US¹⁵. Japan and Europe are following this model by patenting micro-organisms. WTO TRIPS provision on microorganisms also follows this model by allowing for the patent of microorganisms.

The AU Model Law however rejects the patent of any living organism. If Nigeria should adopt the AU Model, then only a *sui generis* system that is different from the present patent law in Nigeria can be used to protect any existing but newly discovered microorganism, or a newly created microorganism which is often achieved by genetic engineering/modification technique.

2.5. Reform of Nigeria's IP laws in conformity with TRIPS

It is noteworthy that, the Nigerian IP legal framework seems to have been tailored towards what obtained in Britain/United Kingdom, which colonized Nigeria and established a system similar to what its home government had on ground.

¹⁵ <http://supreme.justia.com/us/447/303/>

But despite the country's active participation in international conventions as outlined above and growing interest in IPR's protection in the international scene, the colonial model had persisted without considerable variation. It is only recently that the nation's legislation on IP is being reviewed in conformity with WTO/TRIPS obligation. Presently the country has no legislations on Geographical Indications, Plant Varieties Protection (Plant Breeders Right), Integrated Circuit Design, Undisclosed Information or Trade Secrets, Biodiversity and Traditional knowledge in various sectors. It also has not reviewed its existing patent law to provide for the patent of microorganisms and its processes of production.

With respect to geographical indication (GI) which identify a good as originating in a locality where a given quality, reputation, or other characteristic geographic origin, some countries separately protect geographical indications for goods such as French cognac or Scotch whiskey. In the United States, geographical indications are protected together with collective marks as certification trade marks. They are treated as a subset of trademarks with the aim of preventing consumer confusion and protect business interests¹⁶. This is the system that Nigeria is practicing now and is not planning to create a separate law or registry for GI.

Recently in Nigeria (2006), there had been recommendations and steps taken for the different Intellectual Property schedules to be placed under one umbrella institutional framework for effective administration and management. To this extent there was a proposal to establish Nigerian Intellectual Property Organization (NIPO) by the Ministry of Science & Technology and NOTAP, to bring all the agencies under one umbrella and ensure an effective and balanced development of the IP system in the country. The quest for a paradigm shift in the framework led to a move to secure the approval by the then President Olusegun Obasanjo of the Intellectual Property Commission of Nigeria (IPCON) under the aegis of the Federal Ministry of Justice, thus bringing the Nigerian Copyright Commission and the Registry of Trademark, Patents and Design together under one umbrella organization to be hosted by the Federal Ministry of Justice.

A draft national IP bill was prepared by a committee with members drawn from the stakeholder institutions. The draft bill also includes some of the WTO requirements such as Plant Breeders Rights, Animal Breeders Rights and Farmers Rights. But the delay in addressing the issue of an umbrella body for IP administration in Nigeria has prevented the bill from making any significant progress. The effect is that Nigeria is not benefitting from the gains associated with the WTO's TRIPS including associated increased investments in agriculture and allied industries from within and outside the country. Nigeria also faces the threat of sanctions from WTO as time elapses.

A more detailed study showing which of the two modes of IP offices– centralized or distributed- that is more effective may, need to be carried out to determine which model that Nigeria should adopt. The result will help to guide the country in taking a quicker decision over the present impasse. But irrespective of the outcome of such a study a survey carried out in this study can serve as a guide. Historically, the different types of IP and their administrative frameworks had not developed collectively hence their location in different administrative set-ups in different countries. An internet survey of 191 countries shows that only 8 countries of the world have both their different offices for Copyright and Industrial Property under their Ministry of Justice. These countries are: Kazastan, Saint Kitts and Nevis, Samoa, Solomon Islands, Swaziland, Sweden, Uganda and the Holy See (Vatican City)¹⁷.

In the South African Model, what they have is Companies and Intellectual Property Registration Office (CIPRO) in the Department of Trade and Industry (DTI). This was after a merger of two former directorates of the DTI: SACRO – South African Companies Registration Office and SAPTO – South African Patents & Trade Marks Office, from 1st March 2002 into a single Business Agency. Such a

¹⁶ Field Thomas G. What is Intellectual Property: file://E:\IPR\Focus on Intellectual Property, <http://www.piercelaw.edu/tfield/tgf.htm>., 19th March, 2007, p. 6

¹⁷ www.wipo.int/directory/en/urls.jsp

merger within the same Ministry/Department would be easier than a merger cutting across different Ministries/Departments as Nigeria is trying to implement since Nigeria's Ministries are averse to losing any of their agencies. It was observed that the Federal Ministry of Commerce and Industry in Nigeria is averse to losing the Trademarks, Patent and Designs Registry that has been under its administration since the amalgamation of Northern and Southern Nigeria into one country in 1914. In Tanzania both Copyright and Industrial Property is done by the Business Registration and Licensing Agency (BRELA) under the Ministry of Industry and Trade. Similarly, United States has both the Copyright Office and the Industrial Property Office in the Commerce Department. The example of India which has amended all the relevant legislations for the various forms of intellectual property with respect to the mandatory requirement of WTO is presented in table 2 below showing a distributed and not an umbrella system of IP offices.

Besides, WTO's TRIPS requirement for nations to make reforms to provide for different types of IP including the new technology patents does not recommend an umbrella IP office nor make it compulsory. About 65 countries under the membership of the Union for the Protection of Plant Varieties have got Plant Varieties Protection (PVP) law. Some other countries have got the law but are not yet members of UPOV. The European Union Office is called Community Plant Variety Protection Office distinct from the European Patent Office. The trend around the world is to have the Plant Variety Protection (PVP) as a separate office from the other IP offices, the reason being that it is a *sui generis* (different, other, unique) technology patent. In Kenya, Tanzania and India (see table 2 below), they are in the Ministry of Agriculture.

Table 2.0 Broad Institutional Mechanism of the Indian IPR Regime¹⁸

S/N	IP	Legislation	Nodal Agency
1	Patent	The Patent Act, 1970	Department of Industrial Policy & Promotion(DIPP), Ministry of Commerce and Industry
2	Design	The Design Act, 2000	
3	Trademark	The Trade Marks Act, 1999	
4	Geographical Indication	The Geographical Indications(Registration and Protection) Act, 1999	
5	Copyright	The Copyright Act, 1957	Department of Secondary and Higher Education, Ministry of Human Resource Development
6	Integrated Circuit Design	The Semiconductor Integrated Circuits Layout-Design Act, 2000.	Department of Information Technology, Ministry of Communications and Information Technology
7	Plant Varieties	The Protection of Plant Varieties and Farmers Rights Act, 2001	Department of Agriculture and Cooperation, Ministry of Agriculture
8	Undisclosed Information	The Contract Act, 1872 Common(law) Law	Ministry of Law and Justice
9	Biodiversity	The Biological Diversity Act, 2002	Ministry of Environment and Forests
10	Traditional Knowledge	None	The concerned ministries Ministry of Commerce and Industry, Ministry of Human Resources Development.

¹⁸ Kochar, Sudhir (2008). Institution and Capacity building for evolution of IPR regime in India: Protection of Plant Varieties and Farmers Rights. Journal of Intellectual Property Rights. Vol. 13, January 2008, pp. 51-56

Meanwhile the Nigerian Natural Medicine Development Agency (NNMDA) supervised by the Ministry of Science and Technology is said to be developing a legal framework for IP in Nigeria's Traditional Medicine Knowledge and Practice (TMKP). The Convention on Biodiversity (CBD) has IP implications. There are also emerging IP issues such as the Domain name eg bbc.com, wsu.edu, unn.ed, nabda.ng etc which are used to occupy a cyberspace with some being more recognizable than others and are thus being protected from duplication. This goes to show that IP is very diverse and there may be difficulty accommodating everything under one roof.

3. National Office for Technology Acquisition and Promotion (NOTAP) – Experience In Intellectual Property

3.1 NOTAP–Formation and mandate

The Federal Government initiated bold reforms of Nigeria's Science, Technology and Innovation system and has assumed more direct and broader involvement in promotion at all levels the awareness of the importance of Intellectual Property Rights to enhance creativity and boost innovation in the fields of Information and Communication Technology (ICT), Space technology, Agriculture and Biotechnology, Medical and Pharmaceuticals, Industrial Production and Engineering Materials, Nuclear Energy, Sciences, Arts, Culture and literature, etc by establishing a conducive environment as well as creating a favourable legal framework for the management, protection and enforcement of Intellectual Property.

The National Office for Technology Acquisition and Promotion (NOTAP), a parastatal under the aegis of the Federal Ministry of Science and Technology was established by Decree No. 70, 1979 as National Office of Industrial Property (NOIP). The name was changed to National Office for Technology Acquisition and Promotion (NOTAP) in 1992 to ensure that the new name adequately reflect its entire functions as contained in Decree No. 70 of 1979 and also to remove any ambiguity or misconception that may arise in relation to the activities of the agency and that of the Intellectual Property Registry¹⁹.

