THE ROLE OF INTELLECTUAL PROPERTY LAW IN THE PHARMACEUTICAL INDUSTRY

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BEING A LONG ESSAY IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF A BACHELOR OF LAWS (LL.B HONS) SUBMITTD TO THE FACULTY OF LAW, UNIVERSITY OF BENIN, BENIN CITY, NIGERIA.

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CERTIFICATION

I, **Victory ODU** with **Mat No. LAW1504368** hereby certify that apart from references made to other people's works as duly acknowledged herein, this entire project is the product of my personal research and it has neither in part nor in whole been presented for another degree elsewhere.

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APPROVAL

This Project has been read and approved as meeting the requirement for the award of a Bachelor of Laws (LL.B Hons) in the Faculty of Law of the University of Benin, Benin City, Nigeria.

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DECLARATION

I hereby declare that this project **'THE ROLE OF INTELLECTUAL PROPERTY LAW IN THE PHARMACEUTICAL INDUSTRY'** is the product of my own research effort undertaken under the supervision of **Dr. (Mrs) E. O. ERHAGBE** and has not been presented elsewhere for the award of any degree or certificate. All sources have been clearly stated and acknowledged.

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DEDICATION

This research work is dedicated to the Almighty God, Jehovah, the source of true knowledge and the giver of good gifts and perfect presents.

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Finally, this research work is completed. I could not have done this alone, without the support of several persons.

Family is everything. This has been proven repeatedly by my family which has given me everything necessary to see me through my studies in the university. Daddy, Mummy, Oluchi, Ephraim and my late sister, Glad. I would not have made it this far without them all.

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TABLE OF ABBRIEVATIONS

BIRPI	United International Bureaux for the Protection of Intellectual Property
COSON	Copyrights Society of Nigeria
EPO	European Patent Office
FDA	Food and Drug Administration Agency
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GSK	GlaxoSmithKline
ICC	International Chamber of Commerce
IND	Investigational New Drug Process
IPIC	Treaty on Intellectual Property in Respect of Integrated Circuits
IPR	Intellectual Property Rights
KOPINOR	Reprographic Rights Organisation of Norway
NAFDAC	National Agency for Food and Drug Administration and Control
NCC	Nigerian Copyright Commission
OAPI	African Intellectual Property Organistion
OTC drugs	Over-the-counter drugs
PCT	Patent Cooperation Treaty
R&D	Research and Development
REPRONIG	Reproduction Rights Society of Nigeria
TB	Tuberculosis
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNCITRAL	United Nations Commission on International Trade Law
USPTO	United States Patent and Trademark Office
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

ABSTRACT

Intellectual property rights (IPR) refers to the ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property.

IPR provide certain exclusive rights to the inventors or creators of that property, in order to enable them to reap commercial benefits from their creative efforts or reputation.

There are several types of intellectual property protection like patent, copyright, trademark, etc. Patent is recognition for an invention, which satisfies the criteria of global novelty, non-obviousness, and industrial application. IPR is prerequisite for better identification, planning, commercialization, rendering, and thereby protection of invention or creativity. Each industry should evolve its own IPR policies, management style, strategies, and so on depending on its area of specialty. Pharmaceutical industry currently has an evolving IPR strategy requiring a better focus and approach in the coming era.

This work will focus on The Role of Intellectual Property in the Pharmaceutical Industry, critically examining how it has been structured to protect investments, time, money, effort invested by the inventor/creator of an IP, since it grants the inventor/ creator an exclusive right for a certain period of time for use of his invention/creation. Thus IPR, in this way aids the economic development of a country by promoting healthy competition and encouraging industrial development and economic growth. In conducting this research, the researcher will employ the doctrinal research method. This method was considered appropriate because it explains the law through primary internal evidence offered by case law, statutes, and materials derived from both primary and secondary sources.

CHAPTER ONE

GENERAL INTRODUCTION

1.0 Introduction

Intellectual property is all about the results of human creativity. Its subject matter is formed from new ideas generated by man. New ideas may be applied in as many ways as the human mind can conceive. Their application to human needs and desires can be of considerable benefit to mankind. New ideas can be embodied in familiar things such as books, music and art, in technical machinery and processes, in designs for household objects and for commercial ventures, and in all other sources of information. The list is immeasurable, as is the potential for discovery of new means of expression. Once applied to human needs, the value of ideas ranges from the industrial and commercial to the world of literature, art and design, contributing to technological, economic, social and cultural progress. Protecting the development and application of new ideas aids realisation of the benefits which can be derived from them.

Intellectual property law is the means used to provide this protection. It comprises a discrete body of rights (whether statutory, tortious or equitable) which are applied to the many and varied forms in which the human intellect expresses itself.[1] The common feature that lies behind each of the intellectual property rights is that they allow right owners to stop from others taking their creations. This preserves the integrity of, and reserves the exploitation and presentation of, those creations for the right owners. It is an area of law which concerns legal rights associated with creative effort or commercial reputation and goodwill. The law deters others from copying or taking unfair advantage of the work or reputation of another and provides remedies where this arises.

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[1] Catherine Colston and Jonathan Galloway, *Modern Intellectual Property Law* (3rd edition, Routledge 2010)2.

Intellectual property law has a long history. The Romans used marks on pottery to denote its maker and a Venetian law of 1474 established 10-year privileges to those inventing new machines.[2] The industrial and transport revolutions, which saw an explosion in new ideas and new means with which to spread their benefits, gave the law increased significance. The commercial and information age has only served to enhance the importance of intellectual property law.

Intellectual property, as a concept, was originally designed to cover ownership of literary and artistic works, inventions (patents) and trademarks.[3] What is protected in intellectual property is the form of the work, the invention, the relationship between a symbol and a business. However, the concept of intellectual property now covers patents, trademarks, literary and artistic works, designs and models, trade names, neighboring rights, plant production rights, topographies of semi-conductor products, databases, when protected by a *sui generis* right, unfair competition, geographical indications, trade secrets, etc.

Those types of intellectual property have been characterized as "pieces of information which can be incorporated in tangible objects at the same time in an unlimited number of copies at different time and at different locations anywhere in the world".[4] In other words, intellectual property rights are intangible in nature, different from the objects they are embodied in. The property right is not in those copies but in the information, which creates in them.

In today's world, the international dimension of intellectual property is of ever increasing importance for three compelling reasons. First, the composition of world trade is changing. Currently, commerce in intellectual property has become an even greater component of trade between nations. The value of information products has been enhanced greatly by the new

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2 Ibid.

3 Balew Mersha & G/Hiwot Hadush, *Law of Intellectual Property: Teaching Material* (Justice and Legal System Research Institute, 2009) 4.

4 Ibid.

technologies of the semi-conductor chip, computer software and biotechnology. Second, the world commerce has become even more interdependent, establishing a need for international cooperation. No longer can a single country impose its economic will on the rest of the world. Accordingly, countries have recognized this interdependence and have called for a broadening of international agreements/arrangements involving intellectual property. Third, new reprographic and information storage technologies permit unauthorized copying to take place faster and more efficiently than ever, undermining the creator's work. There is a general feeling in the developed countries that much of this sort of copying takes place in the third world due to the relaxation of legal standards. All these factors have prompted the international community as a whole to accord due recognition to intellectual property and intellectual property regime.

In the area of pharmaceutical industry, there have been innovative drug treatments which have offered cures from illnesses previously considered life threatening, and have improved lifestyles and diminished the effects of ageing on those fortunate enough to be able to afford treatment. Due to its cost structure, time-consuming processes and extreme innovativeness, the pharmaceutical industry beats every other industry in term of the need to acquire and protect intellectual property. From copyright in publications and materials to trademark protection of brands, from manufacturing data used to support regulatory approval to the transfer of technology by publicly funded institutions, IP affects a broad spectrum of business in the pharmaceutical industry. IP has been recognized as the most valuable resources of any pharmaceutical outlet.

Empirical evidence shows that pharmaceutical research and development process is lengthy, expensive, uncertain, and risky. Even with billions of dollars invested in research and development, few drugs actually make it through clinical trials and stringent regulatory

clearances. Industry estimates[5] confirm that developing a new drug and bringing it to the market takes 12-15 years and costs a pharmaceutical company around $3 billion. In addition, out of every 5,000-10,000 compounds that a pharmaceutical company tests, only one will be approved after all the clinical test. Knowing this, no company will like to risk its IP becoming public property without adequate returns.

Therefore, it has been come necessary for pharmaceutical industries to implore the aid of intellectual property law. Pharmaceutical companies use patents and the patent system for the purpose of avoiding infringement, acquiring patent rights, preventing acquisition of rights, research and development, technology transfer, business strategy and industry development. Generic companies, on the other hand, conduct patent searches to avoid patent infringement. They also use the patent system to innovate and improve on existing products or processes.

Pharmaceutical companies also utilize other intellectual property rights such as (a) trademarks, to protect their investment and to promote public health; (b) copyright, to protect original works necessary in research and development, securing regulatory approval, pharmacovigilance and product support; and (c) trade secrets to protect vital but un-patentable proprietary information such as clinical trial data, product formulations and manufacturing process.

This work will focus on The Role of Intellectual Property in the Pharmaceutical Industry, critically examining how it has been structured to protect investments, time, money, effort invested by the inventor/creator of an IP, since it grants the inventor/ creator an exclusive right for a certain period of time for use of his invention/creation. The work then explores the impact of patent on the balance of interests between pharmaceutical companies, governments, and the public.

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5 'Pharmaceutical', Finnegan,<https://www.finnegan.com/en/work/industries/pharmaceutical.html> accessed 21 January 2021.

This research work concludes and made salient recommendations which if implemented could successfully enhanced the application of intellectual property law to the protection of pharmaceutical industry in Nigeria.

1.1 Historical Background of Intellectual Property Rights

The history of the protection of intellectual property rights can roughly be divided into three periods. The first period, the territorial period, is essentially characterized by an absence of international protection. The second, the international period, begins in Europe towards the end of the 19th century with some countries agreeing to the formation of the Paris Convention for the Protection of Industrial Property, 1883 (the Paris Convention) and a similar group agreeing to the Berne Convention for the Protection of Literary and Artistic Works, 1886 (the Berne Convention). The third period, the global period, has its origins in the linkage that the United States of America (the U.S.A) made between trade and intellectual property in the 1980s, a linkage which emerged at a multilateral level in the form of the Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994 (the TRIPS Agreement).[6]

The dates of the various conventions do not represent a sharp epochal divide. They do mark a significant change in the evolutionary direction of intellectual property protection.

1.1.1 The Territorial Period

The different subject areas of intellectual property originate in different places and at different times. Very probably all these laws can be traced back to the system of royal privilege-giving which seems to have operated in most of medieval Europe. The Venetians

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[6] The TRIPS Agreement is binding on all members of the World Trade Organization. See Article II. 2 of the Agreement Establishing the World Trade Organization (the WTO Agreement). Both the TRIPS Agreement and the WTO Agreement are part of the Final Act Embodying The Results Of The Uruguay Round Of Multilateral Trade Negotiations, Marrakech, April 15, 1994.

are credited with the first properly developed patent law in 1474. In England the Statute of Monopolies of 1623 swept away all monopolies except those made by the "true and first inventor" of a "method of manufacture." Revolutionary France recognized the rights of inventors in 1791 and, outside of Europe, the U.S.A. enacted a patent law in 1790. These patent laws were nothing like today's complex systems. They were mercifully short, simply recognizing the rights of the inventor. After these beginnings, patent law spread throughout Europe in the first half of the nineteenth century.[7] Statutory forms of trade mark law only make their appearance late in the second half of the nineteenth century, even though trademarks had been in use for much longer.[8] The English courts developed protection for trademarks through the action of passing off.[9] For a variety of reasons, this proved unsatisfactory and statutory systems of trade mark registration began to make their appearance in Europe: England 1862 and 1875, France 1857, Germany 1874 and the U.S.A. 1870 and 1876.[10] Copyright follows a similar kind of pattern, modern copyright law beginning in England with the Statute of Anne of 1709.

The second part of the nineteenth century saw the proliferation in Europe of national intellectual property regimes. It was a period of somewhat chaotic growth with much borrowing and cross-pollination of intellectual property law between states. The principles of patent law to be found in the English Statute of Monopolies were gradually recognized in other states. The English devised the first law on designs in 1787, but they were influenced by the French design law of 1806 when they reformulated their law in 1839. Outside of Europe, intellectual property grew along colonial pathways. So, for example, the self-

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7 F. Machlup and E. Penrose, 'The Patent Controversy in the Nineteenth Century' (1950) 10 Journal of Economic History, 3.

8 F. Schechter, 'The Rational Basis Of Trademark Protection' (1927) 40 Harvard Law Review 813-833.

9 S. Ricketson, *The Law of Intellectual Property* (Law Book, Sydney, 1984) 599.

10 S. Ladas, *Patents, Trademarks, and Related Rights: National and International Protection*, Vol. 1 (Harvard University Press, Cambridge, 1975) 8.

governing colonies of Australia enacted copyright and patent statutes that were essentially faithful copies of English models.