NOTAP is mandated to carry out the following activities

- Registration and Monitoring of foreign technology transfer agreements.
- Promotion of Intellectual Property Rights and Innovation Systems.
- Provision of technology information to SMEs, researchers, inventors, etc. from the Patent Information and Documentation Centre (PIDC) located in NOTAP, etc.
- Commercialization of indigenous R&D results and inventions
- Research Industry Linkages/Technology Database Development
- Extension of Technology Advisory Services to researchers and entrepreneurs
- Preparation of industrial Project Profiles

In boosting innovation NOTAP promotes Intellectual Property Rights (IPRs) using the Intellectual Property System (IPS)- in particular, the patent system which has accumulated pool of technological information to spur inventiveness and creativity. Intellectual property system guarantees the holder of a patent or copyright, for example, the exclusive rights to the exploitation of the invention over a given period of time (20 years) in the case of patents and ensures that no one else would copy, adopt or use the innovation or invention without authorization from the holder, usually granted after payment of a royalty or through outright purchase or under a specific agreement. Today, virtually all innovations

¹⁹ Araba Funke (Mrs.), Director, Technology Acquisition, Documentation and Information (TADI): *Measures taken by the government to promote intellectual property system in Nigeria – Experience of the National Office for Technology Acquisition and Promotion (NOTAP)* a paper contribution. National Office for Technology Acquisition & Promotion (NOTAP), Abuja, Nigeria, 2008.

are patented as soon as they are developed. Thus it is imperative that all research results and inventions in Nigeria be patented. Furthermore, the intellectual property system encourages the creation of public pool of information of new technologies by virtue of disclosure and thus has become a tool for boosting innovation, as well as planning R&D and acquisition of technology.

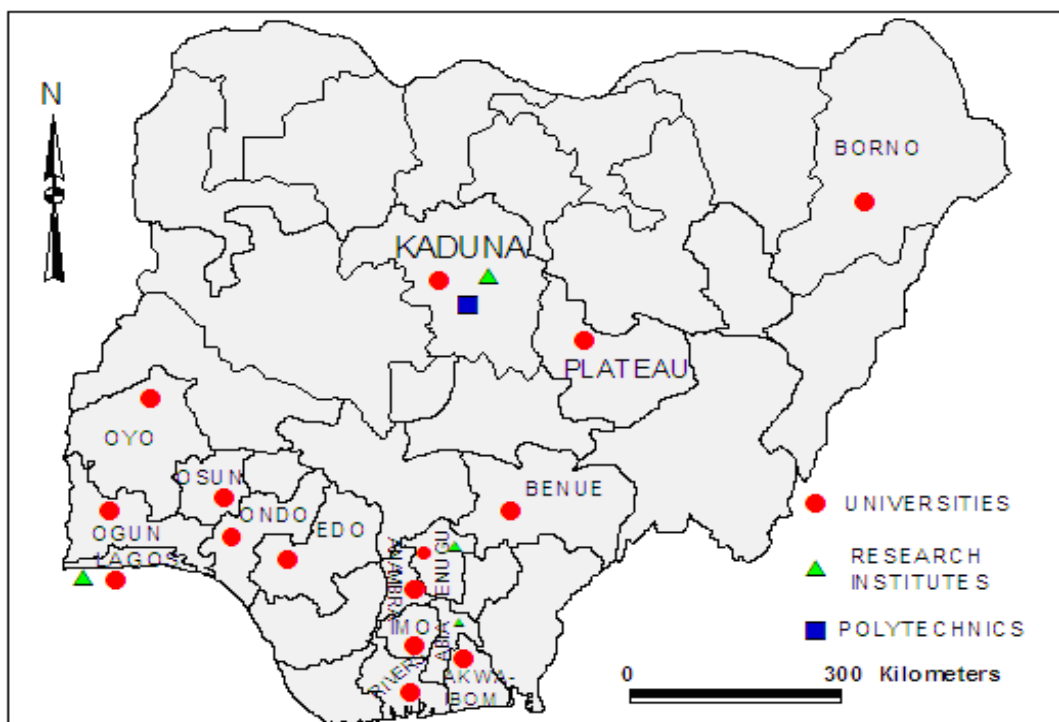
Boosting innovation in Nigeria is thus intimately linked to:

- boosting patent awareness among researchers/inventors,
- increasing the number of patents secured, and
- active commercialization of patents to create industries, employment, wealth and enhanced national competitiveness.

3.2. Establishment of Intellectual Property and Technology Transfer Offices (IPTTOs)

NOTAP has established twenty-three (23) Intellectual Property and Technology Transfer Offices (IPTTOs) in some Nigerian Universities, Research Institutes and Polytechnics with the aim of ensuring that R&D activities are demand-driven, thereby facilitating their being exploited commercially and transformed into a marketable product or system. Each IPTTO has been adequately equipped to provide the requisite support structures for the research community where it is located and various capacity building programmes were carried out in collaboration with World Intellectual Property Organisation (WIPO), Geneva.

Figure 1: Location of existing IPTTOs in Nigeria



3.3. Patent Information and Documentation Centre (PIDC)

The Patent Information Documentation Centre (PIDC) is a computerized data bank in NOTAP and it provides access to patent information available globally through internet. The Centre was established with the technical assistance of World Intellectual Property Organization (WIPO), Geneva and this facility is established to assist end-users in Nigeria to focus on new research activities that are demand-driven and of market value.

In addition, end-users are assisted to source global technology information via the Internet. The PIDC offers opportunities for the dissemination and distribution of information and performs searches on the state of the art in various fields of technology and assists researchers with necessary technical information to avoid re-inventing the wheel. More specifically, the following are the benefits of information from patent documents:-

3.4. Functions of NOTAP on Patent

By virtue of the functions of NOTAP as embodied in its enabling Decree No. 70 of 1979, NOTAP has sustained the promotion of patent culture (which had been abysmally low in Nigeria among researchers, scientists, inventors, etc) and has demonstrated that patents are vital means of promoting and developing indigenous technologies and innovations. Thus, local inventors and researchers are assisted by NOTAP to patent their R&D results and inventions, with NOTAP paying all fees charged at the Trademark and Patent Registry. In rendering this service, NOTAP adopts the following procedure:

- provision of search of the invention in patent documents in NOTAP's Patent Information and Documentation Centre (PIDC) and other technological database to establish the novelty of the invention which is one of the major criteria of patentability,
- assistance in appropriately completing the patent application forms, assistance in the preparation of patent application forms,
- assistance in preparation of patent specifications consisting of title of invention abstract, background of the invention, detailed description of the invention including drawings, claims,
- filling of the applications for patents and payment of the processing fees at the Trademark, Patent and Design Registry. In case of application for foreign patent grant, the application is submitted in line with the Patent Corporation Treaty (PCT). This activity strengthens the grant of patents from the Nigerian Patent and Trademark Registry which does not conduct any examination whatsoever before the grant of patents.
- assistance in scouting for licenses for the commercialization of the indigenous inventions,
- assistance in negotiation and drafting of the licensing agreement for the transfer of patented indigenous technologies by the inventors to the entrepreneurs.

NOTAP offers these services principally on patents to clients that approach it. In this capacity NOTAP operates partially as a patent agent.

3.5 Patent Applications Filed and Granted

NOTAP commenced processing the patent for public and private sectors in 1999 and a total of 233 innovations/inventions have been submitted to NOTAP for processing. After evaluation, 86 applications were filed at the Patent Registry, and 61 were granted patent rights. One hundred and forty seven (147) applications are pending because these applications have not met the prerequisites for patenting. This has spurred many researchers and inventors to recognizing the importance of patenting before publication disclosure. See Table I and Pie Chart for details on patent processed for applicants. Table 3 below indicates the number of Patent Applications submitted to NOTAP from 1999 to 2008.

Table 3: Summary of R&D results/inventions submitted to NOTAP for assistance to file application for Patent January,1999 –September, 2008

YEAR	NUMBER OF INVENTIONS SUBMITTED TO THE OFFICE	NUMBER OF PATENT APPLICATION FILED BY THE OFFICE AT PATENT REGISTRY	NUMBER OF PATENT APPLICATION PENDING (UNDER EVALUATION/AWAITING RESPONSE FROM INVENTOR)	NUMBER OF PATENT APPLICATION GRANTED / APPROVED BY REGISTRY
1999	2	1	1	1
2000	32	14	18	9
2001	14	8	6	3
2002	17	2	15	3
2003	8	0	8	0
2004	27	12	15	7
2005	41	14	27	18
2006	24	16	8	14
2007	28	13	15	4
2008 Sept.	40	6	34	2
TOTAL	233	86	147	61

Figure 2: Number of inventions submitted to the office between 1999 - Sept. 2008

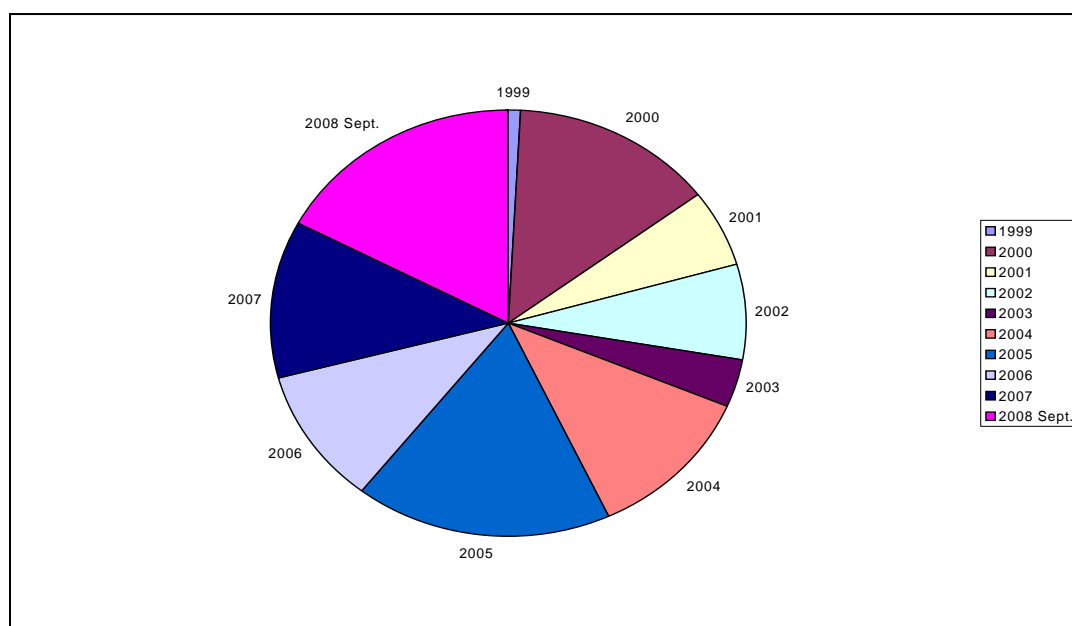
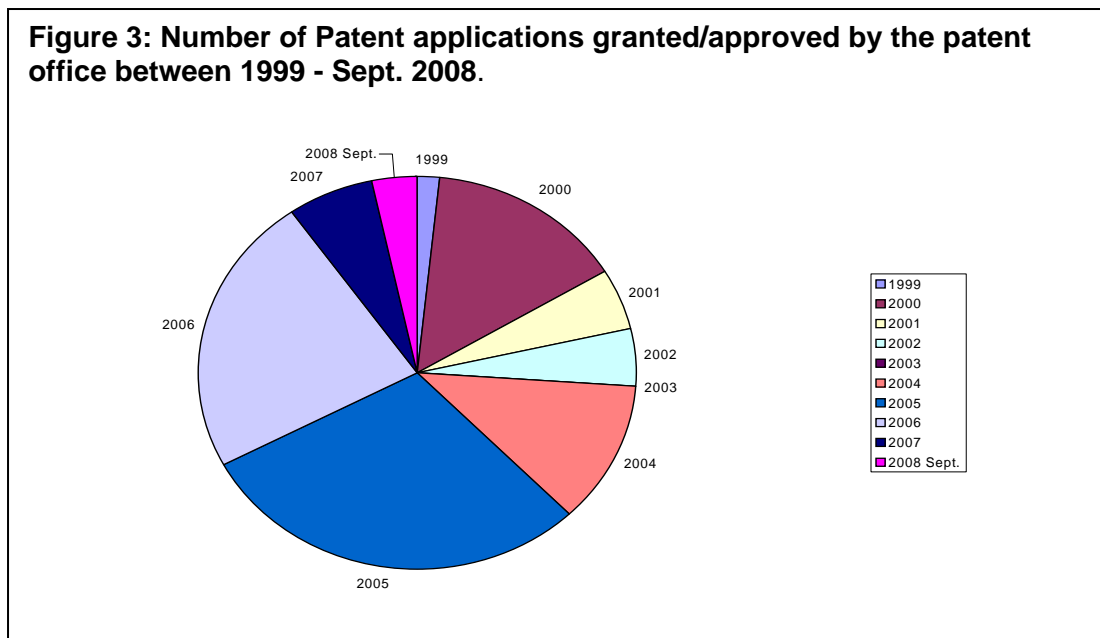


Figure 3: Number of Patent applications granted/approved by the patent office between 1999 - Sept. 2008.



3.6 Developing Intellectual Property Culture in Nigeria

The IP culture in Nigeria especially patent is very low as compared to other countries e.g. Japan, China and South Korea. The evolution of patent applications and patent granted is analyzed below. In Nigeria, the data collated in Table 4 below from 1998-2007 (span of 10years) shows that out of a total of 4,823 patent applications filed, 4,257 patent applications were filed by foreign applicants, while 566 were filed by local applicants at the Nigerian Registry for Trademark, Patent and Industrial Design.

The non-conventional (local) patents filed was 566 representing 11.7% of the total applications filed at the registry, while the conventional(foreign) patents filed was 4,257 representing 88.3% of the total patents filed. For patents granted, non-conventional (local) has 318 applications granted representing 11.7% of the total granted, while the conventional (foreign) has 2,398 representing 88.3% of the total number of patents granted.

The trend of the patent applications filed in Nigeria as shown in Figures 3 and 4 also reveals that more foreign patents (conventional) are filed in Nigeria than local patents compared with countries like Japan, China and Korea where more local patents are filed than foreign patents. For instance, in 2007, 565 foreign patents were filed in Nigeria while only 84 local patents were filed representing 12.9% of the total number of patents filed in the country; whereas in Japan, China and Korea in 2007, 333, 498, 153,060 and 128,701 local patent applications were filed representing 84.1%, 62.4% and 74.6% of the total patents filed in the countries respectively.

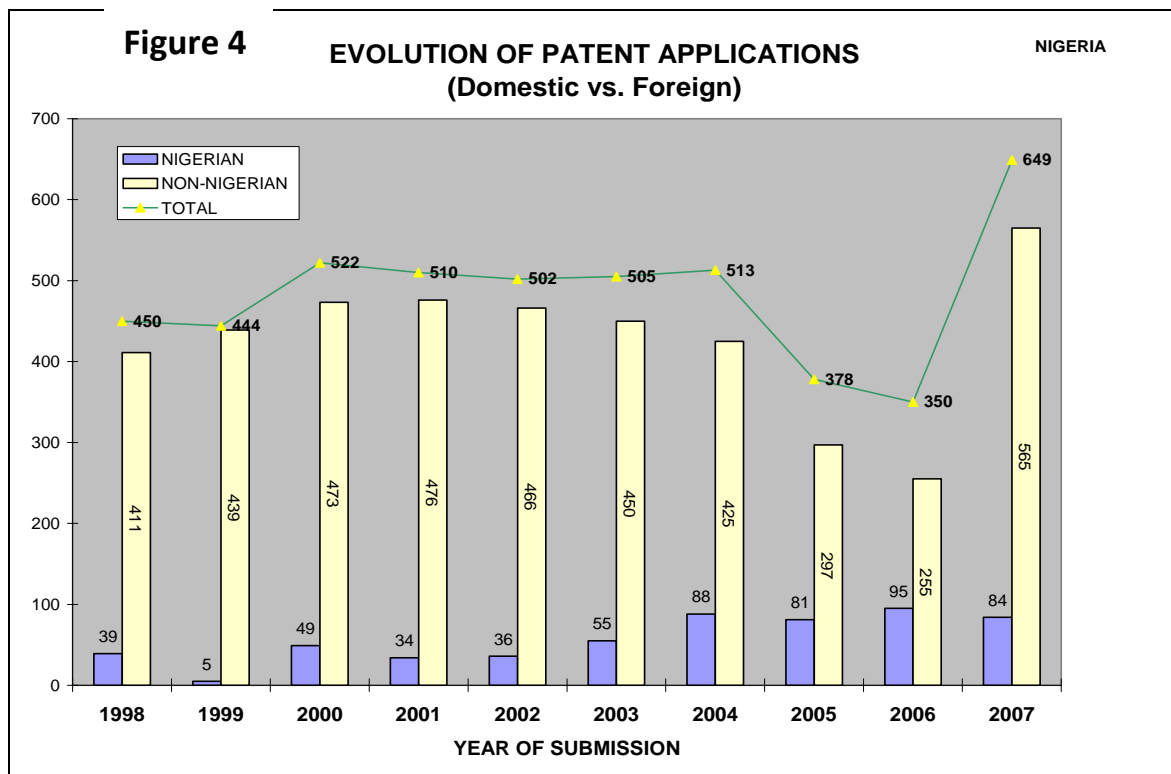
Table 4: Number of Patent applications filed and granted in Nigeria from 1998 – 2007

YEARS	FOREIGN PATENTS (CONVENTIONAL)		LOCAL PATENTS (NON CONVENTIONAL)	
	No. of Applications Filed	No. of Applications Granted	No. of Applications Filed	No. of Applications Granted
1998	411	185	39	2
1999	439	312	5	19
2000	473	351	49	42
2001	476	142	34	13
2002	466	62	36	3
2003	450	179	55	15
2004	425	421	88	40

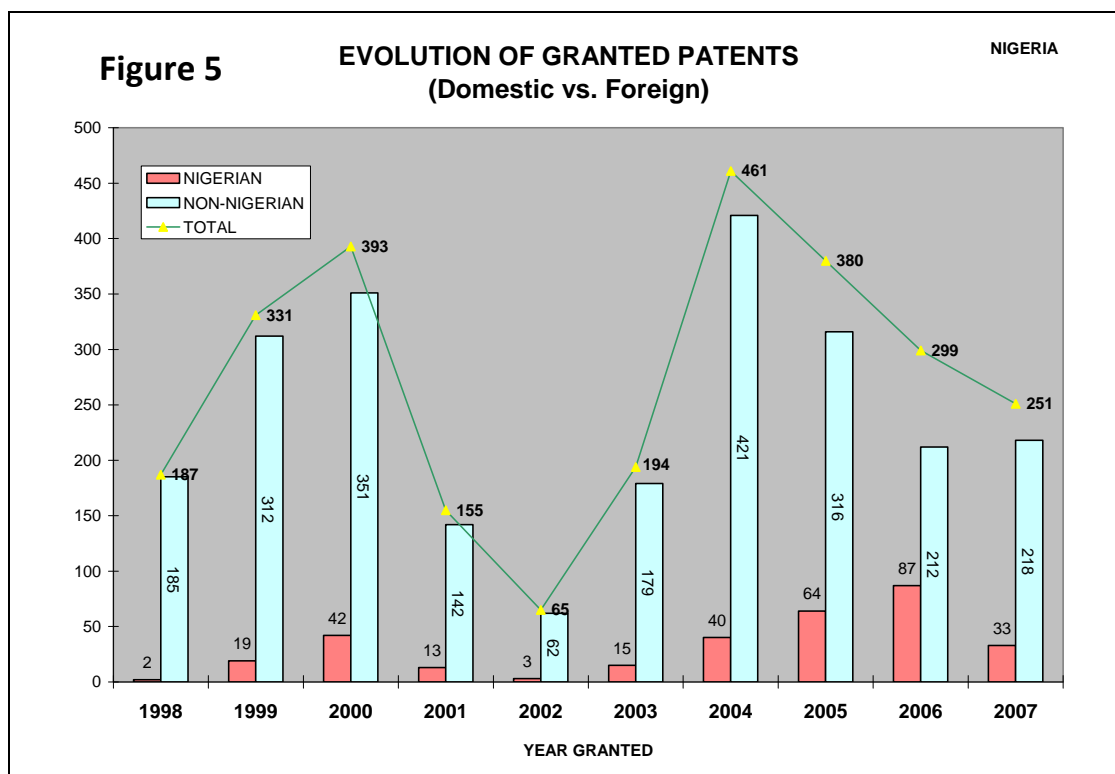
2005	297	316	81	64
2006	255	212	95	87
2007	565	218	84	33
Total	4257	2398	566	318

Source: Compiled by NOTAP from Trademarks, Patents and Industrial Design Office, Abuja, October 2008

The low turnout of patent in Nigeria is as a result of lack of IP culture in the tertiary and research institutes' environment and the society in its entirety. This low level of evolution of patent is also a reflection of current level of technological development, using patent as one of the indices or determinants of economic growth.