The territorial period is dominated by the principle of territoriality, the principle that intellectual property rights do not extend beyond the territory of the sovereign which has granted the rights in the first place. The principle is the product of the intimate connections to be found between sovereignty, property rights and territory. It was a principle which courts recognized in the interests of international comity.[11] A world in which states regularly claimed jurisdiction over the property rights established by other nations would be a world in which the principle of negative comity would have largely vanished. The principle of territoriality meant that an intellectual property law passed by country A did not apply in country B. Intellectual property owners faced a classic free-riding problem, or putting it in another way, some countries were the beneficiaries of positive externalities. Dealing with free-riding and positive externalities led states into the next phase of intellectual property protection: the international period.

1.1.2 The International Period

During the nineteenth century states began to take a greater and greater interest in the possibility of international co-operation on intellectual property. At first this interest manifested itself in the form of bilateral agreements.[12] In copyright, a French decree of 1852 granting copyright protection to foreign works and foreign authors without the requirement of reciprocity did much to keep bilateral treaty-making in copyright alive.[13] Those states that

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11 *British South Africa Co. v Companhia de Moçambique* [1893] A.C. 602, 622-24.

12 S. Ricketson, *The Berne Convention for the Protection of Literary and Artistic Works: 1886-1986* (Center for Commercial Law Studies, Queen Mary College, Kluwer, 1987) 25-38.

13 H. G. Henn, 'The Quest For International Copyright Protection' (1953) 39 Cornell Law Quarterly 43, 45.

were worried about the free-riding problem began to negotiate bilateral treaties with other states. Those states that saw themselves as recipients of a positive externality remained isolationist. The United Kingdom (the U.K.) and the U.S.A. provide an example of each response. The U.K. found in the nineteenth century that many of its authors were having their works reproduced abroad without permission and without receiving royalties. Much of the "piracy" was taking place in America, where authors like Dickens were very popular with the American public and therefore American publishers.

The UK response to this problem was to pass in 1838 and 1844 Acts that protected works first published outside of the UK. These Acts grounded a strategy of reciprocity. Foreign works would only gain protection in the UK if the relevant state agreed to protect UK works. The 1844 Act saw a considerable number of bilateral agreements concluded between the UK and other European states.[14] International copyright policy in the U.S.A. took a different turn to that of the UK. The U.S.A. Copyright Act of 1790 only granted copyright protection to citizens and residents of the U.S.A. This form of national protectionism prevailed in US copyright policy for a surprisingly long period: "For over a hundred years, this nation not only denied copyright protection to published works by foreigners, applying the 'nationality-of-the-author' principle, but appeared to encourage the piracy of such works."[15] In fact, it was not until after the Second World War that the U.S.A. began to exercise real leadership in international copyright.[16] It did so with a boldness that few could have foreseen.

Like copyright, the different parts of industrial property also became the subject of bilateral treaty making, mainly between European states. By 1883 there were 69 international

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14 B. Sherman, 'Remembering and Forgetting: The Birth of Modern Copyright Law' (1995) 10 Intellectual Property Journal 10.

15 H. G. Henn, 'The Quest for International Copyright Protection' (1953) 39 Cornell Law Quarterly 52.

16 B. Ringer, 'The Role of the United States in International Copyright - Past, Present, and Future' (1968) 56 Georgetown Law Journal 1050-1079.

agreements in place, most of them dealing with trademarks.[17] They operated on the basis of the national treatment principle, this principle itself being the outcome of reciprocal adjustment between states. States had come to accept that if they not discriminate between nationals and foreigners when it came to the regulation of intellectual property rights, neither would other states. In this way states could secure protection for the works of their authors in foreign jurisdictions.

Bilateralism in intellectual property in the nineteenth century was important in that it contributed to the recognition that an international framework for the regulation of intellectual property had to be devised, and it suggested a content in terms of principles for that framework. But this bilateralism was more by way of prelude. The protection it gave authors was never satisfactory.[18] The main movement towards serious international co-operation on intellectual property arrived in the form of two multilateral pillars: the Paris Convention of 1883 and the Berne Convention of 1886. The Paris Convention formed a Union for the protection of industrial property and the Berne Convention formed a Union for the protection of literary and artistic works.

The Paris Convention had its beginnings in some US disgruntlement with a world fair for inventions which was being planned for Vienna in 1873. These world fairs, like the trade fairs of medieval Europe, were important meeting places. The U.S.A., echoing the fears of other countries, suggested that many inventions at the fair would end up benefiting the Austrian public without foreign inventors seeing any returns. The idea of a unified international patent system had been an idea circulating for some time, Prince Albert having raised the possibility of a harmonized patent system at the London World Exposition in

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17 S Ladas, *Patents, Trademarks, and Related Rights: National and International Protection*, Vol. 1, (Harvard University Press, Cambridge, 1975) 43.

18 S. Ricketson, *The Berne Convention for the Protection of Literary and Artistic Works: 1886-1986* (Center for Commercial Law Studies, Queen Mary College, Kluwer, 1987) 25-38.

1851.[19] It was a German engineer, Karl Pieper, who managed to persuade the Austrians to hold in 1873 a Congress for Patent Reform. After another Congress in 1880, the Paris Convention of 1883 was opened for signature. Within 25 years most major trading nations had joined the Convention.

The Berne Convention was also a product of meeting places in Europe.[20] The bilateral copyright treaties that states had signed were more often than not just a paper reality. They also produced great complexity. An author wanting to know the extent of his protection in other countries would have had to consult a series of treaties and domestic laws. Influential authors like Victor Hugo, whose reputations and works crossed boundaries, formed the International Literary Association in Paris in 1878.[21] This Association began to hold regular meetings in Europe. At its 1883 meeting in Berne it produced a draft text of an international copyright agreement. The Swiss government was persuaded to organize an international conference using this draft text as a starting point for a multilateral convention on copyright. Berne became the site of intergovernmental conferences in 1884, 1885 and 1886, the year in which the Berne Convention was completed and opened for signature and ratification to the world at large. Like the Paris Convention, the Berne Convention had as its axis the principle of national treatment and a set of minimum rights which states had to recognize.

The Paris and Berne Conventions ushered in the multilateral era of international cooperation in intellectual property. The twentieth century saw the proliferation of international intellectual property regimes. Examples of areas that became the subject of international agreements include trade marks (Madrid Agreement (Marks), 1891 and Madrid Agreement

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19 F-K Beier, 'One Hundred Years of International Co-operation - the Role of the Paris Convention in the Past, Present and Future' 15 (1984) International Review of Industrial Property and Copyright Law 1, 2.

20 S. Ricketson, *The Berne Convention for the Protection of Literary and Artistic Works: 1886-1986* (Center for Commercial Law Studies, Queen Mary College, Kluwer, 1987) 41-46.

21 M. Kampelman, 'The United States and International Copyright' (1947) 41 American Journal of International Law 410-411.

(Indication of Source), 1891), designs (Hague Agreement, 1925), performance (Rome Convention, 1961), plant varieties (International Convention for the Protection of New Varieties of Plants, Acts of 1961 and 1991), patents (Patent Cooperation Treaty, 1970), semiconductor chips (Treaty on Intellectual Property in Respect of Integrated Circuits, 1989). The Paris and Berne Conventions also underwent numerous revisions.

Treaty-making in intellectual property was accompanied by the rise of international organizational forms. The Paris and Berne Conventions saw the creation of international bureaus (secretariats) which were merged in 1893 to form the United International Bureaux for the Protection of Intellectual Property (known by the French acronym of BIRPI).[22] BIRPI was superseded by a new organization, WIPO, which was established by treaty in 1967. WIPO became a specialized agency of the United Nations in 1974.

The international world of intellectual property over which BIRPI and then WIPO presided was a world in which sovereign states had agreed to certain foundational principles, the most important being the principle of national treatment. But by no means was it a world in which there was a harmonization of technical rules. States retained enormous sovereign discretion over intellectual property standard setting. The U.S.A. continued with its "first to invent" patent system while other countries operated with a "first to file'"system. Civil code countries recognized the doctrine of moral rights for authors while common law countries did not. Developing countries (and for a long time many developed countries) did not recognize the patenting of chemical compounds. Standards of trade mark registration varied dramatically, even between countries from the same legal family. The law of unfair competition was a projection of local instinct even though the Paris Convention required all member states to protect against it.

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22 A. Bogsch, *Brief History of the First 25 Years of the World Intellectual Property Organization* (World Intellectual Property Organization, Geneva, 1992) 7-8.

Despite the fact that WIPO in 1992 administered 24 multilateral treaties, it presided over an intellectual property world of enormous rule diversity. By 1992 the organization also sensed, perhaps more strongly than anyone, the sea change that was about to take place in the regulation of intellectual property. The General Agreement on Tariffs and Trade (the GATT), across the road from WIPO in Geneva, was about to see to that. WIPO stood by as trade lawyers forced the world of intellectual property into the global era.

1.1.3 The Global Period

During the international period the harmonization of intellectual property was a painstakingly slow affair. After the Second World War more and more developing countries joined the Paris and Berne Conventions. These conventions ceased to be Western clubs and under the principle of one-vote-one-state, Western states could be outvoted by a coalition of developing countries. Developing countries were not simply content to play the role of a veto coalition. They wanted an international system that catered to their stage of economic development and so, in the eyes of the West at least, they began to throw their weight around. In copyright, led by India, developing countries succeeded in obtaining the adoption of the Stockholm Protocol of 1967. The aim of the Protocol was to give developing countries greater access to copyright materials. Its adoption provoked something of a crisis in international copyright.[23] The Paris Convention also became the subject of Diplomatic Conferences of Revision in 1980, 1981, 1982 and 1984 with developing countries pushing for more liberal provisions on compulsory licensing.

During the 1960s, India had experienced some of the highest drug prices in the world. Its response was to design its patent law to help to bring about lower drug prices. Under Indian law, patents were granted for processes relating to the production of pharmaceuticals, but not

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[23] H. Sacks, 'Crisis in International Copyright: The Protocol Regarding Developing Countries' (1969) Journal of Business Law 26.

for chemical compounds themselves. When it came to reforming the Paris Convention, countries like India pushed for provisions that would give developing countries more and more access to technology that had been locked up by means of patents. For India this was rational social policy for the educational and health care needs of its citizens. For the U.S.A., it was a case of free-riding. The U.S.A. in particular found itself more and more isolated at meetings relating to the Paris Convention.[24]

The international period was a world in which a lot of free-riding was tolerated. The only enforcement mechanism under the various intellectual property treaties were appeals to the International Court of Justice and most states took reservations on such clauses. No state was in a position to cast the first stone when it came to free-riding. The U.S.A. was not a member of the Berne Convention, but U.S. publishers took advantage of its higher standards of protection 'through the back door' method of arranging simultaneous publication in a Berne country like Canada.[25]

Not everybody in the U.S.A. was happy with this *laissez faire* attitude towards the enforcement of intellectual property rights. For the U.S. film and pharmaceutical industries in particular, intellectual property (copyright for the former, patents for the latter) represented the backbone of their industries. For pharmaceutical companies like Pfizer, intellectual property was an investment issue. They wanted to be able to locate production anywhere in the world safe in the knowledge that their intellectual property would be protected. Within the lobbying networks that had been organized by these global business entities, an idea began to be bounced around between a small group of consultants, lobbyists and lawyers who

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24 S. K. Sell, 'Intellectual Property as a Trade Issue: From the Paris Convention to GATT' (1989) XIII Legal Studies Forum 407-422.

25 H. G. Henn, 'The Quest for International Copyright Protection' (1953) 39 Cornell Law Quarterly 65.

traveled these networks - that of linking intellectual property to trade.[26] There were two obvious advantages of such a move. First, if a set of intellectual property standards could be made part of a multilateral trade agreement it would give those standards a more or less global coverage. Second, use could be made of the enforcement mechanisms that states had developed for settling trade disputes.

During the 1980s, the U.S.A. reshaped its trade law to give it a series of bilateral enforcement strategies against countries it considered had inadequate levels of intellectual property enforcement or which were weak on the enforcement of such rights.[27] In 1984, the U.S.A. amended its Trade Act of 1974 to include intellectual property in the 'section 301' trade process. The 1984 amendment had a sequel in the form of the Omnibus Trade and Competitiveness Act of 1988. This latter Act strengthened the 301 process by adding more processes called 'Regular 301', 'Special 301' and 'Super 301.'[28] Essentially these provisions required the Office of the United States Trade Representative to identify problem countries, assess the level of abuse of US intellectual property interests and to enter into negotiations with those countries to remedy the problems. Ultimately, if this proved futile, the U.S.A. could impose trade sanctions. Countries caught up in the 301 process came to learn a simple truth. If they failed to act on intellectual property they would, sooner or later, face retaliatory action from the U.S.A.

At the Ministerial Meeting at Punta del Este in September of 1986, the meeting which launched the Uruguay Round of trade talks, intellectual property was included as a negotiating issue. The U.S.A. had the support of Europe, Canada and Japan for the inclusion

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26 P. Drahos, 'Global property rights in information: the story of TRIPS at the GATT' (1995) 13 Prometheus 6-19.

27 M. Blakeney, *Trade Related Aspects of Intellectual Property Rights* (Sweet & Maxwell, London, 1996) Ch.1.

28 M. Getlan, 'TRIPS and Future of Section 301: A Comparative Study in Trade Dispute Resolution' (1995) 34 Columbia Journal of Transnational Law 173, 179.

of intellectual property in the Round but it was basically a U.S. initiative. It was the U.S.A., more specifically the U.S. business community, which had made all the running on the matter of intellectual property.