Source: Compiled by NOTAP from Trademarks, Patents and Industrial Design Office, Abuja, October 2008



Source: Compiled by NOTAP from Trademarks, Patents and Industrial Design Office, Abuja, October 2008

3.7. Promotion of Incentives/Reward System

NOTAP is promoting a framework on Incentives and Reward-System for creators of Intellectual Property in Tertiary and Research Institutions.

Empirical study of the Incentives and Reward System in Tertiary and Research Institutions in industrialized and most developing countries like India, Brazil, South Korea, etc, shows that creators of intellectual property receive from 33% to 50% net income of revenue generated by the institutions due to commercial exploitation of intellectual property. The existence of such reward systems encourages the creators to devote their time and energy to carry out research in demand/market-oriented projects for the generation of revenue.

In the pursuit of this, an Intellectual Property Policy Guideline to assist University and Research Institutes to develop Incentives/Reward System was published by NOTAP and forwarded to all Universities, Polytechnics and Research Institutes in Nigeria.

4. The Place of IP in Nigeria's R&D System

4.1. Agricultural research

4.1.1 Public Sector Investment in Agricultural Research Nigeria

The development of agriculture in Nigeria has, and is still benefiting mainly from public investments; the private sector plays an insignificant role. However, the public goods investments policy in agriculture is facing a bleak future for a number of reasons, principal amongst which are:

- i). Increased emphasis on market mechanisms facing public funded organizations to respond to broad economic opportunities;
- ii) Tendency to limit freely, germplasm for National Agricultural Research; and
- iii) Changes brought about by the introduction of intellectual property rights (IPR).

The Nigeria Agricultural Research System (NARS) comprises the National Agricultural Research Institute (NARIs), universities of agriculture and faculties of agriculture and veterinary medicine in conventional universities, non-governmental organizations (NGOs), and the private sector. The bulk of the research is, however, publicly funded and goods produced are public goods. These goods, which are information, data, or products, are released into the public domain for adoption and utilization by and for the benefit of all people of the nation. As a matter of fact, the refusal of the NARIs for free access to their research results is contradictory to their mandate and mission. The Agricultural Research Council of Nigeria (ARC/N) in the Ministry of Agriculture is supervising 15 agricultural research institutes. Some agricultural research institutes are not placed in the ministry of agriculture and fall outside the supervision of the Ministry of Agriculture²⁰.

4.1.2. Changes in the Ownership of Research Results

Recent external developments like the integration of markets, growing activities of the private sector and innovations in national and international legal and regulatory regimes are, however, changing trends in research management and management of intellectual property in the developing countries. These changes are occurring in response to global trends, each having the potential to redefine how the national agricultural research system would provide public goods to meet the national needs for crop and animal varieties. Management needs to ensure that all who use the property respects ownership of intellectual property used by a research institution. It should also ensure that organizations are in a position to identify, secure, manage and exploit the intellectual property they generate.

4.1.3 Current Situation in Agricultural Research in Nigeria

In Nigeria as in many developing countries, no structure has been put in place for the management of IP in agriculture particularly Plant Variety Protection (PVP), Animal Breeders Rights. In April 2002, Nigeria held its first workshop to review the first draft of the Nigeria Intellectual Property Laws titled "Fostering a New Intellectual Property Regime". It was co-sponsored by the United States Department of Commerce, Commercial Law Development Programme; the Federal Ministry of Commerce (Trademarks, Patents and Design Registry); the Nigeria Copyright Commission; and the National Office for Technology Acquisition and Promotion (NOTAP)-Federal Ministry of Science and Technology- in a public/private partnership with the Nigeria Intellectual Property Bar. When this document is put into law, it will form a basis to put in place regulatory framework to manage IP in the Nigeria NARS. This is because the resulting draft IP bill has provision for Plant Variety Protection (PVP) or Plant Breeders Right (PBR) as well as Farmers Right..

Currently, there are no institutional frameworks for agriculture related IPR issues nor any office or persons responsible for assisting the researchers on issues of IP, access to adapted technologies, technology transfer, or ways to protect their inventions. The researchers have been functioning without institutional support needed to address these issues for their research. However, it should be noted that the National Office for Technology Acquisition and Promotion (NOTAP) is assisting researchers particularly on patents to register their inventions with the Trademarks, Patents and Designs Registry free of charge as government measure to promote technological development. It is also establishing Technology Transfer Offices (TTO) in universities and research institutes across the country. But IP in agriculture require specialized tools and specialized approaches to handle.

Now is actually the beginning of a transition from periods when products and processes for research resided in the public domain. Nigeria and the rest of the developing countries are seeking for appropriate IPR arrangements for owning and protecting IP and for the use of proprietary technologies in their research so that the final products developed would have legal instruments to support their dissemination to clients. Proprietary technology and materials are technologies and

²⁰ Abubakar B. Y.(Prof); Executive Secretary, Agricultural Research Council of Nigeria(ARC/N); *Nigeria Agricultural Research System (NARS): Prospects For Intellectual Property Promotion: A paper contribution, 2008*

materials that are privately owned, managed and protected through some sort of IPRs. The United States Bayh Dole Act seeks to address this issue within the Universities and RIs in USA. Presently, the CGIAR centres and some few larger national agricultural research organizations in the developing countries address such institutional mechanisms, for example Brazil Research and Development Agency EMBRAPA, Agency for Agricultural Research, and Development (AARD) in Indonesia and Malaysia Agricultural Research and Development Institute (MARDI).

4.1.4. Central IP Management Body

Considering these challenges and the objectives of establishing the Agricultural Research Council of Nigeria (ARCN), the Council has plans of setting up a central IP management body to be housed in the Legal Unit of the Council. A committee on, "Establishment of effective IPRs policy and management guidelines for Agricultural Research in Nigeria" has been set up and is already collecting information. The central IP management body will have the following functions:

- Develop institutional or legal frameworks for related IPRs issues ;
- Educate research institutions on the importance of international collaboration and purchase of proprietary technologies;
- Assist the researchers in issues of IP, access to adapted technologies, technology transfer and ways of protecting their inventions;
- Initiate and promote negotiations needed for licensing proprietary assets at institutional level;
- Develop and introduce criteria for the management of information related to proprietary technologies in the research institutions, that is confidentiality and timing of publications; and
- Introduce the use of IP management parameters during research project planning.

4.2. The Bayh Dole Act. (University and Small Business Patent Procedures Act) and IP in Nigeria

This is a United States legislation dealing with intellectual property. However, many developing countries are modeling their patent laws after this US law as part of the transition away from public ownership of research results and thus making it very significant to Nigeria. Passed in 1980, the Bayh-Dole Act (Patent and Trademark Act Amendments of 1980) created a uniform patent policy among the many federal agencies funding research. As a result of this law, universities retain ownership to inventions made under federally funded research. In return, universities are expected to file for patent protection and to ensure commercialization upon licensing. The royalties from such ventures are shared with the inventors; a portion is provided to the University and department/college; and the remainder is used to support the technology transfer process. The main purpose of the act is to further development and commercialization.

4.3. Policy Linkage of Nigerian R & D Institutions

A knowledge of the linkage between the science, technology, research and related institutions in formulating S & T policy can be harnessed to support the effort to reform the country's IPR system to meet our national aspirations and the demands of our bilateral partners. This is because of the positive impact a functional IPRs system will have on R & D.

Since the colonial era Government of Nigeria has taken steps to establish research institutes in different sectoral areas of Agriculture, Health, Environment and Industry. Similarly science based facilities in the Universities were also engaged in scientific research activities. It became obvious that science and technology –based research and development system in Nigeria could only make impact on the national development if the R&D activities were coordinated. The first major and concrete step taken by Government towards coordinating research efforts was the establishment of the Nigerian Council for Science and Technology (NCST). The mandate of the NCST was:

- To determine priorities for scientific activities in the federation in relation to the economic and social policies of the country and its international commitments;
- To ensure the application of the results of scientific activities to the development of agriculture, industry and social welfare in the federation;
- To advise the Federal Government on a national science policy, including general planning and assessment of the requisite financial resources;

- To ensure cooperation and coordination between the various agencies involved in the machinery for making the national science policy; and
- To promote public confidence in scientific expenditure and create an atmosphere conducive to scientific activities.

The NCST through various stages eventually evolved to the present Federal Ministry of Science and Technology. However, under the aegis of the Federal Ministry of Science and Technology a National Council of Science and Technology (NCST) comprising the Minister of Science and Technology, representatives of other Ministers connected with S& T and State Commissioners of Science and Technology meets once a year to deliberate on national S&T policy issues.

In a similar effort aimed at R&D coordination, the government under the aegis of the Federal Ministry of Science and Technology in 2008 established the National Research and Development Coordinating Council (NRDCC) with a mandate of coordinating R&D policy. This council though still very young has proposal for two organs: the technical committee which is made up of directors of research institutes and the relevant directors in the various ministries. The other organ is the board of the council which is made up of the Ministers of the various relevant ministries. While the technical committee is to meet every month, the board is to meet every quarter.

The NCST and the NRDCC are important organs through which S&T policy issues including IPR affecting R&D can be harmonized and addressed. They are therefore important instruments of national technology policy.

4.4. National Biotechnology Development Agency (NABDA)

Biotechnology is a package of techniques that employ organisms, or parts of organisms to make or modify products, improve plants and animals, or to develop microorganisms for specific applications. The Nigerian government, convinced of the fact that biotechnology is a cutting-edge technology that will drive the 21st century's global food, health, industrial and environmental sectors, took appropriate steps to ensure that Nigeria becomes a key global participant in the biotechnology revolution for the benefit of all Nigerians. As a move to enhance coordination and give a boost to the biotechnology research work in our universities and research institutes, the government took a major step by putting the National Biotechnology Policy in place by April, 2001. This led to the establishment of the National Biotechnology Development Agency in November of that year. The objectives of the agency include amongst others:

- Develop appropriate legislation compatible with international regulations, so as to ensure biosafety, in line with social and ethical considerations and to protect intellectual property, industrial property and farmers' rights.
- Maintain sustainable exploitation of bioresources for our food and agriculture, healthcare delivery and industrial utilization
- Ensure that Nigeria become self reliant in the development and application of biotechnology-based products and services.

In line with these objectives NABDA can take the necessary steps to support the enactment and reform of the nations laws that will enhance the development of biotechnology including the nations obligations to WTO TRIPS which made provisions for biotechnology products and processes, genetic resources/bioresources exploitation for food, drugs and nutraceuticals as well as laws on micro-organisms, plants and animals. Biochemistry, Microbiology, Molecular Biology and Bioinformatics are essential tools of biotechnology.

4.5 OBD-Plus Technology- a Nigerian microbial invention

OBD-Plus, the *microbial* formula invented by Professor B.A. Oso, of Arati Environmental Ltd Lagos, Nigeria (formerly of the University of Ibadan, Nigeria) has been shown to be a very effective agent in the management of oil pollution, liquid and solid wastes. It bio-degrades crude oil and their refined products as well as solid and liquid wastes at a fast rate.

Hence, it is a useful agent in the bio-remediation of polluted environment (land and water). Oil polluted soil bio-remediated with OBD-Plus for example becomes more fertile than before. Professor Gideon Okpokwasili of the University of Port Harcourt, Nigeria is another expert on bioremediation, employing microorganisms. Such inventions are very significant in the discussion on whether or not to

patent microorganisms in Nigeria as it shows that such inventions (local or foreign) may be common and thus calling for an urgent need for a protection system to spur investment in R&D and Commercialization.

4.6. Nigeria's Draft National Biosafety Bill and the Cartagena Protocol

A related regulatory framework, Biosafety refers to efforts to reduce and eliminate the potential risks resulting from modern biotechnology and its products including possible harm/effects that might be done to the environment, biodiversity and human health. With the advent of modern biotechnology, genetically modified organisms and other products, and their perceived adverse impacts on the environment and human health, Nigeria joined the league of nations in taking precautionary safety measures, by signing and ratifying Cartagena Protocol on Biosafety (CPB) of year 2000. The vision of Nigeria's Biosafety is to ensure that the practice, processes and procedures of Modern Biotechnology are undertaken within the limits of a regulatory system, that guarantees its safe use, protects Nigeria's Biodiversity and provides minimum risk to human health and the environment. The Draft Biosafety Bill prepared under the aegis of the Federal Ministry of Environment and presented to the Federal Executive Council is undergoing passage at the National Assembly as an Executive Bill.

4.7. National Varietal Release Committee and the National Agricultural Seed Service (NSS)

The National Crop Varieties and Livestock Breeds Registration and Release Committee Decree 33 of 1987 was promulgated to inject sanity into the system of naming, release and registration of crop varieties and livestock breeds and consequently checkmate the seed industries.

The decree spelt out the responsibilities of members and functions of the National Varietal Release Committee. The committee was charged with receiving the processing applications for the registrations, naming and release of old and new crop varieties and livestock breeds: officially releasing the list of superior crop varieties and livestock breeds recommended by the sub-committee established for that purpose. Decree 33 was later complimented by the Seed Decree 72 of 1992. In a meeting held on January 13, 2000, the committee noted the need for harmonization of the Decree 33 of 1987, establishing the National Crop Varieties and Livestock Breeds Registration and Release Committee and Decree 72 of 1992 establishing the National Agricultural Seed Service. While Decree 72 focused on seed only, Decree 33 of 1987 on the other hand had in addition to provisions on crop varieties release and registration the provision on livestock breeds release and registration. On the last count, since the inauguration of the National Committee in 1989 about 361 crop varieties have been officially registered and released. These were done retroactively and actively. However, not many achievements have been recorded in the area of livestock breeds. Shika Brown from National Animal Production Research Institute (NAPRI), which was a product of about 15 years of research, remains the only livestock breed to be officially registered and released. The release procedure is as follows:

- The release process of 2 – 3 years.
- Adequate seed quantity must be available with the breeder nominating the crop variety for multi-location testing.
- The breeder or the Institution concerned must submit the appropriate name for the new variety which must be simple, brief and pronounceable.
- Data from 2 years multi-location and OFAR (On Farm Adaptive Research) must be available before the nomination of crop variety.
- 1 kg (or adequate quantity in case of vegetables) of the newly released varieties must be sent to the National Centre For Genetic Resources and Biotechnology (NACGRAB) to be kept in the Gene Bank.
- National Seed Service (N.S.S) is mandated to produce Foundation Seed after signing an M.O.U. with the concerned N.A.R.'s.

From the above procedure it can be seen that Plant Variety Protection (PVP), Animal Breeders Rights and Farmers Rights does not form part of the above process requiring that another mechanism

is in need. This requires that the Plant Variety Release Act may be modified to include Plant Variety Protection provisions or a new PVP law should be put in place.

4.8. Nigeria Natural Medicine Agency

The Nigerian Natural Medicine Development Agency (NNMDA) is working to develop a legal framework for IPR regime to enable the exploitation of our indigenous Traditional Medicine Knowledge (TMK). This will compliment the effort towards development and promotion of the nation's biodiversity and bioresources. NOTAP is supporting NNMDA in this direction. The two agencies (which are in the Ministry of Science and Technology), with the support of World Intellectual Property Organization(WIPO), the International Association for the Promotion of Traditional Medicine (PROMETRA), Dakar, Senegal, the African Union Scientific, Technical and Research Commission(AU-STRC) and other local organizations jointly organized a workshop in 2005 with the theme "Appropriate Intellectual Property Rights(IPR) Regime – a necessity for Maximizing the potentials of Traditional Medicine for Improved Healthcare Delivery, Economic Growth and Development." A draft law on Nigeria's Traditional Medicine Knowledge is being put in place by the NNMDA.

4.9. Space and Information Technology Strategies

As part of government's effort to reform the Science, Technology and Innovation sector, attention was also directed at building capacity in Space Technology and Information Technology. Thus, the National Space Research and Development Agency (NASRDA) was established. In realization of one of the objectives for which it was established NASRDA successfully launched the Nigerian Satellite (Nigeria Sat 1) in November 2003 which is currently yielding data for local and international use on weather and environment. Nigeria with technical support from China also successfully launched the first African Communication Satellite, (NIGCOMSAT), in the first quarter of 2007 meant to meet the communication needs of our nation. Furthermore, for the purpose of managing the products of NIGCOMSAT, two companies, Nigerian Communications Satellite Ltd and the Galaxy Backbone Plc have been registered and are now operating. Both companies are together expected to coordinate to manage the National Information and Communication Technology Infrastructure Backbone (NICTIB).

Also established by government is the National Information Technology Development Agency (NITDA) as the clearing house for IT projects in the public sector. The Agency is committed to the drive to bring government and its services closer to the people through IT. Entrusted with the implementation of the National IT policy, which seeks to make Nigeria an IT capable country in no distant future, NITDA has been mandated to supervise the management of the country code Top Level Domain as a national resource. The operations of NASRDA and NITDA have wide IP implications including the emerging IP issues like dormain names: for instance bbc.com, wsu.edu, nabda.ng. These names are being protected. Just as postal addresses indicate physical locations, dormain names indicate unique locations in the "cyberspace". Some of the names assume celebrity persons, places and institutions with greater need to be protected. Various entities control the registration, renewal and transfer of domain names, depending on the final portion of any alphanumeric address. Addresses ending with country codes "fr" or uk are subject to laws of France and the UK respectively. Those ending with "com" and a few other terms have a global reach. They are governed by rules established by the Internet Corporation for Assigned Names and Numbers (ICANN), under agreement with the US Department of Commerce²¹. Nigeria's domain name is .ng and NITDA has been mandated to supervise it. NITDA should also explore the possibility of developing an IP system for Semiconductor Integrated Circuits Layout-Design for Nigeria.

"The United States, Japan, and many EU countries protect the topography of semiconductor chips and integrated circuits under *sui generis* laws, some of whose aspects are borrowed from patent

²¹ Field Thomas G. What is Intellectual Property: file://E:\IPR\Focus on Intellectual Property, <http://www.piercelaw.edu/tfield/tgf.htm>, 19th March, 2007

or copyright law²². The U.S. law, is called the Semiconductor Chip Protection Act of 1984²². In India this is administered in the Department of Information and Communication Technology of the Ministry of Communication and Information Technology (Table 2 above).