On 15 April 1994, the Uruguay Round concluded in Marrakech with the signing of the Final Act Embodying the Results of The Uruguay Round of Multilateral Trade Negotiations. More than 100 countries signed the Final Act. It contained a number of agreements including the Agreement Establishing the World Trade Organization and the TRIPS Agreement. The TRIPS Agreement was made binding on all members of the World Trade Organization (WTO). There was no way for a state that wished to become or remain a member of the multilateral trading regime to side-step the TRIPS Agreement.

The TRIPS Agreement marks the beginnings of the global property epoch. The TRIPS Agreement is built on the edifice of the principles of territoriality and national treatment. But it also represents the beginnings of property globalization. Via the trade linkage, the TRIPS Agreement reaches all those states that are members of the multilateral trading system or which, like China, wish to become members. The regional commercial unions that have developed in the last few years have as one of their key objectives the implementation of the TRIPS Agreement.[29] More generally, intellectual property has come to feature strongly in regional arrangements of the 1990s, particularly trade arrangements.[30]

Intellectual property norms are also becoming a part of the emerging *lex cybertoria* (the trade norms of cyberspace). The International Chamber of Commerce (the ICC) in a discussion paper stated that "[i]n cyberspace, all assets are intangible and can be classified as intellectual

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29 M. Blakeney, 'The Role of Intellectual Property Law in Regional Commercial Unions in Europe and Asia' (1998) 16 Prometheus 341, 349.

30 An early example of regionalism in intellectual property are the Montevideo Conventions of 1889 which dealt with patents and trademarks, involving Argentina, Bolivia, Brazil, Chile, Paraguay, Peru, and Uruguay. The Treaty of Rome (1957), the treaty that constituted the European Common Market, provided for conditional protection of national intellectual property rights in Article 36.

property."[31] More generally, governments and business nongovernmental organizations (NGO's) have agreed that the intellectual property issues raised by electronic commerce have to be clearly settled. So far norm-setting on the intellectual property issues has proceeded largely by way of model laws that have been generated by international organizations of states (for example, the UNCITRAL Model Law on Electronic Commerce), national law reform bodies (for example, the work of National Conference of Commissioners on Uniform State Laws on Article 2B (dealing with the licensing of intellectual property rights)) or business NGO's (for example, the ICC).

1.2 History and Evolution of Intellectual Property Rights for Pharmaceuticals

Patent medicines originally referred to medications whose ingredients had been granted government protection for exclusivity. In actuality, the recipes of most 19th century patent medicines were not officially patented. Most producers (often small family operations) used ingredients quite similar to their competitors—vegetable extracts laced with ample doses of alcohol.

As intellectual property law developed, countries retained the flexibility to customise intellectual property policy and laws to meet specific national priorities. The *German Patent Act* (Reichspatentgesetz) of 1877 was in line with several laws of the time in not allowing the patenting of inventions that were considered to be against public order or morality.[32] The Act also prohibited the patenting of luxury goods, medicines, articles of food and chemical products,[33] on the basis that they were essential goods, which should not be subject to a

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31 International Chamber of Commerce, 'E-commerce Roles, Rules and Responsibilities: A Roadmap', June 4, 1998, 11.

32 UNCTAD-ICTSD, *Intellectual Property rights and Development: A Policy Discussion Paper*, (Project on IPRs and Sustainable Development S2002) 34.

33 Ibid.

monopoly, and that more was to be gained by allowing access to foreign technology than relying on the domestic industry to stimulate innovation.[34] Countries such as Switzerland had only a patent system from 1799 to 1802 and did not re-establish it until 1888.[35] Switzerland was motivated to re-establish the patent system not because it believed that patent protection was beneficial to the economy, but because Swiss authorities had come under intense pressure from Germany to adopt a patent law and did not wish to face retaliation for failing to do so. Eventually, when a patent law was passed it included strong compulsory licencing and government use provisions and excluded chemicals and textile dyes from patent protection.[36] This policy choice favouring compulsory licences was also codified in Article 5 A(2) of the *Paris Convention for the Protection of Industrial Property* (Paris Convention).[37] Compulsory and government-use licences for medicines are expressly authorised in the patent laws of several industrialised countries and were granted extensively.[38] Canada for instance, granted 613 licences to import or manufacture pharmaceutical products between 1969 and 1992.[39]

In the late 1970s, Azithromycin was discovered by a team from Pliva, a small pharmaceutical company from Croatia. A patent application for Azithromycin was filed by Pliva in 1981 in the former Yugoslavia and subsequently patented worldwide. The patenting initiative by Pliva was the key to the commercial success of Azithromycin. Scientists from pharmaceutical

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34 Report of UK Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property rights and Development Policy* (2002) Available at: <http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf>> Accessed 21 January 2021.

35 F Dessemontet, (2000), Intellectual Property Law in Switzerland, The Hague, London and Bern: Kluwer Law International, AT 23.

36 Report of UK Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property rights and Development Policy* (2002) 19

37 1883 Paris Convention, .

38 J H Reichman and C Hasenzahl, 'Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA' (2003).

39 *Ibid* at p.4.

multinational Pfizer Inc. came across Pliva's patent while searching the database of the US Patent and Trademark Office (USPTO) and realized the great potential of the antibiotic. As one of the largest drug makers in America with an international presence, Pfizer was able to offer Pliva the channel to commercialize its antibiotic. In 1986, talks between Pliva and Pfizer eventually led to a licensing agreement. Under the agreement, Pfizer acquired the right to sell Azithromycin worldwide while Pliva maintained the right to sell the product in Central and Eastern Europe and would earn royalties on Pfizer's sales.[40]

In Africa, Asia and the Pacific, the formal introduction of intellectual property laws began in the late nineteenth century, initiated by European colonial powers after the 1884 Congress of Berlin.[41] The United Kingdom imposed versions of its 1911 *Copyright Act* through East Africa, Malaysia, and Nigeria.[42] France also applied its intellectual property laws to its colonies until the end of the colonial period.[43] Despite the imposition of colonial laws, some countries, particularly Asian countries, used the relative flexibility available to countries, to customise intellectual property laws to meet their development objectives. As was the case with many colonies, pharmaceutical patents were first introduced to India in the nineteenth century[44] Concerned by high prices and the domination of the pharmaceutical industry by foreign firms[45] post independence, the Indian government passed a *Patent Act* in 1970[46]

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40 WIPO, 'Azithromycin: A world best-selling Antibiotic'.

41 C Deere, *The Implementation Game: The TRIPS Agreement and the global politics of intellectual property reform in developing countries*, (Oxford University Press 2009) 35.

42 Gana, 'Two Steps forward: reconciling Nigeria's Accession to the Berne Convention and the TRIPS Agreement', 27 (4) International Review of Industrial Property and Copyright Law 446-489.

43 C Deere, *The Implementation Game: The TRIPS Agreement and the global politics of intellectual property reform in developing countries* (Oxford University Press 2009) 35-36.

44 India's first patent law was passed in 1856 just before the beginning for the British Raj. See P Nayaranan, *Patent Law* (3rd edition 1998) 541.

45 See for instance S Chaudhuri, *The WTO and India's Pharmaceutical Industry: Patent Protection, TRIPS and Developing Countries,* (2005) 1, 29 which suggests that foreign market share was as high as 68% of the total Indian market.

which excluded pharmaceutical products from patent protection. Kapczynski[47] notes that until the passing of the 1970 Act, colonial style laws in India were used effectively by foreign companies to suppress competition by Indian generic companies. In fact, when Great Britain enacted the first *Indian Patent Act* in 1856, it was specifically designed to enable British patent holders to acquire control over Indian markets. However, with the passing of the 1970 Act which eliminated patent rights for pharmaceutical and agricultural *products*, the number of patents declined by as much as 75% according to some estimates.[48] This, together with other important measures implemented by the government led to Indian pharmaceutical companies increasing in manufacturing sophistication over a short period of time[49]and eventually becoming so skilled at reverse-engineering that some firms were able to launch generic products in the Indian market even before the originator companies did. By the 1990s, Indian generic manufacturers were able to offer some of the lowest prices globally. However, with India having to pass a new *Patent Act* by 2005 in order to comply with the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPS or TRIPS Agreement),[50] some of the effects of this extraordinary phase of growth have begun to be reversed, with the increased consolidation of the generic industry through the acquisition of several generic pharmaceutical manufacturers by multinational originators.

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46 Act 39 of 1970.

47 A Kapczynski, 'Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector' (2009) 97 California Law Review 1571.

48 J O Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?* (National Bureau of Economic Research, Working Paper No. 6366. 1998) 3.

49 A Kapczynski, 'Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector' (2009) 97 California Law Review 1578.

50 *Marrakesh Agreement Establishing the World Trade Organization*, art. 8(1), annex 1C, 33 I.L.M. 81 (1994), *available at* <http://www.wto.org/english/docs_e/legal_e/27-trips.pdf> accessed 21 January 2021.

Aside from India, a number of countries in east Asia including Taiwan and South Korea grew their indigenous innovation capacity benefitting from having the policy space to adopt Intellectual Property (IP) systems which allowed imitation and reverse engineering.

With the passage of the TRIPs agreement, pharmaceutical Patent now have global recognition. According to the TRIPS Agreement, pharmaceutical product patents represented one of the most divisive issues, being opposed by developing countries because of concerns that stronger patent protection would hinder access to drugs and prevent the development of a domestic pharmaceutical industry. The TRIPS agreement forced developing country members of the WTO to grant patents with a statutory lifetime of 20-years from the patent application also to pharmaceutical compounds.[51] Countries such as India, Brazil, and South Africa have already implemented TRIPS compliant patent laws[52] and have introduced patent protection for both pharmaceutical products and processes.

1.3 The Stakeholders in the Intellectual Property Rights

Intellectual Property Rights stakeholders at the level of the institutional Intellectual Property Rights environment include those individuals, public and private sector organisations and firms as well as other groups (for example government, IPR offices, industry associations and activists) that have both an interest in how IPR regulation is designed and how the IPR offices manage the patenting process or copyright process. They also include those firms and consumers who aspire to become users of the IP, or of the goods and services protected by

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51 Section 5 of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement).

52 *See* Prabhu Ram, 'India's New "Trips-Compliant" Patent Regime Between Drug Patents and The Right to Health' (2006) 5 Chi.-Kent J. Intell. Prop. 195; Luciano Martins Costa Póvoa, Roberto Mazzoleni & Thiago Caliari, 'Innovation in the Brazilian Pharmaceutical Industry Post-TRIPS', in Sunil Mani & Richard R. Nelson (eds) Trips Compliance, National Patent Regimes & Innovation: Evidence & Innovation (2013) 21 Bernard Maister & Caspar van Woensel,' Is Compliance Enough: Can the Goals of Intellectual Property Rights Be Achieved in South Africa?' (2013) 2 Leiden Law Sch. Legal Studies Research Paper Series.

Intellectual Property Rights.[53] The dominant stakeholders are those who hold the rights associated with potential ownership; they are therefore those with the most direct relationship to these processes.

We will now describe these stakeholders in further detail in relation to the design of the IPR-rules, their primary objectives, the role of Intellectual Property Rights in achieving those objectives and the outcomes that are expected.

1.3.1 Society and Government

Perhaps the most obvious stakeholder in an IPR regime is the society in which it is embedded. If government in principle should represent the interests of society, a spectrum of IPR system policy goals can be identified. The IPR policy goals are underpinned by theories or economic rationales explaining the influence of IPRs on economic behaviour and hence the mechanisms by which they contribute to the achievement of societal level welfare goals. As reviewed by Andersen, IPRs are assumed to provide economic incentives to invest in invention and innovation activities. They are said to stimulate competition and market development through the 'protection of entrepreneurial talent;' and they play an important role in organising science, technology and creativity which are believed to stimulate knowledge spillovers. However, as reviewed in detail by Andersen,[54] the social contract and political expediency rationales are problematic as the expected outcomes of the IPR institution rely on flawed assumptions. Thus, they are indeed speculative. Also, the fact that various groups within society experience the effects of the IPR regime in different ways is not a matter of consideration in the mainstream IPR literature. However, it is particularly

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53 Birgitte Andersen and Sue Konzelmann, 'In Search of a Useful Theory of the Productive Potential of Intellectual Property Rights' No 15 (September 2006) DIME Working Papers on Intellectual Property Rights

54 Andersen, B. 'If 'Intellectual Property Rights' is the Answer, What is the Question? Revisiting the Patent Controversies.' (2004) 13(5) Economics of Innovation and New Technology 417-442.

apparent when national and international negotiations with respect to the design of the IPR regime are considered.

1.3.2 IPR Offices

IPR offices offers a comprehensive range of intellectual property services to individual and firms. Their position is that because patents generate growth and benefit to society, firms and individuals should accept that the IPR regime plays a positive role in promoting general economic welfare.[55] Every country with a patent system has a national patent office where claims of inventors may be made a matter of public record. Example of IPR office in Nigeria are Nigerian Copyright Commission, Patent and Design Registry. At the international level, there is the World Intellectual Property Organization (WIPO) with headquartered in Geneva, WIPO is the specialized United Nations Agency that serves as the secretariat for administration of most of the global intellectual property treaties. It is the principal forum for negotiation of new patent treaties and the leading provider of technical assistance to developing countries in the field of intellectual property rights. WIPO was created in 1967 as the successor organization to the International Bureau for the Protection of Intellectual Property, which had been in existence since the 19th Century. WIPO Currently has 179 member states.

1.3.3 IPR career people: IPR agents and IPR lawyers working in IPR offices, IPR agencies and IPR divisions within firms.

Because IPR offices are an important part of the machinery granting and enforcing IPRs, they employ an enormous number of people whose jobs, salaries and careers depends upon the continued existence of the IPR system. There are thus strong incentives for the officials and

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55 Presentation by David Sant, European Patent Office (EPO), Brussels Liaison Bureau, in the European Parliament April 14th 2004.

employees working within IPR Offices to support both the granting of patents and the existence of the IPR regime.[56] There are also many private lawyers and managers working in firms engaged in the administration, maintenance and enforcement of the IPR system, whose jobs, incomes and careers are based on the existence of the IPR system.

1.3.4 The individuals or firms who have been excluded from above IPR systems

Other stakeholders in the IPR systems include those individuals and firms who have an interest in how the IPR is used and how the value from it is distributed, but who may not have control over the IPRs or an influence on these processes. For example, because an IPR is an exclusive right, many firms and individuals are either excluded from access to the knowledge base they protect or cannot afford the licensing fees required to access the knowledge base. As a result, they are unable to access the stream of benefits associated with using the IPR protected inventions.

1.3.5 Consumers

In mainstream theory, consumers are assumed to benefit from the existence of the IPR regime. (This is for all of the reasons mentioned above in section "1.3.1 Society and government".) However, for many industries there is little or no evidence that the IPR system has been able to stimulate production of a 'wide variety' of products at a 'high quality' and 'low price'. This is particularly true for the creative industries, and to some extent for the software industry. For consumers in a capitalist economy, the objectives of variety, quality and price are central; and they are often cited as the rationale for 'privatization' of goods and services. Furthermore, critics of the IPR regime, however, argue that IPRs increase the costs of

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[56] Birgitte Andersen and Sue Konzelmann, 'In Search of a Useful Theory of the Productive Potential of Intellectual Property Rights' No 15 (September 2006) DIME Working Papers on Intellectual Property Rights

production, and therefore also price, which in turn reduces direct welfare for consumers, and that this welfare loss is not offset by the benefits of the system.[57] This welfare loss is accentuated by the fact that the IPR owner pays a registration and maintenance fee to the IPR Office and the manufacturer pays royalties to the inventor of the knowledge imbedded in the product they produce. As a result, the price of the good exceeds the marginal costs of production, which from an economic perspective is inefficient and damaging to social welfare.

1.4 Legislation on Intellectual Property Rights in Nigeria

In Nigeria, a number of laws have a bearing on the protection and administration of the different rights that make up intellectual property. However, the three main statutes governing the intellectual property Law in Nigeria are the Copyright Act, the Patents and Designs Act, and the Trademarks Act.

1.4.1 Copyright Act[58]

This Act makes provisions for the definition, protection, transfer, infringement of and remedy and penalty thereof of the copyright in literary works, musical works, artistic works, cinematograph films, sound recordings, broadcast, and other ancillary matters in Nigeria.

Section 1(1) of the Copyright Act provides for works protected by copyright which include;

(a) Literary works

(b) Musical works

(c) Artistic works

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57 Birgitte Andersen and Sue Konzelmann, 'In Search of a Useful Theory of the Productive Potential of Intellectual Property Rights' No 15 (September 2006) DIME Working Papers on Intellectual Property Rights

58 Copyright Act Cap 28 LFN 2004.

(d) Cinematograph films

(e) Sound recordings

(f) Broadcasts

It is important to note that copyright does not protect ideas unless it original and fixed. According to section 1(2), a literary, musical or artistic work must satisfy the twin requirements of originality and fixation.

Copyright in literary, musical or artistic works other than photographs last until seventy (70) years following the death of the author. In the case where the work is owned by a government or corporate body, the copyright in the literary, musical or artistic work will expire seventy (70) years after the work was first published. Copyright in films and photographs lasts 50 years after the year the work was first published. Copyright in sound recordings also lasts 50 years after the recording was first published. Performance rights subsist until the end of the period of fifty years from the end of the year in which the performance first took place.

1.4.2 Patent Act and Design Act[59]

The Act makes comprehensive provisions for the registration and proprietorship of Patents and Designs in Nigeria and other matters ancillary thereto. Section 1 of the Patent and Design Act sets out the requirement of a patentable invention (a) If it is new, results from inventive activity and is capable of industrial application; or (b) If it constitutes an improvement upon a patented invention and also is new, results from inventive activity and is capable of industrial application.

Section 1 (4), (5) provides for the exceptions to patentability. These include plants or animal varieties, or essentially biological processes for the production of plants or animals.

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[59] Patent and Design Act Cap P2 LFN 2004.

Inventions the publication of which will be contrary to public order and morality are also excluded, so also are principles of a scientific nature.

Section 13(1) of the Patent and Designs Act 1990 provides that an industrial design is registrable if;

(a) it is new

(b) it is not contrary to public order or morality.

The lifespan of the patent lasts for 20 years provided the annual renewal fees are paid for the duration of its potential life. Where the patentee defaults in the payment of the annual renewal fee, the patent lapses, after a 6 months period of grace, if still not be renewed and cannot be revived again.

1.4.3 Trademark Act[60]

The Trademark Act make provisions for the registration of trademark and other matters ancillary thereto. Section 9 of the Trademark Act CAP T13 LFN 2004 provides that in order for a trademark to be registrable under part A, the mark must contain one of the following:

i. The name of a company, individual, or firm represented in a special or particular manner;

ii. The signature of the applicant for registration or some predecessor in his business;

iii. An invented word or invented words;

iv. A word or words having no direct reference to the character or quality of the goods, and not being according to its ordinary signification a geographical name or surname;

v. Any other distinctive mark.

To be registrable under part B, the mark has to be capable of being distinctive.

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60 Trademark Act Cap T13 LFN 2004.

1.5 Conclusion

In this chapter, which is the general introduction to the work, the researcher has been able to discussed the background to the study and the importance of the study. In this chapter the history and the evolution of the protection of intellectual property was examined. This was done in three phases, the territory, international and the global area and it was observed that from an early point in the development of intellectual property regulations, countries retained the flexibility to customise intellectual property policy and laws to meet specific national priorities including transfer of technology, developing certain industrial sectors and attracting foreign direct investment. It further examines the extent to which safeguards have historically been used in patent laws to safeguard public interest and how both developed and developing countries have made use of exceptions to patent rights to meet policy objectives. The chapter then traces efforts by industry in developed countries to increase the level of intellectual property protection and enforcement in the 1970s and 1980s culminating in the inclusion of intellectual property to the Uruguay trade round and the creation of the Agreement on Trade Related Aspects of Intellectual Property rights (TRIPS) which made it a requirement for every World Trade Organisation (WTO) Member to apply minimum standards on intellectual property.

The chapter further examined the history and evolution of intellectual property right protection in pharmaceutical industry. It was noted that at the earlier stage of intellectual property right protection, pharmaceutical industry and medicine were usually excluded but later on especially in the 20th century, countries started extending intellectual property right protection to pharmaceutical industry and medicine.

This also examined the Intellectual Property Rights stakeholders, which include government, Intellectual Property Rights offices, firms and customers.

Lastly the chapter examined the legislation on Intellectual Property Rights protection in Nigeria. It was observed that there are three main legislation on IPR in Nigeria. The three main statutes governing the intellectual property Law in Nigeria are the Copyright Act, the Patents and Designs Act, and the Trademarks Act.

CHAPTER TWO

THE NATURE OF PHARMACEUTICAL INDUSTRY

2.0 Introduction

Today pharmaceutical industries have become an indispensable part of health care system around the globe. Historically pharmaceutical industries have played a vital role in the human development by improving the quality of life and reducing the time spent in the hospitals. Thanks to innovative pharmaceutical industry that almost all epidemics and chronic diseases are curable today. Due to its direct link with the welfare and wellbeing of human beings pharmaceutical industry is of strategic importance for the development of a healthy and productive nation. Today, pharmaceutical industry is considered to be one of the largest and rapidly growing global industries. It is a major source of employment generation and foreign exchange earnings for many countries around the globe.

This chapter examines the nature of pharmaceutical industry, the types of pharmaceutical industry and the stages involved in the production of drugs by a pharmaceutical industry. The chapter also examined the types of Intellectual property rights that need to be protected by pharmaceutical industry. Lastly the chapter discussed the economic importance of pharmaceutical industry.

2.1 Nature of Pharmaceutical Industry

A pharmaceutical Industry, or drug company, is a commercial business licensed to research, develop, market and/or distribute drugs, most commonly in the context of healthcare. The pharmaceutical industry is an important component of health care systems throughout the world; it is comprised of many public and private organizations that discover, develop,

manufacture and market medicines for human and animal health.[61] The pharmaceutical industry is based primarily upon the scientific research and development (R&D) of medicines that prevent or treat diseases and disorders. Drug substances exhibit a wide range of pharmacological activity and toxicological properties.[62] Modern scientific and technological advances are accelerating the discovery and development of innovative pharmaceutical industries with improved therapeutic activity and reduced side effects. Molecular biologists, medicinal chemists and pharmacists are improving the benefits of drugs through increased potency and specificity. These advances create new concerns for protecting the health and safety of workers within the pharmaceutical industry.[63]

Many dynamic scientific, social and economic factors affect the pharmaceutical industry. Some pharmaceutical companies operate in both national and multinational markets. Therefore, their activities are subject to legislation, regulation and policies relating to drug development and approval, manufacturing and quality control, marketing and sales.[64] Academic, government and industry scientists, practicing physicians and pharmacists, as well as the public, influence the pharmaceutical industry. Health care providers (e.g., physicians, dentists, nurses, pharmacists and veterinarians) in hospitals, clinics, pharmacies and private practice may prescribe drugs or recommend how they should be dispensed. Government regulations and health care policies on pharmaceuticals are influenced by the public, advocacy groups and private interests. These complex factors interact to influence the

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61 A. Gennaro, *Remington's Pharmaceutical Sciences* (18th edition. Easton, PA: Mack Publishing Company 1990)

62 Hardman, J. A. Gilman and L Limbird, *Goodman and Gilman's The Pharmacologic Basis of Therapeutics* (New York: McGraw Hill Co. 1996)

63 R, Agius, 'Occupational Exposure limits for Therapeutic Substances' (1989) 33 Ann. Occ. Hyg. 555-562; B. Naumann, E. V. Sargent, B. S. Starkman, W. J. Fraser, G.T. Becker and G. D. Kirk, 'Performance-based exposure control limits for pharmaceutical active ingredients' (1996) 57Am Ind Hyg Assoc J 33-42.

64 B. Spilker, *Multinational Pharmaceutical Companies: Principles and Practices* (2nd edition. New York: Raven Press 1994)

discovery and development, manufacturing, marketing and sales of drugs. The pharmaceutical industry is largely driven by scientific discovery and development, in conjunction with toxicological and clinical experience. Major differences exist between large organizations which engage in a broad range of drug discovery and development, manufacturing and quality control, marketing and sales and smaller organizations which focus on a specific aspect. Most multinational pharmaceutical companies are involved in all these activities; however, they may specialize in one aspect based upon local market factors. Academic, public and private organizations perform scientific research to discover and develop new drugs. The biotechnology industry is becoming a major contributor to innovative pharmaceutical research.[65] Often, collaborative agreements between research organizations and large pharmaceutical companies are formed to explore the potential of new drug substances.

Many countries have specific legal protections for proprietary drugs and manufacturing processes, known as intellectual property rights. In instances when legal protections are limited or do not exist, some companies specialize in manufacturing and marketing generic drugs.[66] The pharmaceutical industry requires large amounts of capital investment due to the high expenses associated with R&D, regulatory approval, manufacturing, quality assurance and control, marketing and sales.[67] Many countries have extensive government regulations affecting the development and approval of drugs for commercial sale. These countries have strict requirements for good manufacturing practices to ensure the integrity of drug

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65 J. Swarbick and J. Boylan (eds.), *Encyclopedia of Pharmaceutical Technology* (New York: Marcel Dekker, Inc. 1996)

66 Medical Economics Co. 1995. Physician's Desk Reference, 49th edition. Montvale, NJ: Medical Economics Co.

67 B. Spilker, *Multinational Pharmaceutical Companies: Principles and Practices* (2nd edition. New York: Raven Press 1994)

manufacturing operations and the quality, safety and efficacy of pharmaceutical products.[68] International and domestic trade, as well as tax and finance policies and practices, affect how the pharmaceutical industry operates within a country.[69] Significant differences exist between developed and developing countries, regarding their needs for pharmaceutical substances. In developing countries, where malnutrition and infectious diseases are prevalent, nutritional supplements, vitamins and anti-infective drugs are most needed. In developed countries, where the diseases associated with ageing and specific ailments are primary health concerns, cardiovascular, central nervous system, gastrointestinal, anti-infective, diabetes and chemotherapy drugs are in the greatest demand.