5. Case Study of A Licensed Nigeria Patent

Development Of Nicosan /Hemoxin: A Drug For The Management Of Sickle Cell Disease^{23 24 25}

5.1 Historical Background

NICOSAN/HEMOXIN (formerly called and patented as NIPRISAN) is a drug first developed by the Nigerian National Institute for Pharmaceutical Research and Development (NIPRD) for the management of Sickle Cell Disease (SCD). NIPRD was then in the Federal Ministry of Science and Technology before it was transferred to Federal Ministry of Health. NICOSAN consists of a mixture of extracts from four tropical medicinal/food plants some of which are cultivated and others found in the wild both within and outside Nigeria- *Piper guineenses* seeds, *Pterocarpus osun* stem, *Eugenia caryophyllum* fruit and Sorghum bicolor leaves.

The story of NICOSAN (outside of Africa the medicine is known as HEMOXIN will be incomplete without acknowledging some of the great minds, which have contributed immensely towards its development. Historically, a similar remedy was mentioned in the book titled "Iwosan" published by the late Dr. Odumosu at the turn of the century. However, the modern day origin of what later became patented as NIPRISAN was due to the late Rev. Paul Ogunyale, then Pastor of the First Baptist Church in Ibadan, Oyo State, Nigeria, who brought the attention of Prof. Charles Wambebe, former Director General, NIPRD in late 1992 to a herbal recipe of the drug. He practiced traditional medicine after his retirement as a pastor before his death. From 1992 to 2001, Prof. Wambebe and his team of researchers at NIPRD, supported by the Federal Government of Nigeria (FGN) and the World Health Organization (WHO), worked tirelessly to develop NIPRISAN as a potent drug for the management of SCD and was patented in the United States of America(as NIPRISAN) under the leadership of Prof. Wambebe. After the retirement of Prof. Wambebe from NIPRD, his successor, Dr. Uford S. Inyang continued tirelessly with more developmental work in taking NIPRISAN to a higher level.

5.2 The Birth of NICOSAN/HEMOXIN

In August 2001, a joint conference on biotechnology was organized at Cook College, New Brunswick, NJ between the Sheda Science and Technology Complex (SHESTCO) of the Federal Ministry of Science and Technology, Abuja, Nigeria and Rutgers University New Jersey USA, under the leadership of two Nigerians in the US Diaspora - Dr. Soji Adelaja, who was then Dean of Research at Cook College and New Jersey Agricultural Experiment Station (Cook/NJAES), and Dr. Albert Ayeni, then Weed Scientist at Cook/NJAES and later Coordinator of International Programs of

²² http://en.wikipedia.org/wiki/Sui_generis

²³ Sheda Science and Technology Complex -SHESTCO *Sheda Science and Technology Complex (SHESTCO): In Focus* Abuja Nigeria, [http:// www.shestco.org](http://www.shestco.org) , 2006

²⁴ Xechem Pharmaceuticals Nigeria Limited, Abuja, Nigeria. Interview with the Managing Director, Mr. Ireliolu Oniyide Dec. 2008

²⁵ National Institute of Pharmaceutical Research and Development (NIPRD), Abuja, Nigeria. Interview with Prof. Oloyode Kunle. Head, Dept of Pharmaceutical Technology (NIPRD). February, 2009

Cook/NJAES on the one hand, and Dr. Ayodele Coker, Director-General/CEO of SHESTCO on the other hand. It should be noted that while NIPRD developed and owns the patent for NICOSAN, SHESTCO took interest to promote the commercialization of the product because one of its mandates is Advanced Biotechnology R & D. New Jersey was a favourable place to hold such a biotechnology conference. Known in US as “the nation’s medicine cabinet”, New Jersey ranks first in the United States in the manufacturing of pharmaceutical products. Annual sales for pharmaceutical firms in New Jersey exceeds \$700 billion, fueled by the fact that fifteen of the twenty largest drug companies in the world have major facilities in New Jersey. With 116 biotechnology companies, New Jersey currently ranks fourth in the US for its cluster of biotechnology companies²⁶.

Dr. Ramesh C. Pandey, Chairman & CEO, Xechem International, Inc. (USA) represented his company at this conference. What transpired during and after the conference propelled Dr. Pandey to explore the possibilities in the applications of biotechnology for drug production in Nigeria. At the instance of Prof. Turner T. Isoun, the Honourable Minister of Science and Technology, Dr. Pandey visited Nigeria for the first time in October 2001 with Dr. Albert Ayeni. This visit aroused in Dr. Pandey the interest in exploiting biotechnology for drug development in Nigeria. The first product of interest, NIPRISAN was thus, introduced to him by Dr Ayodele Coker, the Director-General of SHESTCO, and later by Dr. Uford S. Inyang, the Director General of NIPRD.

In July 2002, negotiations were successfully concluded between NIPRD and Xechem International under the direction of Prof. A. B. C. Nwosu, then the Honourable Minister of Health-NIPRD’s supervising ministry. Xechem International was granted the exclusive rights for development, production and marketing of NIPRISAN. To give effect to the agreement, Xechem Pharmaceuticals Nigeria Ltd, with its production factory located within the premises of the Sheda Science and Technology Complex (SHESTCO), Abuja Nigeria, was incorporated in 2002 while production was launched on July 6th, 2006 by the then Nigerian President Olusegun Obasanjo.

5.3 About Sickle Cell Disease

Sickle cell Disease is a hereditary blood disorder caused by an abnormality in the hemoglobin molecule. The condition causes the production of abnormal hemoglobin that contains portions that stick together after the release of oxygen. This phenomenon produces stiff, sickle shaped red blood cells that do not flow freely through blood vessels. These sickle-shaped cells create clogs in the blood vessels which prevent the flow of normal hemoglobin and oxygen round the body. The result is severe pain or “crises”, ulcers, organ and tissue damage and breakdown, which eventually lead to stroke and acute chest pain. The body’s immune system also attacks and seeks to destroy the abnormally shaped cells, often leaving the body with an insufficient number of normal oxygen-carrying red blood cells, which in turn results in anaemic condition that manifest in fatigue and enhanced susceptibility to infection. It is estimated that there are 12 million sufferers of SCD worldwide with greater prevalence among black people, out of which about 4 million are Nigerians.

Repeated crisis can also result in damage to the kidneys, lungs, bones, eyes and the central nervous system. The most feared complication for children with SCD is a stroke which affects infants as young as 18 months. Many children with SCD do not survive infancy or early childhood. Adults with SCD often experience a reduction in the quality of life due to severe physical problems such as pain, Hard-foot syndrome and acute lung complications that can result in death. Frequent episode of severe bone pain, crises and hospitalization significantly affect the lives of these patients. It limits their ability to participate in normal physical activities, thus retarding their social and economic advancement; it also deprives them of the joy of living life to the fullest and instills the fear of early death in them. Before the advent of NICOSAN/HEMoxin the only known cure for the disease is a bone marrow transplant to replace defective red blood cells with donor healthy cells. Treatment has generally consisted of supporting therapies, which include folic acid for anemia, penicillin to prevent infections, pneumococcal and influenza vaccination, pain killing drugs and intravenous injection of fluids. In the United States of America, Hydroxyurea is the only drug approved by the US Food and Drug

²⁶ Witriol Andrew S (Author), Prepared under the supervision of Dr. Fernando Alvarez Biotechnology and Entrepreneurship. January 20, 2004, P. 14

Administration (FDA) for the treatment of SCD. It is very expensive and toxic and patients treated with hydroxyurea exhibit severe side effects.

5.4 Hope for the Sicklers

NICOSAN/HEMOXIN is a non-toxic, phyto-pharmaceutical product composed of extracts from four tropical plants, seeds, stems, fruits and leaves. Each plant is indispensable in the manufacturing of NICOSAN/HEMOXIN as the extracts are more potent when used as a group than when used independently. Xechem Pharmaceuticals Nigeria Limited has developed refined and standardized small-scale formulations of NICOSAN/HEMOXIN for consistent production in strict compliance with the recommended procedures and policies of the World Health Organization (WHO).

NICOSAN/HEMOXIN has already undergone phase I, phase IIa and phase IIb clinical trials conducted in Nigeria by the NIPRD. A Phase IIb trial of Nicosan was conducted at an army base hospital in Yaba, Lagos, Nigeria between 1996 and 1997. Xechem reports that "73% of the 30 patients who participated in the study experienced no crisis during the 12 month trial period and the remaining 27% experienced less frequent and less severe crises."²⁷ Based on phase IIa and IIb trials Nicosan was given a 2 year listing license by National Agency for Food and Drug Administration and Control (NAFDAC) of Nigeria on July 3, 2006. Results from the phase III trials which require greater number of samples and is multi-locational, if found satisfactory, will form the final basis for an application to NAFDAC for regulatory approval that will last for 5 years but subject to renewal²⁸.

Further laboratory testing among others have also been done at the National Heart, Lung and Blood Institute - Sickle Cell Disease Reference Laboratory (NHLBI-SCDR Lab) located at the Children's Hospital, Philadelphia, Pennsylvania, USA. The results of these trials show that NICOSAN/HEMOXIN has "a strong antisickling effect"²⁹ and drastically reduced the frequency and severity of SCD crises. Liver and kidney functions remained normal and patients gained appreciable weight. No adverse effects were reported during the trials. These clinical studies suggest that NICOSANTM is a safe and efficacious phytomedicine for the management of SCD. It may have just paved the way for ending the misery and pain of millions of SCD sufferers in Nigeria and the world at large.