Human and animal health drugs share similar R&D activities and manufacturing processes; however, they have unique therapeutic benefits and mechanisms for their approval, distribution, marketing and sales.[70] Veterinarians administer drugs to control infectious diseases and parasitic organisms in agricultural and companion animals. Vaccines and anti-infective and antiparasitic drugs are commonly used for this purpose. Nutritional supplements, antibiotics and hormones are widely employed by modern agriculture to promote the growth and health of farm animals. The R&D of pharmaceuticals for human and animal health are often allied, due to concurrent needs to control infectious agents and disease.

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68 A. Gennaro, *Remington's Pharmaceutical Sciences* (18th edition. Easton, PA: Mack Publishing Company 1990).

69 J. Swarbick and J. Boylan (eds.), *Encyclopedia of Pharmaceutical Technology* (New York: Marcel Dekker, Inc. 1996)

70 J. Swarbick and J. Boylan (eds.), *Encyclopedia of Pharmaceutical Technology* (New York: Marcel Dekker, Inc. 1996)

2.2 Classification of Pharmaceutical Industry

There are basically two types of pharmaceutical industries, namely generic and research pharmaceutical industries.

2.2.1 Generic pharmaceutical Industry

Generic pharmaceutical companies are low-cost, low-margin and low-risk businesses. The products that they choose to manufacture and sell have already been shown to be valuable and commercially successful in the market place and they usually sold under their generic names.[71] Generic companies do not need to incur any research and development costs, although some of the larger companies do undertake process-orientated research and development in order to introduce more efficient, and lower cost, manufacturing.[72] Although manufacturing in the industry is highly regulated, product volumes are small and manufacturing costs are relatively low. Marketing costs are also very low since the products are already well established in the marketplace and the demand is well understood. In many ways, generic pharmaceutical companies are in commodity markets where competitive differentiation is based on cost of goods and profitability is determined by market share.[73]

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71 Management Sciences for Health, *Intellectual property and Access to Medicine* (Management Sciences for Health, 2012) <http://www.msh.org/> Accessed 24 January 2021.

72 David Taylor, 'The Pharmaceutical Industry and the Future of Drug Development' (2016) 41 Issues in Environmental Science and Technology 1.

73 David Taylor, 'The Pharmaceutical Industry and the Future of Drug Development' (2016) 41 Issues in Environmental Science and Technology 1.

2.2.2 Research Pharmaceutical Industry

The research pharmaceutical companies operate under a completely different business model. It is these innovative companies that bring the new pharmaceuticals to the market.[74] This is very expensive, time consuming, and involves extremely high risks. Research and development in the pharmaceutical industry is very expensive, but it is the development activity that dominates the costs, particularly in the clinical trials which follow the pre-clinical development.

Research into ill health and disease can sometimes identify targets where chemical intervention could generate positive outcomes. High-throughput screening and other techniques can then be used to identify possible substances that might be suitable candidate drugs.[75] The most likely candidate(s) then move from research into development. This not only involves the major issues of determining whether the candidate drug works satisfactorily (efficacy) but also whether it causes any significant side effects (safety). It is also necessary to investigate whether the active substance can be delivered to the patient satisfactorily, i.e. can the substance be turned into a useable drug?

2.3 The Stages of Drug Development

Drug development is an expensive, long and high-risk business taking 10–15 years and is associated with a high attrition rate. It is driven by medical need, disease prevalence and the likelihood of success.[76] Drug candidate selection is an iterative process between chemistry and biology, refining the molecular properties until a compound suitable for advancing to

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74 David Taylor, 'The Pharmaceutical Industry and the Future of Drug Development' (2016) 41 Issues in Environmental Science and Technology 1.

75 Ibid.

76 G. O. Elhassa and K.O. Alfarouk, 'Drug Development: Stages of Drug Development' (2015) 3 (3) Journal Pharmacovigilance 3.

man is found.[77] Typically, about one in a thousand synthesised compounds is ever selected for progression to the clinic. Prior to administration to humans, the pharmacology and biochemistry of the drug is established using an extensive range of in vitro and in vivo test procedures. It is also a regulatory requirement that the drug is administered to animals to assess its safety. Later-stage animal testing is also required to assess carcinogenicity and effects on the reproductive system. Clinical phases of drug development include phase I in healthy volunteers to assess primarily pharmacokinetics, safety and toleration, phase II in a cohort of patients with the target disease to establish efficacy and dose-response relationship and large-scale phase III studies to confirm safety and efficacy. Experience tells us that approximately only 1 in 10 drugs that start the clinical phase will make it to the market.[78]

2.3.1 The Stage of Discovery

Selecting therapeutic areas or indications to invest in is driven by "medical need" and the prevalence of the disease.[79] Additional factors also include technical feasibility, research and development costs and commercial considerations such as competition in the market place and potential market share.[80] Even if these criteria are met, there is only a limited research and development budget and each new project must be prioritized against the company research and development portfolio, with only high priority projects within the budget being selected for progression. For many companies, this is typically an annual review process for

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77 A. Dutta, Discovery of New Medicines; in Griffin JP and O'Grady J (eds): The Textbook of Pharmaceutical Medicine. (London, BMJ Books, 2002) 25.

78 G. O. Elhassa and K.O. Alfarouk, 'Drug Development: Stages of Drug Development' (2015) 3 (3) Journal Pharmacovigilance 3.

79 A. B. Deore, J.R. Dhumane, H.V. Wagh, R. B. Sonawane, 'The Stages of Drug Discovery and Development Process' (2019) 7(6) Asian Journal of Pharmaceutical Research and Development 62.

80 Ibid.

products at all stages of development. This may lead to stopping a programme even at an advanced stage of development.[81]

Early chemical starting points have been identified from naturally occurring substances in plants, humans or animals but lead compounds are more often sourced from targeted chemical synthesis directed to bind to the known structures of receptors and enzymes or from random or receptor-targeted high-throughput screening.[82] This has become more popular in the last few years as it is helpful in accelerating drug discovery. Initial problems encountered in the last decade have eased with improving technology. With the advent of modern computer technology, robotics and multi-well assay plates (384 growing to 1,536 wells per plate), high-throughput screening can test vast 'libraries' of chemical compounds in multiple screens (which can deliver up to 120,000 assays every 24 h).[83] Another method of lead identification is 'virtual screening' (also named in silico screening) which is defined as the 'selection of compounds by evaluating their desirability in a computational model'[84]. Compounds testing positive in screening have their potency and selectivity confirmed by in vitro biochemical or cellular assays. This is typically followed by functional biochemical and pharmacological testing in vitro, followed by pharmacodynamic and pharmacokinetic testing in vitro and in vivo.[85] The next step is to complete pilot toxicology testing to inform us of the likely safety profile. Once all preclinical testing has satisfied the minimum selection criteria,

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81 A. B. Deore, J.R. Dhumane, H.V. Wagh, R. B. Sonawane, 'The Stages of Drug Discovery and Development Process' (2019) 7(6) Asian Journal of Pharmaceutical Research and Development 62.

82 A. Dutta, Discovery of New Medicines; in Griffin JP and O'Grady J (eds): The Textbook of Pharmaceutical Medicine. (London, BMJ Books, 2002) 25.

83 A. B. Deore, J.R. Dhumane, H.V. Wagh, R. B. Sonawane, 'The Stages of Drug Discovery and Development Process' (2019) 7(6) Asian Journal of Pharmaceutical Research and Development 62.

84 International Union of Pure and Applied Chemistry: Glossary of terms used in combinatorial chemistry, U-Z (Research TrianglePark, International Union of Pure and Applied Chemistry. 1999) <http://www.iupac.org/reports/1999/7112maclean/u-z.html> accessed January 23, 2021.

85 U Rester, 'From virtuality to reality – virtual screening in lead discovery and lead optimization: a medicinal chemistry perspective' (2008) 11 Curr Opin Drug Discov Devel 559– 568.

the compound transitions from a 'lead' to a 'candidate' and is nominated for progression to the clinic.[86]

At this stage, drug production is scaled up to meet the increased compound demand, work commences on developing a suitable formulation for clinical use (often a tablet is the preferred dosage form) and the candidate is progressed through the required toxicology testing (including genotoxicity, safety pharmacology in all biological systems, single and multiple dose toxicity and toxicokinetic studies) to enable the first in human and subsequent clinical studies. Reproductive toxicology in male and female animals (required prior to testing in women of child-bearing potential) and long-term carcinogenicity testing are also prerequisites for filing a drug approval request.[87]

2.3.2 The Stage of Clinical Trials

Clinical trials are conducted in people (volunteer)and intended to answer specific questions about the safety and efficacy of drugs, vaccines, other therapies, or new methods of using current treatments.[88] Clinical trials follow a specific study protocol that is designed by the researcher or investigator or manufacturer. As the developers design the clinical study, they will consider what they want to complete for each of the different Clinical Research Phases and starts the Investigational New Drug Process (IND), a process they must go through

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86 A.M. Nihad and Tamimi Peter Ellis, 'Drug Development: From Concept to Marketing!' (2009) 113 Nephron Clinical Practice 125.

87 DJ Tweats, 'Scales MDC: Toxicity testing' in Griffin JP and O'Grady J (eds): *The Textbook of Pharmaceutical Medicine* (London, BMJ Books, 2002) 134.

88 G. O. Elhassa and K. O. Alfarouk, 'Stem Cell Therapy in Drug Discovery and Development' (2015) 3 J Pharmacovigilance 140.

before clinical research begins. Before a clinical trial begins, researchers review prior information about the drug to develop research questions and objectives.[89]

2.3.2.1 Phases of Clinical Drug Development

The clinical trials stage consists of three main phases and all new medicines have to go through these parts before they can be prescribed to patients. The clinical phase is there to establish the dose and best form of the drug, its safety, how it is absorbed by the body and furthermore whether the treatment works.[90]

Phase 1: Safety and dosage

Phase I trials are the first tests of a drug with a lesser number of healthy human volunteers.[91] In most cases, 20 to 80 healthy volunteers with the disease/condition participate in Phase 1. Patients are generally only used if the mechanism of action of a drug indicates that it will not be tolerated in healthy people. Phase 1 studies are closely monitored and collect information about Pharmacodynemics in the human body.[92] Researchers adjust dosage regimen based on animal study data to find out what dose of a drug can tolerate the body and what are its acute side effects. As a Phase 1 trial continues, researchers find out research mechanism of action, the side effects accompanying with increase in dosage, and information about effectiveness.

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89 Fitzpatrick S. *The clinical Trial Protocol* (Buckinghamshire: Institute of Clinical Research; 2005).

90 'What are the stages of drug development process?'< https://www.weneedyou.co.uk/blog/what-are-the-stages-of-drug-development-process/blog/> Accessed 24 January 2021.

91 'What are the stages of drug development process?'< https://www.weneedyou.co.uk/blog/what-are-the-stages-of-drug-development-process/blog/> Accessed 24 January 2021.

92 A.M. Nihad and Tamimi Peter Ellis, 'Drug Development: From Concept to Marketing!' (2009) 113 Nephron Clinical Practice 125.

This is imperative to the design of Phase 2 studies. Almost 70% of drugs travel to the next phase.[93]

Phase 2: Efficacy and side effects

Phase II trials are conducted on larger groups of patients (few hundreds) and are aimed to evaluate the efficacy of the drug and to endure the Phase I safety assessments.[94] These trials are not sufficient to confirm whether the drug will be therapeutic. Phase 2 studies provide with additional safety data to the researchers. Researchers use these data to refine research questions, develop research methods, and design new Phase 3 research protocols.[95] Around 33% of drugs travel to the next phase. Most prominently, Phase II clinical studies aid to found therapeutic doses for the large-scale Phase III studies.[96]

Phase 3: Efficacy and adverse drug reactions monitoring

Researchers plan Phase 3 studies to prove whether a product deals an action benefit to a specific people or not. Sometimes known as pivotal studies, these studies comprise 300 to 3,000 volunteers. Phase 3 studies deliver most of the safety data.[97] The previous study might not able to detect less common side effects. But phase 3 studies are conducted on large number of volunteers and longer in duration, the results are more probable to detect long-

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93 A. B. Deore, J.R. Dhumane, H.V. Wagh, R. B. Sonawane, 'The Stages of Drug Discovery and Development Process' (2019) 7(6) Asian Journal of Pharmaceutical Research and Development 62.

94 A. B. Deore, J.R. Dhumane, H.V. Wagh, R. B. Sonawane, 'The Stages of Drug Discovery and Development Process' (2019) 7(6) Asian Journal of Pharmaceutical Research and Development 62.

95 Ibid; A.M. Nihad and Tamimi Peter Ellis, 'Drug Development: From Concept to Marketing!' (2009) 113 Nephron Clinical Practice 125

96 'What are the stages of drug development process?'< https://www.weneedyou.co.uk/blog/what-are-the-stages-of-drug-development-process/blog/> Accessed 24 January 2021.