Through the instrumentality of Dr. Pandey, and based on the background of work done at the Children's Hospital, Philadelphia (CHOP) and other published literature in various indexed journals, on August 15th, 2003, NICOSAN (NIPRISAN) was granted an Orphan Drug status by the Food and Drug Administration of the United States of America (US-FDA). An orphan drug is a drug produced for orphan diseases, a class of rare conditions that the larger pharmaceutical companies tend to ignore because the profit potential is low. The Orphan Drug designation, entitles a company to various incentives including the waiver of Regulatory filing fees, access to potential funding for non-clinical and clinical research to generate required data for marketing approval, and seven years of marketing exclusivity once approved by the FDA. This was a major break-through since it was a far-fetched possibility that the US-FDA would designate NICOSAN (NIPRISAN) Orphan Drug status. The Orphan Drug status has thus, added credibility and international acceptability to NICOSAN (NIPRISAN) as a potent drug for the management of SCD.

²⁷ "Xechem International - Annual Report". December 31 2005.

http://sec.gov/Archives/edgar/data/919611/000114420406015544/v040579_10ksb.txt. Retrieved on 2006-07-21. - submission to U.S. Securities and Exchange Commission

²⁸ Kella Hauwa (Mrs.), Director of Enforcement, National Agency for Food and Drug Administration and Control (NAFDAC), Abuja, Nigeria. Interview, February, 2009.

²⁹ Iyamu E, Turner E, Asakura T (2002). "In vitro effects of NIPRISAN (Nix-0699): a naturally occurring, potent anti-sickling agent.". *Br J Haematol* 118 (1): 337-43. doi:10.1046/j.1365-2141.2002.03593.x. PMID 12100171.

5.5 Production and Marketing of NICOSAN by Xechem Pharmaceuticals Ltd

The factory buildings for Nicosan production was built by the Federal Government of Nigeria through Sheda Science and Technology Complex(SHESTCO) where it is located supposedly under an agreement for a certain period of time and with the intention to support the company in its infancy. At its new location, "the company used U.S.-built plant, equipment and machinery. For this, Ex-Im Bank (of USA) provided a comprehensive guarantee for a \$9.4 million loan, which funded about three-quarters of the project's total cost".³⁰ From production of 5000 capsules per day in January 2007 the company is presently producing 50,000 capsules daily as at December, 2008. The drug is mainly marketed in bulk through state governments and some major hospitals in Nigeria. Some of the state hospitals have reported significant reduction in SCD patients coming to the emergency room. Effort is being made to make the drug more affordable to the general public. Record of sale of the drug outside Nigeria was not available at the time of this write up.

In 2004 with 19 employees and \$300,000 in revenue, Xechem was still in the high-growth startup because of its investment in low revenue orphan therapies. Xechem has had a negative operating income since 2002 and has dropped from around \$40.00 per share two years ago and traded at around \$0.15 per share³¹. On December 30th, 2003, Xechem acquired Ceptor Inc., a privately held biotechnology company. Ceptor provides Xechem a neuromuscular platform technology that will produce both orphan drug products for the Company to develop under its business model as well as large-market products appropriate for partnering with major companies. Xechem also acquired the exclusive worldwide rights for five membered heterocyclic anti-sickling compound known as 5-HMF, in December 2005 under a license agreement with Virginia Commonwealth University (VCU) , USA and on May 26th, 2006, Xechem was successful in obtaining Orphan Drug designation from the US Food and Drug Administration (FDA) for the drug. The research for the drug was led by Dr. Donald Abraham of VCU.

It is however disturbing to learn that Xechem International, Inc. announced on November 10, 2008, that it and one of its subsidiaries, Xechem, Inc., filed voluntary petitions for relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Northern District of Illinois (the "Bankruptcy Court") to suspend all litigation and to restructure its debt. The Company intends to work with all of its constituencies to reach mutually acceptable resolutions and to exit bankruptcy as expeditiously as possible. Xechem's operations are expected to continue as normal throughout the bankruptcy process, while the Company executes on its reorganization plans. Xechem's other subsidiaries are not part of this Chapter 11 filing including Xechem's Nigerian subsidiary, Xechem Pharmaceuticals Nigeria Limited which will continue its normal operations of the manufacturing and sale of NICOSANTM.

5.6. Intellectual Property issues arising from NICOSAN

The birth of NICOSAN a phyto-pharmaceutical drug for the management of sickle cell disease SCD represents a milestone in IP management in Nigeria. This drug is of significance in IP management in many ways. It was developed Nigeria's National Institute for Pharmaceutical Research and Development (NIPRD) and patented in US (U.S. Patent # 5,800,819 - September 1, 1998) in a total of 42 countries which was informed by the fact that patent registration is country specific. The traditional knowledge as a herbal remedy for the treatment of SCD was made known to NIPRD by the late Rev. Ogunyale who practiced traditional medicine. NIPRD developed it into a drug, patented it and later licensed it to a United States company. When the issue of benefit sharing by both parties in the exploitation of genetic resources/bioresources as required by the Convention on Biodiversity(CBD) and the AU Model Law is considered with respect to NICOSAN, it was reported that the name of the holder of the traditional knowledge was mentioned

³⁰ Lambright James H. (Chairman and President Export-Import Bank of the United States) Remarks before the Africa Trade & Investment 2007 Conference Cape Town, South Africa , February 1, 2007. Office of Communications 202.565.3200 • www.exim.gov

³¹ Witriol Andrew S., Ibid

in the patent and in some of the journal publications and that he was considered for royalty along with NIPRD. Though late, he was said to have set up a foundation before his death where the royalty is to be paid and utilized. However, Xechem has not started paying any royalty but NIPRD is optimistic that the company will pay when it is fully established.

On the issue of the effect of cost of patent, the observation is that the cost of patenting is a very significant factor in the whole process of commercializing a product. Although it was not possible to find out the amount for which the product was patented at the IP national offices or licensed to Xechem, what is obvious is that the issue of paying the patent renewal fee became a problem and UNIDO came to the rescue and paid the fees. The implication is that in the absence of the support that came from UNIDO the patent would have been badly affected without a renewal. If this is the case with a government institution then an individual inventor would have been worse off. It was also not clear whether it is the patent owner or the licensee that ought to have paid the renewal fees and whether this clause was reflected in the licensing agreement.

5.7. Challenges in the Commercialization of Nicosan

i. Resistance to the drug. In spite of the laudable attributes of this new drug, some people including the Sickle Cell Foundation of Nigeria are still resisting the drug. Its acceptability in the international market was not assessed in the course of this study.

ii. Quality of local manpower in Nigeria: The average science graduates in biochemistry and microbiology in Nigeria are not adequately prepared for quality of scientific analysis needed in the company. They are unfamiliar with the use of state of the art equipment for chemical analysis of substances such as High Performance Liquid Chromatography(HPLC). The company also observed low morale among some of the young graduates that resulted from their inappropriate career choices-a feeling that they would have read other things other than the science courses. This could also have resulted from inadequate motivation by the company as well.

iii. Patent renewal: There was problem of renewal of the patent on the drug. The question arose as to who should be responsible for payment of renewal fees that requires further investigation: the patent owner or the licensee. Having reportedly patented the product in USA and a total of 42 countries, the amount of money required for patent renewal was substantial and UNIDO was reported to have assisted to pay the fee.

iv. Power Supply: Located in Nigeria, the company is experiencing epileptic power supply for its operations. Stable and constant power supply is important to avoid equipment breakdown which when it occurs may need to be replaced from the manufacturers abroad. This requires after-sales service support. With foreign manufactures involved, this takes money and time and disrupts production. Even when generators are made available there is the problem of high cost of diesel which sometimes could be adulterated by some mischievous suppliers, causing serious damage to the generators.

6. Lessons and Recommendations of the Study

i. Reform of Nigerian IP laws

A number of recommendations have been offered with respect to reforms in the IP system of the country.

- a. The impasse between the Copyright Commission under the aegis of the Ministry of Justice and the Trademarks, Patents and Designs Registry under the aegis of the Ministry of Commerce and Industry on hosting host of the proposed national umbrella body on IP is delaying the reform of the country's IP laws in line with WTO requirements. The matter should be taken to the Presidency for quick resolution.
- b. It should be noted that having one umbrella body on IP is one (but a very rare) model that countries could adopt in the course of reforming their IP laws. Another model is to leave the different registries where they are presently historically located and allow the emergence of the expected new ones that will be placed in the ministries where they are most suited. This argument is based on the fact that some of the specialized IP registries such as Plant Variety

Protection may be marginalized and will not attract enough of the right caliber of specialists and infrastructure if it is lumped together under an umbrella Intellectual Property Office. More importantly, the new offices will also address the issue of the sui generis patents (PVP, Animal Breeders Rights, Farmers Rights and microorganisms and Semiconductor Integrated Circuit Layout- Design which are different, 'standalone' systems and should be administered differently.

- c. The AU Model law with respect to patent of living organisms was endorsed by all AU Heads of State. It provides for non patent of any living organism because of the sacred nature of life. This is in line with one of the fears expressed by many countries over TRIPS thus requiring that the country shall develop a sui generis (different) system of IP for patenting microorganisms, plant and animal varieties, and farmers' rights. Such a sui generis scheme will function better if located in the technology related ministries. This will allow for due processes that guarantees respect to life forms to be employed and for better technical capacity development of the offices. They should however employ full compliment of needed professionals including lawyers.