97 A. B. Deore, J.R. Dhumane, H.V. Wagh, R. B. Sonawane, 'The Stages of Drug Discovery and Development Process' (2019) 7(6) Asian Journal of Pharmaceutical Research and Development 62.

term or uncommon side effects.[98] Around 25-30% of drugs travel to the next phase of clinical research. If a drug developer has data from its previous tests, preclinical and clinical trials that a drug is safe and effective for its intended use, then the industry can file an application to market the medicine.

New Drug Application

A New Drug Application expresses the full story of a drug molecule. Its purpose is to verify that a drug is safe and effective for its proposed use in the people studied. Developers must include reports on all studies, data, and analysis in the application.[99] Beside with clinical trial outcomes, developers must include:

a. Proposed labeling

b. Safety updates

c. Drug abuse information

d. Patent information

e. Institutional review board compliance information

f. Directions for use.[100]

Phase 4: Post-Market Drug Safety Monitoring

Phase 4 trials are conducted when the drug or device has been approved by Food and Drug Administration Agency of the particular country.[101] These trials are also recognized as post-

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98 A.M. Nihad and Tamimi Peter Ellis, 'Drug Development: From Concept to Marketing!' (2009) 113 Nephron Clinical Practice 125.

99 A. B. Deore, J.R. Dhumane, H.V. Wagh, R. B. Sonawane, 'The Stages of Drug Discovery and Development Process' (2019) 7(6) Asian Journal of Pharmaceutical Research and Development 62.

100 Ibid.

101 Ibid.

marketing surveillance involving pharmacovigilance and continuing technical support after approval. There are numerous observational strategies and assessment patterns used in Phase 4 trials to evaluate the efficacy, cost-effectiveness, and safety of an involvement in real-world settings.[102] Phase IV studies may be required by regulatory authorities (e.g. change in labelling, risk management/minimization action plan) or may be undertaken by the sponsoring company for competitive purposes or other reasons. Therefore, the true illustration of a drug's safety essentially requires over the months and even years that mark up a drug's lifespan in the market. Food and Drug Administration Agency reviews reports of complications with prescription and OTC drugs, and can decide to add precautions to the dosage or practice information, as well as other events for more serious adverse drug reactions.[103]

2.4 Types of Intellectual Property Rights that Pharmaceutical Companies need to Protect

2.4.1 Patent

A patent provides its owner the exclusive right to prevent others from making, using, offering for sale, selling, or importing the patented invention without the owner's permission.[104] Patents are arguably the most valuable IP rights that any innovative company must possess. This is especially true of the pharmaceutical industry where millions of dollars is spent on clinical researches and processes, pharmaceutical formulations and drug combinations, drug

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102 'What are the stages of drug development process?'< https://www.weneedyou.co.uk/blog/what-are-the-stages-of-drug-development-process/blog/> Accessed 24 January 2021.

103 C. P. Adams, and V. V. Brantner 'New Drug Development: Estimating entry from Human Clinical Trials' (Bureau of Economics Federal Trade Commission. 2003).

104 'Intellectual Property Rights for SMEs in the Pharmaceutical Industry' WIPO, <http://www.wipo.int/sme/en/documents/ip_pharma_fulltext.html> accessed 23 January 2021.

trials and approval.[105] Without patents protection on these sequences, there would be no way to recoup expenses or make profits, since copycats could simply copy or reverse-engineer any discoveries or processes. Patents also attract investors. No one wants to put their money in a venture where there are absolutely no guarantees. Again, by patenting IP, pharmaceutical companies can make money from their time, efforts, and investments by monetizing their patents through licensing or sale. In case of an infringement, they can also validly sue and demand compensations.[106]

To be patentable, an innovation must be novel, inventive, and capable of industrial application. Under the Nigerian law, a patent shall expire at the end of the twentieth year from the date of the filing of the relevant patent application.[107]

2.4.2 Copyright

Copyright grant exclusive rights to the author/owner of an original idea expressed in a fixed form, and as a consequence, prevent anyone from using the protected work without the express permission of the owner.[108] Blueprints, customer files, databases, manuals, and software qualify as works protected under the domain of copyright. In the copyright case of *Mazer v Stein* , the US Supreme Court opined that "[T]he economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare

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105 As seen in the preceding section.

106 Ademola Adeyoju, Intellectual Property as the Heartbeat of the Pharmaceutical Industry, <www.infusionlawyers.com.ng>accessed 23 January 2021.

107 Section 7 of the Patents and Designs Act, Chapter 344, Laws of the Federation of Nigeria 2004.

108 Ademola Adeyoju, Intellectual Property as the Heartbeat of the Pharmaceutical Industry, <www.infusionlawyers.com.ng>accessed 23 January 2021.

through the talents of authors and inventors… Sacrificial days devoted to creative activities deserve rewards commensurate with the services rendered"[109]

Under the Nigerian Copyright Act, copyright in the case of a body corporate last for until the 70 years after the end of the year in which the work was first published.

2.4.3 Trademark

A trademark is a sign capable of distinguishing the goods and services produced or provided by one enterprise from those of other enterprises.[110] Basically, it protects the name of a product rather than the idea behind the product.

Although patent is the weapon of choice, a strong pharmaceutical brand will strategically places a company in a league of its own, helps it gain worldwide recognition, and brings financial reward in the long term.

Also, "pharmaceutical companies acquire trademark protection for drug names, colours, or shapes to extend their market monopoly beyond the expiry dates of acquired patents" When doing this, they should be extremely careful[111] not to make a common name a trade name. "For instance, Motrin and Tylenol are both trade names of pharmaceuticals for curing fever. They share the same common name (paracetamol), but by bearing different trade names, consumers can distinguish between the two."[112]

Apart from the common function of limiting consumer confusion, pharmaceutical trademarks can also have an indirect influence on improving general public health strong trademarks not

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109 *Mazer v Stein* 347 US 201 (1954) per Justice Stanley F. Reed

110 'Intellectual Property Rights for SMEs in the Pharmaceutical Industry' WIPO, <http://www.wipo.int/sme/en/documents/ip_pharma_fulltext.html> accessed 23 January 2021.

111 'IPR in a Pharmaceutical Company' Indian Institute of Patent and Trademark Attorneys (IIPTA) <http://www.iipta.com/ipr-pharmaceutical-company/>accessed 23 January 2021.

112 Helika Jurgenson, 'Drug Innovation through Better Enforcement, IPR Protection in the Pharmaceutical Industry in China', <https://www.youripinsider.eu/drug-innovation-enforcement-ipr-protection-pharmaceuticalindustry/> accessed 23 January 2021.

only assist healthcare professionals in limiting common mistakes when forced to choose from among a large number of medical products with similar names, it also increases the ability of consumers to rapidly identify the drug of their choice.[113]

Under the Nigerian law, trademark registration is initially valid for 7 years, and is renewable indefinitely for periods of 14 years.

2.3.4 Trade Secrets

The alternative to obtaining patent protection is to keep the information confidential. Confidential information that gives an enterprise competitive edge is generally referred to as trade secrets. Unlike patents, there is no requirement for a trade secret to demonstrate any statutory requirements before qualifying for protection. Therefore, trade secrets relating to subject matter excluded from patentability, such as abstract ideas, client information and experimental data may represent valuable assets.[114] Trade secrets may include such things as chemical compounds, dosage regimens, improved variations, processes, and undisclosed test data. Disclosure, misappropriation, and unauthorized use of trade secrets are often seriously punished.[115]

Sometimes firms prefer to rely on secrecy to protect their position. For example the precise formula for Coca Cola has never been patented, but has been kept secret. The basic elements of the recipe are apparently widely known; what's not known is the precise mix, and it is the mix of ingredients that gives a soft drink its distinctive taste. Had Coke been patented, its

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113 'Creating Strong Pharmaceutical Trademarks' <https://www.lexology.com/library/detail.aspx?g>accessed 23 January 2021.

114 A. Sanderson and L. Zhuang, 'Life Sciences Intellectual Property Review: The Value of Secrecy for Big Pharma' (2016); <http://www. lifesciencesipreview.com/contributed-article/the-value-of-secrecy-forbig-pharma> accessed 23 January 2021.

115 Ademola Adeyoju, Intellectual Property as the Heartbeat of the Pharmaceutical Industry, <www.infusionlawyers.com.ng>accessed 23 January 2021.

patent would have expired long ago and anyone who wanted to would be able to produce their own exact copy of Coke (although they wouldn't be able to sell it in bottles identical to Coke bottles becuase that design is trademarked). The management of Coca-Cola Company has been using this form of IP for decades now.[116] One disadvantage of trade secret is that trade secrets, unlike patents, do not confer exclusivity. The proprietor of a trade secret cannot enforce any rights over parties who independently derive or reverse-engineer the same information. A competitor who discloses the trade secret, irrespective of means, could also render it worthless.[117] In order to protect their trade secrets, pharmaceutical companies generally have a strict policy regarding the proprietary nature of all information relating to R&D and manufacture.

But one big disadvantage of trade secrets in Nigeria is that Nigeria has no trade secrets law, unlike copyrights, patents, and trademarks. The legal effect of this is that trade secrets are only enforceable as contracts against the parties involved only, not the public.

2.5 Economic Importance of Pharmaceutical Industry

1. It helps in promoting and ensuring the health of citizens of any nation, through the manufacturing and provision of pharmaceutical products and drugs that are necessary for the health and well being of a society.[118] By so doing it helps in improving the human the quality of life as well as the life expectancy

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116 Ademola Adeyoju, Intellectual Property as the Heartbeat of the Pharmaceutical Industry, <www.infusionlawyers.com.ng>accessed 23 January 2021.

117 MBC Research Report, *Exploitation of Intellectual Property Rights by Pharmaceutical Companies in the Philippines* (Makati Business Club, Philippines 2017)

118 David Taylor, 'The Pharmaceutical Industry and the Future of Drug Development' (2016) 41 Issues in Environmental Science and Technology 1.

2. It also catalyze the access to improved health care and health care facilities at large; New medicines and vaccines help save money, They reduce hospitalisations and surgeries as well as death rates.[119]
3. It helps in wealth creation; next to health of a nation is wealth creation.
4. It contributes significantly to the GDP of a nation; For example; in India it contributes about 40% of their GDP, in China 38%, in Canada 26% and In Nigeria over 20% respectively.[120]
5. It attracts huge investment from individuals and corporations.
6. It manufactures goods and services that are worth Billions of Naira thereby creating markets and potentials, for example India's pharmaceutical market is values at $4.5 billion and that of Nigeria at about $187 Million.[121]
7. Improves the welfare of the populace by improving the control of management of infectious diseases, especially HIV/AIDS, malaria, TB, and neglected childhood diseases[122]
8. It helps in promoting research, innovation and development; resulting in: highly-skilled job creation,[123] and increased scientific knowledge.
9. Capital formation, pharmaceutical manufacturing facilitates the use of savings thereby stimulating capital formation, which is the engine of economic growth and development.

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119 Mustapha Muktar, 'Role of Pharmaceutical Manufacturing in the Economic Development of A Nation' <http://www.mustaphamuktar.blogspot.com> accessed 23 January 2021.

120 Ibid.

121 Ibid.

122 Keith D. Tait, 'Pharmaceutical Industry' < www.ilocis.org/en/default.html> Accessed 26 January 2021.

123 Anurag Sharma, *Economic Impact of the Pharmaceutical Industry Massachusetts* (University of Massachusetts, 1999).

10. It helps in extending business ethics and social responsibility to the nation by making donations, awareness and wide array of capacity building interventions that have strengthened healthcare institutions.[124]

2.6 Conclusion

The pharmaceutical industry is one of the evergreen industries in the world. No matter what happens, whether the economy is on its most stable behaviour or in recession mode. Any day a person can fall sick or might require his supplement pills. Basically, the products are used 24/7.

In this chapter, the researcher examined the nature of the pharmaceutical industry, the types of pharmaceutical industry. It was observed that there are two major types of pharmaceutical industry, they are generic pharmaceutical industry and research pharmaceutical industry. Generic pharmaceutical companies are low-cost, low-margin and low-risk businesses while the research pharmaceutical industry is innovative pharmaceutical companies that bring the new pharmaceuticals to the market.

The stage in the production of drugs by pharmaceutical industry was also examined. It was observed that the production of drugs starts with drug discovery which is a process which aims at identifying a compound therapeutically useful in curing and treating disease. This process involves the identification of candidates, synthesis, characterization, validation, optimization, screening and assays for therapeutic efficacy. Once a compound has shown its significance in these investigations, it will initiate the process of drug development earlier to clinical trials. New drug development process must continue through several stages in order to make a medicine that is safe, effective, and has approved all regulatory requirements.

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124 Ibid

It further examined the type of intellectual property rights that a pharmaceutical industry needs to protect. Lastly the economic importance of pharmaceutical industry was discussed.

CHAPTER THREE

PATENT AS A VITAL INSTRUMENT IN THE PHARMACEUTICAL INDUSTRY

3.0 Introduction

Patent is a form of intellectual property rights providing exclusive rights over an invention to the inventor. The owner of a patent has the right to exclude making, using, or selling the new invention for a limited period, subject to a number of exceptions. For encouraging pharmaceutical Research and Development, the patent system is the best mechanism. Patent protection for pharmaceutical products and processes has become the global norm. For the advancement of research, the pharmaceutical patent is essential to disclosure system.

This chapter seeks to highlight and explore the inter-relationship and the functioning of the intellectual property right in the pharmaceutical industry. The rising tide of patent applications can be witnessed globally in this industry as the need for such protection and licensing has become imperative so as to safeguard the rights of the inventor and also to encourage and promote new talents, inventions and innovations which can be a boon for the economy.

3.1 The Concept of Patent

A patent is a kind of Intellectual Property. The term patent can be defined as "a monopoly right conferred to the inventor who has invented a new product or process through his/her intellectual efforts capable of industrial application.[125] Patents are exclusive property rights in intangible creations of the human mind and it is awarded in recognition of innovation and

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125 SKR Chowdry and HK Sahang, *Law of Trademarks, Copyrights, Patents and Designs*, volume 2 (second edition, Kamal Law House, Calcutta ,1999) 76.

more particularly the investment required to foster technical advance and the development of new ideas.[126]

The owner of a patent has the right to exclude others from making, using, offering for sale, or selling his or her invention for a period of 20 years from the filing of the patent application.[127] An *invention* is any new or useful process, machine, article of manufacture, or composition of matter. An improvement on any of these items also can be an invention. Patent rights are territorial in nature and exist only in the national jurisdictions in which the patentee has applied for and received recognition of his property rights.

Whether a claimed invention meets the tests of novelty and non-obviousness is determined by comparing it to the body of previously disclosed information in the same field. This information is usually called "prior art." The most commonly used prior art consists of published patents that have already been issued or published by the world's patent offices.[128]

While all countries require that the tests of novelty and non-obviousness be met before patent rights can be enforced against infringers, many countries do not determine whether these tests have been met though a substantive examination as in the United States, Japan, the U.K. and Germany. In counties, such as France, claims to patent rights are registered with the state but not actually tested for their validity until or unless they are asserted in a judicial proceeding. At that time the responsible judicial authorities engage in the factfinding process necessary to determine whether the tests of patentability have been met.

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126 SKR Chowdry and HK Sahang, *Law of Trademarks, Copyrights, Patents and Designs*, volume 2 (second edition, Kamal Law House, Calcutta ,1999) 76; Bruce Lehman, *The Pharmaceutical Industry and the Patent System* (International Intellectual Property Institute; 2003).

127 Patent and Design Act

128 Bruce Lehman, *The Pharmaceutical Industry and the Patent System* (International Intellectual Property Institute; 2003).

The benefit of granting an inventor the exclusive property right of a patent for the limited period of 20 years is that he or she is given a powerful incentive to create.[129] The inventor is assured that investors will be given the incentive to commit the financial resources necessary to support the inventor's research and to develop it to the point where it can be manufactured and made available to the market.

In the pharmaceutical industry Patents are distinguished as primary patent and secondary patent.

Primary patent: Patents, those are usually filed already during the research phase in the development of a new drug, in the pharmaceutical industry are called primary patents. In that primary patent, patents give on the active ingredients.[130] These early patents are filed to protect potential active ingredients that form the basis of the new drug. Since the early stages of drug development are characterized by an enormous amount of uncertainty that 1 in 5,000-10,000 test active ingredients results in a successful drug, early patent filings in this, in that case, many of these filings will either not be pursued, or if granted, will never be related to a marketed drug.

Secondary patents: After drug development, patents are filed on other aspects of active ingredients such as different dosage forms, formulations, and production methods[131]

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129 Bruce Lehman, *The Pharmaceutical Industry and the Patent System* (International Intellectual Property Institute; 2003).

130 Susanta Kumar Rout, 'Intellectual Property Rights and Its Application Toward Pharmaceutical Industry with Special Reference in India' **(**2016) 4 (4) Innovare Journal of Education 5-7.

131 M. J. Abud, B. Hall, C. Helmers, 'An Empirical Analysis of Primary and Secondary Pharmaceutical Patents in Chile' (2015) 10(4) PLoS One; A. Tahir and A. S. Kesselheim 'Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV drugs could be Extended for Decades' (2012) 31(10) Health Aff 2286-94.

3.2 The Criteria for Patentability

Section 1 of the Patents and Designs Act[132], prescribes the conditions for patentability. It provides:

> 1 (1) Subject to this section an invention is patentable
>
> (a) if it is new, results from an inventive activity and is capable of industrial application or.
>
> (b) if it constitutes an improvement upon a patented invention, and also is new, results from inventive activity, and is capable of industrial application.

Broadly, the invention itself has to meet three main requirements:

(i) Novelty

(ii) Inventive step, and

(iii) Industrial applicability.[133]

The secondary provision which is made under section 1(1)(b) is that an invention will still be patentable if it is an improvement on an already patented invention.

We shall now examine each requirement for patentability to understand the precise meaning of the provisions of the Act.

3.2.1 Novelty

An invention is new (or novel) if it does not form part of the prior art. The prior art is, in general, all the knowledge that has been made available to the public prior to the filing date (or priority date) of the relevant patent application or prior to when the invention was "made". This has been judicially interpreted in *Gentech Inc's Patent*[134]as meaning: "thus to form part of the state of the art, the information given (by the user) must have been made available to at

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132 Patent and Design Act Cap P2 LFN 2004

133 Section 1 Patent and Design Act Cap P2 LFN 2004.

134 (1989) R.P.C. 147 at 204

least one member of the public who was free in law and in equity to use it". The implication of the judicial interpretation is that if the information regarding the invention is disclosed confidentially to a person or a group of persons, under circumstances which makes it obvious that they are not expected to disclose to any other person or to make use of the information, then the invention has not been made available to the public as to form part of the state of the art.

However, it must be noted that the definition of "prior art" differs from country to country. In many countries, any invention made available to the public anywhere in the world in written form, by oral communication, by display or through use constitutes the prior art. Thus, in principle, the publication of the invention in a scientific journal, its presentation in a conference, its use in commerce or its display in a company's catalogue before the filing date (or priority date) of the application claiming that invention would constitute acts that could destroy the novelty of such invention and render it not patentable.

The English the Court of Appeal in the case of *General Tire & Rubber Co. v. Firestone Tyre &*

Rubber Co. Ltd[135] clearly explain novelty at 485 of the law report. In that case, the Court of Appeal stated:

> "The earlier publication and the patentee's claim must each be construed as they would be at the respective relevant dates by a reader skilled in the art to which they relate having regard to the state of knowledge in such art at the relevant date. The construction of these documents is a function of the court,, being a matter of law, but since documents of this nature are almost certain to contain technical material, the court must by evidence, be put in a position of a person of the kind to whom the document is addressed, that is to say, a person skilled in the relevant art at the relevant date. ……. If the prior inventor's publication contains a clear description of , or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's

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135 (1972) R.P.C 457

> patent, the patentee's claim would have been shown to lack the novelty, that is to say, it will have been anticipated …… If of the other hand, the prior publication contains a direction which is capable of being carried out in a manner which would infringe the patentee's claim, but would be at least as likely to be carried out in a way which would not do so, the patentee's will not have been anticipated, although it may fail on the ground of obviousness. To anticipate the patentee's claim the prior publication must contain clear and unmistakable directions to do what the patentee claims to have invented"

If an invention is publicly disclosed before a patent application is filed, it will not be able of protection. In the case of pharmaceutical product, a prior use of that product will be considered as a publication. In *Merrell Dow Pharmaceuticals Inc. v Norton & Co. Ltd*,[136]it was held that the prior use of a product was to be considered in the same way as a prior published document.

3.2.2 The inventive step

Inventive activity is defined in Section 1(2)(b) of the Act as follows:

> "an invention results from an inventive activity if it does not obviously follow from the state of the art, either as to the method, the application, the combination of methods, or the product which it concerns, or as to the industrial result it produces "

The second requirement by definition is reached whenever an invention is not obvious to someone with a good knowledge and experience in the corresponding technical field.

In *Technograph Printed Circuits Ltd. v Mills & Rockley (Electronics) Ltd*[137] It was held that in considering whether an invention is obvious it is necessary to examine the question whether the new product or process could have been suggested to persons skilled in the art and undertaking a study of other relevant documents which a diligent researcher would know

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136 (1994) R.P.C 1.

137 (1972) R.P.C. 346.

about. It has however been argued that all published documents have to be assumed to be available for study of persons to whom the patent specifications has been addressed.

This point was further elucidated by the English Court of Appeal in *Allmanna Suenska Elektriska A/B v. The Burntisland Shipbuilding Co. Ltd*.[138] The court stated that:

> The matter of obviousness is to be judged by reference to the "state of the art" in the light of all that was previously known by persons versed in that art derived from experience of what was practically employed, as well as from the contents of previous writings, specifications, textbook and other documents
>
> … When the relevant facts (as regards the state of the art) are known, the question: Was the alleged invention obvious? Must in the end of all be as it were a kind of jury question. The relevant question to be asked and answered is in form and substance the question formulated by Sir Stafford Cripps ……. 'The real question is: Was it for all practical purposes obvious to any skilled chemist in the state of chemical knowledge existing at the date of the patent, which consists of the chemical literature available … and his general chemical knowledge, that he could manufacture that he could manufacture valuable therapeutic agents by making the higher alkyl resorcinols ….'
>
> It remains to say that the question must be answered objectively, for it is immaterial that .. the invention claimed was in truth an invention of [the inventor] in the sense of being the result of independent work and research on his part – without knowledge on his part of many of the matters which must, on any view, be taken into account by the court

What this means is that an invention is considered to involve an inventive step (or to be non-obvious) when, having regard to the prior art, the invention would not have been obvious to a person skilled in the particular field of technology. The non-obviousness requirement is meant to ensure that patents are not granted on developments that a person skilled in the relevant art could easily deduce from what already exists.

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138 (1951) 68 R.P.C 63 at 69

3.2.3 Industrial applicability/utility requirement

Section 1(2)(c) defines the concept of industrial applicability as follows "an invention is capable of industrial application if it can be manufactured or used in any kind of industry including agriculture"

To be patentable, an invention must be capable of being used in industry (or meet the utility requirement). This means that the invention cannot be a mere theoretical phenomenon, but it must be useful and provide some practical benefit. The term "industry" is used in the broad sense, meaning anything distinct from purely intellectual or aesthetic activity, and includes, for example, agriculture. In biotechnology, the utility requirement has become particularly important in the context of the patenting of genetic sequences over which possible industrial applications are unclear. Some countries require that the utility be well established and asserted for the claimed invention in a specific, substantial and credible manner.

The Act further provides that certain matters are not patentable. These are set out in section1(4) and (5) of the Act.[139] These include plants or animal varieties, or essentially biological processes for the production of plants or animals. Inventions the publication of which will be contrary to public order and morality are also excluded, so also are principles of a scientific nature.

Apart from these exceptions, all products and processes, which meet the qualification for patentability under section 1(1) of the Act[140] are patentable.

3.3 Patent Application

A full application requires a request for grant of a patent, a specification which includes a description of the invention, any drawings and claims and an abstract of the invention and the

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139 Patent and Design Act Cap P2 LFN 2004.

140 Patent and Design Act Cap P2 LFN 2004.

appropriate fees must be paid. A patent application may be filed in a national patent office or supra-national patent offices, such as the world intellectual property organization (WIPO). The date when a patent application is first filed is labeled the priority date. An applicant may filled for patent in as per his own choice; once a patent application is filed it will be either examined or registered. Latter case implies that a patent will automatically be granted, and its validity will only be tested in the court. The patent office, where the applicant applies for patent, will request to deposit the fee to be paid on filing. Within 12 months, the applicant must request and pay the corresponding fee for the preliminary examination - to check whether the application is able to proceed - and search - to look for any relevant documents which may invalidate or restrict what is claimed in a patent application. There is no need to wait 12 months to request preliminary examination and search; it can be done on filing since the priority date is the one taken into account to determine prior art. Unless the one who applied for a patent (applicant) withdraws his/her application, or simply abandon it, the invention will be disclosed soon. An invention is kept secret until the 18th month from the priority date, and then the patent application is published. From that point, the disclosed invention also becomes prior art against any application filed later. From that point, the disclosed invention also becomes prior art against any application filed later. The date when a patent application is first filed with a patent office (priority date) is of crucial importance for the subsequent prosecution of the application. It is the date, which is used to give priority to an invention. It means that if more than one institution, or individual, seek protection for the same invention, a patent might be granted for the one who applied first. Patent systems operate at single country levels (e.g., the UK and US) and at supra-national levels (e.g., European Patent Office and WIPO), but there is no such a thing as an international patent covering all countries in the world. Even if a company chooses to use one of those supra-national systems, it has to designate all countries of interest (as long as the chosen countries

have signed any treaty agreeing with the rules of the system) and pay the corresponding fees.[141]

In Nigeria the formal requirements for a patent application are set out in section 3 of the Patent and Design Act which provides that every patent application

> (a) shall be made to the Registrar and shall contain -
>
> (i) the applicant's full name and address and if that address is outside Nigeria, an address for service in Nigeria,
>
> (ii) a description of the relevant invention with any appropriate plans and drawings,
>
> (iii) a claim or claims, and
>
> (iv) such other matter as maybe prescribed; and
>
> (b) shall be accompanied by –
>
> (i) the prescribed fee,
>
> (ii) where appropriate, a declaration signed by the true inventor requesting that he be mentioned as such in the patent and giving his name and address, and
>
> (iii) if the application is made by an agent, a signed power of attorney (so however that, notwithstanding any rule of law, legislation or certification of the signature of the power of attorney shall be unnecessary)

The Act further provides under section 4 that the registrar shall examine the application.