Consequently, it is recommended that

- i. **An amendment to the National Crop Varieties and Livestock Breeds Registration and Release Act to include PVP, Animal Breeders Rights and Farmers Rights. The existing Plant Variety Release Act is now administered by National Centre for Genetic Resources and Biotechnology (NACGRAB) in the Ministry of Science and Technology. This recommendation is a variant of the UK model. Alternatively, a separate PVP law with its own registry may be created.**
 - ii. **A National Biotechnology Law should be enacted which will give a legal backing to the establishment of the National Biotechnology Development Agency (NABDA) and regulate research on new microorganisms in terms of IP as well as regulate biotechnology research with respect to benefit sharing in biopharmaceuticals and nutraceuticals developed from biological resources. Similarly, a separate sui generis law on microorganisms patent may be enacted as an alternative.**
- d. The reform should also include improved funding that will bring the IP system to international standard. There is a lot of international collaboration in IP matters especially with the expectations of WTO. Databases need to be computerized and brought to international standard. There is more emphasis towards a paperless system in the IP official transactions. This system is already being adopted by other sectors of the economy such as the Corporate Affairs Commission of Nigeria.
 - e. To give support to the reform process, Nigeria's membership of relevant international conventions should be vigorously pursued including Union for the Protection of Plant Varieties (UPOV).

ii. Change of perception on IP as only a profession of law.

There is need to change the perception of IP as merely a judicial matter meant mainly for the legal professionals in Nigeria. It is perhaps this perception that informed the transfer of the National Copyright Commission from the Ministry of Information to the Ministry of Justice as well as the recent move to host the proposed NIPCOM in the Ministry of Justice. This perception may have contributed to the imbalanced development of IP in Nigeria especially with respect to technology patents relative to many countries of the world resulting from sustained denial of the system the right caliber of technologists and other professionals to make the needed input. For instance the UPOV system of plant variety protection came into being with the adoption of the International Convention for the Protection of New Varieties of Plants by a Diplomatic Conference in Paris since December 2, 1961³².

³² source: <http://www.upov.int/eng/brief.htm> 10oct02

This was however the point at which there was recognition of the intellectual property rights of plant breeders in their varieties on an international basis. Today there are over 60 members of UPOV without Nigeria while some countries with PVP are not yet UPOV members.

A very good point to start is a change of IP Curriculum in Nigerian Universities. Although the range of students that can benefit from IP education in this respect is very wide, as students from disciplines including business, law, fine arts, engineering, the sciences, and journalism could be prime beneficiaries, and indeed, many teaching program should include IP in their curricula, IP presently and unfortunately is taught as a course only in faculties of law in Nigerian universities as part of the basic law degree program that gives students a general understanding of the philosophy and application of IP law.

As a law course it is not a compulsory course in the law curriculum approved by the Nigerian University Commission (NUC). And as result of the poor level of awareness of the importance of IP in the country, enrollment for it among law students is very poor. The number of law faculties offering the course at undergraduate level is few while the number offering it at postgraduate level is fewer. As of now, there is no university offering IP as a specialized course in Nigeria. Although at the Nigerian Law School, IP is taken as one of the topics under commercial law which is done through an hour or two lecture often delivered by a guest lecturer, this is grossly inadequate in the light of present day realities of information technology revolution, and increasing pace, impact, and importance of invention and innovation, linked to rapid globalization which have brought IP to the centre stage³³.

This is a sharp contrast to what obtains in the advanced countries of the world and even some so called developing countries like India where IP, Technology Transfer and even Commercial law (with IP curricular for non lawyers) are taught as specialized courses in universities. This step will help to boost the number of IP professionals in the country some of whom can be employed by the emerging technology transfer offices in the universities and research institutes at home and abroad. Recently, NOTAP established 23 of such offices in universities and research institutes across the country.

iii. Low Patronage of Copyright in Nigeria

Low patronage of operations of the NCC by authors and copyright owners is a cause for serious concern for any well meaning Nigerian. Statistics is showing that between 2005 when the scheme was introduced in its present form and June 2008, the NCC received 995 applications only. This does not reflect the robust capacity of the creative industries today in Nigeria. For instance the Nigerian film industry often called Nollywood is ranked as one of the most vibrant in the world. While such may hold true for some authors, especially the uneducated ones, we cannot say the same of the more enlightened sections of the creative industries. The often cited reason for this low patronage which is low level of awareness among authors can be overcome by aggressive marketing and awareness creation strategies by the NCC. NCC should operate as a business agency.

iv. Nigeria's System of technology policy.

Institutions concerned with Nigeria's technology policy such as the National Council on Science and Technology (NCST) and National Research and Development Coordination Council (NRDCC) whose activities are affected by the developments in IP should champion the reform of the IP system.

Similarly an act similar to the United States Bayh-Dole Act should be enacted by the Federal Government of Nigeria. This will make the research institutes and the universities to see their research results as their own properties instead of seeing it as that of public property which does not motivate them to commercialize their inventions.. Since the main purpose of the act is to further development and commercialization of research, Nigeria will stand to benefit from the act's lofty ideals just like other developing countries that have adopted it are reaping the benefits through licensing revenues and formation of start up companies from the research results.

³³Adedeji Oluwale-Dr.(Special Assistant to the Director General NCC), Intellectual Property Education In Nigeria, Nigerian Copyright Commission, Federal Ministry of Justice, Abuja, Paper Contribution, 2008

v. Harnessing the talent of Nigerians in Diaspora.

The role played by the two Nigerians in Diaspora in the USA in the licensing of Nicosan is a classical example of the contribution that Nigerians in Diaspora can make in economic development of Nigeria. Two Nigerians in the US Diaspora - Dr. Soji Adelaja, who was then Dean of Research at Cook College and New Jersey Agricultural Experiment Station (Cook/NJAES), and Dr. Albert Ayeni, then Weed Scientist at Cook/NJAES and later Coordinator of International Programs of Cook/NJAES created the enabling collaboration with their employer-The Rutgers University of New Jersey for the conference where NICOSA was discovered by the licensee to take place. Many such Nigerian professionals whose talents could be sought abroad in many other institutions abroad.

Similarly, Nigeria and indeed Africa has been benefitting from the contribution of a person like Mr Geoffrey Onyeama, Director, Economic Development Bureau for Africa, WIPO, Geneva, Switzerland who on behalf of WIPO has been giving support for the reform of the country's and continents' IP system. It is in recognition of these talents that Nigeria set up the Nigerians in Diaspora Conference under the aegis of the Federal Ministry of Science and Technology in which it holds a conference annually with Nigerian professional abroad. Such a forum can also be used to tap more talents on Nigeria's IP and Technology transfer reforms.

vi. IP in ICT sector

The operations of NASRDA and NITDA have IP implications including the emerging IP issues like domain names, for which Nigeria's domain name is .ng. Just as postal addresses indicate physical locations, domain names indicate unique locations in the "cyberspace". Some of the names assume celebrity persons, places and institutions with greater need to be protected against abuse. NITDA has been mandated to supervise Nigeria's domain name.

NITDA should also explore the possibility of developing an IP system for Semiconductor Integrated Circuits Layout-Design for Nigeria. These as earlier pointed out are *sui generis*³⁴ IP systems that cannot be adequately administered under the existing IP framework.

vii. Development and licensing of NICOSAN

The study on NICOSAN was not exhaustive enough within the time limit available to produce this report. Hence it is recommending that a more detailed study should be carried out especially on the IP issues arising out of the project. The experience with the drug should prompt our government to develop policies and laws guiding traditional knowledge and benefit sharing of gains resulting from exploitation of genetic resources in view of its enormous potential, and considering the nation's wealth of knowledge and endowment in genetic resources. However, enough attention should be paid to benefit sharing between the contracting parties in the exploitation of the nation's genetic resources as required by Convention on Biodiversity (CBD)

If NICOSAN becomes a success it will encourage researchers and entrepreneurs to invest in the search for treatment of other diseases such as malaria, tuberculosis, diabetes and AIDS through traditional knowledge of genetic resources in Africa. Since inability to generate enough similar competitive patents relative to the developed countries is one of the fears of the developing countries on the WTO, capacity building in this area is urgently needed. Meanwhile NIPRD is said to be working on an anti-diabetic drug that has anti-diuretic effect. Similar opportunities could be lurking in other sectors of the economy such as agriculture, food processing, environment and industry as research results of similar potential could be locked away in the file cabinets of our universities and research institutes without hope of commercialization. NICOSAN also offers lessons in international technology transfer management, coming from a research institute in a developing country and licensed in a developed country.

³⁴ http://en.wikipedia.org/wiki/Sui_generis ibid.

7. Conclusion

Like in its other colonies at that time, Britain introduced the British Trademark Ordinance in Nigeria during the colonial era which ushered in the practice of Intellectual Property as an instrument of trade. Since then intellectual property practice in the country has evolved to include legislations on patents, designs and copyright. With the emergence of WTO Trade Related Aspects of Intellectual Property Rights (TRIPS), intellectual property has assumed greater prominence and WTO member countries including Nigeria are obliged to include a minimum number of Intellectual Property in their laws with a given period for implementation. Nigeria ought to be taking the necessary steps to comply. The new IP issues are generally technological in nature and have *sui generis* provisions that make them more generally acceptable. Their *sui generis* status implies that they should be administered outside the existing IP framework. This is the spirit of the AU Model Law which was crafted under the *sui generis* option and endorsed by all African Heads of State. The proposed new offices will perform more efficiently if they are located within the context of the S & T and Agricultural systems of Nigeria as is the case in other countries. This will give them a balanced development by attracting the right compliment of professionals and infrastructure.

Also in recognition of the important role that intellectual property and technology transfer management can play to enhance access to agricultural research results by the resource poor farmers and promote investment in agriculture, the Central Advisory Service on Intellectual Property launched the National Partners Initiative (NPI) for which Nigeria was graciously chosen among the participating countries and for which this study is also carried out. Nigeria should use the opportunity offered by this study to implement necessary and relevant legal and institutional reforms required to have a functional and balanced intellectual property system so as to join the comity of nations that are reaping the benefits of this new intellectual property regime including agricultural development. It is also hoped that Nigeria's experiences in terms of any gains or lapses will be useful to other NPI member countries when they are shared.

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