> 4. (1) The Registrar shall examine every patent application as to its conformity with section 3(1), (3) and (4) of this Act, and-

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141 H. Barros, *Patents and Pharmaceuticals in the UK: An Insight into the Patenting Process* (Technological Innovations Research Unit - Marketing and Strategic Management Group Warwick Business School - University of Warwick).

> (a) if section 3(1) of this Act has not been complied with, the Registrar shall reject the application;
>
> (b) if section 3(3) of this Act has not been complied with, the Registrar shall-
>
> (i) invite the applicant to restrict the application so that it relates to only one invention, and
>
> (ii) notify the applicant that he may within, three months file in respect of the other inventions dealt with in the original application subsidiary applications which shall benefit from the date of filing of the original application and, if relevant, from the date of any foreign priority claimed under section 3(4) of this Act, and, if the applicant does not comply with the invitation mentioned in sub-paragraph (i) of this subsection, shall reject the application, and
>
> (c) if section 3(4) of this Act has not been complied with, the Registrar shall disregard any claim for foreign priority.

According to section 4 (2) of the Act[142] the registrar shall examine the application, and if he is satisfied that all the documents which are required to be submitted with the application have been submitted, shall grant the patent without enquiring into the questions

(a) Whether the subject of the application is patentable under section 1.

(b) Whether the description of the invention and claims made comply with the requirement that they must be sufficiently clear and complete as to enable a person skilled in the art or field of knowledge to which the invention relate be able to put it into effect.

(c) Whether there is a prior application or a prior grant of a patent for the same invention has been made in Nigeria.

The procedure for filing of an application for a Nigerian patent is prescribed in the Patent Rules of 1971, which is also contained in Patent and Design Act Cap P2 Laws of The Federation of Nigeria (LFN) 2004. Specifically rule 8 provides that an application shall be made on Form 1 (please note that there are forms 1(a) and 1(b))and shall relate to only one

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142 Patent and Design Act Cap P2 LFN 2004.

invention, though it may include claims for any number of products, any number of manufacturing processes for those products and any number of application of those products. The most important document to be filed is the patent specification. The specification is the document in which the invention will be described in detail. Section 3(2) of the Act[143] requires that such description should be sufficiently detailed and complete that someone skilled in the field of knowledge to which the invention relates will be able to apply the information and produce thereby the object of the invention.

Normally, the applicable date of state of the art is the date on which the application is filed, because if the patent is granted, its twenty years tenure commences on the date of the application.[144]Thus the filing date is the date from which the application takes priority.

By virtue of Nigeria being a signatory to some international conventions related to patent protection, the Nigerian patents Act allows an applicant for a patent, who had earlier filed the same application in another country which is also a signatory to the convention (referred to in the Act as "a convention country")[145] is long as he files the corresponding application in Nigeria within one year of having filed the first application in the convention country,[146] he is entitled to claim the date on which he filed the convention country application as his priority date for the Nigerian application. Therefore, when the question of novelty as concerns the Nigerian application is being considered, the court will enquire into the state of the art for the period preceding the date on which the convention country application was filed, and not the later date on which the Nigerian application was filed. An applicant who wants to claim a convention country priority date, will make his application on Form 1(b).

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143 Patent and Design Act Cap P2 LFN 2004

144 Section 7(1) of the Act) Patent and Design Act Cap P2 LFN 2004

145 The list of Convention countries in Nigeria is provided in the Patent and Design (Convention Countries) Order L.N. 95 of 1971.

146 Section 27(1) Patent and Design Act Cap P2 LFN 2004

He shall file a declaration showing the date, number and country of the convention country application. The declaration should also contain the name of the person who made the earlier application. Finally, the applicant must file not later than three months after filing of the application, a certified true copy of the application fled in the convention country.

After the filing of the application, the registrar will examine the application, and if all formal requirements have been met, will issue the applicant with a patent certificate. There is further provision under the Nigerian Act that after a patent is granted, the registrar shall publish a notification of the patent granted. Presumably, the publication envisaged by this provision, is publication in the Federal Government Gazette or a Patent Journal.[147]

An applicant for a patent, upon the grant of his application becomes a patentee and enjoys the following rights: to preclude others form making, importing, selling or using the product on stocking it for the purpose of sale or use. If the patent has been granted in respect of a process he has the right of precluding others from applying the process or doing in respect of a product obtained directly by means of the process, or any other Acts mentioned in paragraph (a) of section 6.[148]

It should be noted that the registration of a drug with National Agency for Food and Drug Administration and Control (NAFDAC) does not constitute patent. In *Ducros S.A v Silas Industries and Trading Company Ltd*,[149] the court in deciding whether registration of a product with NAFDAC constitutes registration as envisaged in an infringement action, held that a patent that is not registered under the Patents & Design Act cannot be protected.

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147 Section 27(1) Patent and Design Act Cap P2 LFN 2004

148 Section 6 Ibid. *Pfizer Incorporation v Polyking pharmaceutical Limited and Anor* (1998) FHCL.1

149 FHC/L/CS/1057/2003

3.4 Rationale of License

A license is a contract by which the licensor authorizes the licensee to perform certain activities, which would otherwise have been unlawful. For example, in a patent license, the patentee (licensor) authorizes the licensee to exercise defined rights over the patent.[150] The effect is to give to the licensee a right to do what he/she would otherwise be prohibited from doing, i.e., a license makes lawful what otherwise would be unlawful.[151]

The licensor may also license 'know-how' pertaining to the execution of the licensed patent right such as information, process, or device occurring or utilized in a business activity can also be included along with the patent right in a license agreement. Some examples of know-how are:

a. technical information such as formulae, techniques, and operating procedures and

b. commercial information such as customer lists and sales data, marketing, professional and management procedures.

Indeed, any technical, trade, commercial, or other information, may be capable of being the subject of protection.[152]

Benefits to the licensor:

(i) Opens new markets

(ii) Creates new areas for revenue generation

(iii) Helps overcome the challenge of establishing the technology in different markets especially in foreign countries – lower costs and risk and savings on distribution and marketing expenses Benefits to the licensee are:

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150 Section 23 Patent and Design Act Cap P2 LFN 2004

151 F. Abbott and T. Cottier, F. Gurry, *The International Intellectual Property System: Commentary and Materials. Part I*. (London: Kluwer Law International; 1999).

152 F.K. Beier and G. Schricker, *IIC Studies: Studies in Industrial Property and Copyright Law, from GATT to TRIPS – the Agreement on Trade Related Aspects of Intellectual Property Rights* (Max Planck Institute for Foreign and International Patent. Munich: Copyright and Competition Law; 1996).

(i) Savings on R&D and elimination of risks associated with R&D

(ii) Quick exploitation of market requirements before the market interest wanes

(iii) Ensures that products are the latest

3.5 Infringement of Patent

Infringement of patent is provided for in section 25 of the Patents and Designs Act.[153] Under the section, it is provided that it will be an infringement of patent if any person does or causes the doing of any act which is precluded under the provisions of section 6, referred to above. The section further raises a presumption in respect of process patent to the effect that if a process by which a new product is to be made is patented, it shall be presumed that a defendant who makes the product and is sued for the infringement of the process has manufactured the product by means of the patented process. The onus of disproving the presumption lies on the defendant.

The patentee, whose patent has been infringed shall be entitled to the remedies of damages, injunction and

accounts.

The Federal High Court has the exclusive jurisdiction for entertaining action brought under the Patents and Designs Act.[154] Therefore, patents infringement actions have to be filed in the Federal High Court.

3.6 The Patent Cooperation Treaty

The PCT is an international treaty which provides a system for filing patent applications and assists you in seeking patents in multiple countries around the world on the basis of a single

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153 Patent and Design Act Cap P2 LFN 2004

154 Section 26 Patent and Design Act Cap P2 LFN 2004

patent application. The PCT was signed in June 1970, in Washington, D.C., and became operational in June 1978 with 18 Contracting States. The terms PCT country and PCT Contracting State are both used interchangeably to identify countries which are party to the PCT system. The PCT now has 153 Contracting States.[155]

While the PCT simplifies patent application filing and processing for you, the ultimate decision to grant a patent rests exclusively with each national or regional patent Office.

3.6.1 The Role of Patent Cooperation Treaty

The PCT simplifies the procedure for seeking patent protection in many countries, making it more efficient and economical for: (1) Users of the patent system (applicants and inventors); and (2) National Offices.

Through PCT, an inventor of a member country contracting state of PCT can simultaneously obtain priority for his/her invention in all or any of the member countries, without having to file a separate application in the countries of interest, by designating them in the PCT application. All activities related to PCT are coordinated by the world intellectual property organization (WIPO) situated in Geneva.[156]

In order to protect invention in other countries, it is required to file an independent patent application in each country of interest; in some cases, within a stipulated time to obtain priority in these countries. This would entail a large investment, within a short time, to meet costs towards filing fees, translation, attorney charges, etc. In addition, it is assumed that due

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155 <https://www.wipo.int/pct/en/pct_contracting_states.html> Accessed 24 January 2021.

156 WIPO, *WIPO intellectual property handbook. policy, law and use* (New York: WIPO Publication; 2001).

to the short time available for making the decision on whether to file a patent application in a country or not, may not be well founded.[157]

Inventors of contracting states of PCT on the other hand can simultaneously obtain priority for their inventions without having to file separate application in the countries of interest; thus, saving the initial investments towards filing fees, translation, etc. In addition, the system provides much longer time for filing patent application in the member countries.[158]

The time available under Paris convention for securing priority in other countries is 12 months from the date of initial filing. Under the PCT, the time available could be as much as minimum 20 and maximum 31 months. Further, an inventor is also benefited by the search report prepared under the PCT system to be sure that the claimed invention is novel. The inventor could also opt for preliminary examination before filing in other countries to be doubly sure about the patentability of the invention.[159]

3.7 The Global Institutions Responsible for Administering the Patent System

3.7.1 National Patent Offices

Every country with a patent system has a national patent office where claims of inventors may be made a matter of public record. As mentioned above, in many countries there is an examination before an inventor is given any substantive rights. In other countries patent clams are registered but detailed examination is delayed until a dispute over infringement arises. However, even in these countries a search of the prior art is often conducted as a part of the registration process, and the search results are published so that members of the public

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157 A. S. Gutterman and B. J. Anderson, *Intellectual Property in Global Markets: A Guide for Foreign Lawyers and Managers* (London: Kluwer Law International; 1997)

158 A. S. Gutterman and B. J. Anderson, *Intellectual Property in Global Markets: A Guide for Foreign Lawyers and Managers* (London: Kluwer Law International; 1997); L. Bently and B. Sherman *Intellectual Property Law* (Oxford: Oxford University Press; 2001).

159 L. Bently and B. Sherman *Intellectual Property Law* (Oxford: Oxford University Press; 2001).

can assess the claims made by the registrant. For example, in Nigeria there the Nigerian Intellectual Property Office also known as the Trademarks, Patents and Designs Registry that regulates the administration of intellectual property in Nigeria and is set up as a department under the Ministry of Commerce and is responsible for the management of trademarks, patents and designs applications in Nigeria.[160]

3.7.2 The World Intellectual Property Organization (WIPO)

Headquartered in Geneva, WIPO is the specialized United Nations Agency that serves as the secretariat for administration of most of the global intellectual property treaties. It is the principal forum for negotiation of new patent treaties and the leading provider of technical assistance to developing countries in the field of intellectual property rights. WIPO was created in 1967 as the successor organization to the International Bureau for the Protection of Intellectual Property, which had been in existence since the 19th Century. WIPO Currently has 193 member states.[161]

3.7.3 The World Trade Organization (WTO)

The World Trade Organization was established in 1994 in Marrakech following the successful conclusion of the Uruguay Round of Trade Negotiations. The predecessor to the WTO was the General Agreement on Tariffs and Trade (GATT). A key reform of the Uruguay Round was the Agreement on Trade Related Aspects of Intellectual Property Rights, known as TRIPS, codified as an annex to the treaty establishing the WTO.

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160 C. Djomga, et al, "A – Z of African Official IP websites No. 38. Nigeria", available at <http://afroip.blogspot.com/2012/03/to-z-of-african-official-ip-websites.html> Accessed 4 February 2021.

161 WIPO Member States <www.wipo.int> Accessed 4 February 2021.

It is important to recognize that the TRIPS Agreement was intended to create a more equitable system of international trade. Wealthy countries agreed to reduce barriers to imports of price competitive imports from abroad while developing countries agreed to open their markets to the high value added exports of the developed nations. These high value added exports disproportionately consist of technology in which much of the value is intangible and must be protected by strong intellectual property regimes to be effectively exploited. Pharmaceutical products constitute one of the most important categories of high technology products.

Among the major requirements of the TRIPS agreement are the following:

i. WTO Member States must provide a level of rights equal to those provided in the major global intellectual property treaties administered by WIPO, including the Paris Convention on Industrial Property.

ii. WTO member states may not discriminate among technologies in providing patent protection, meaning that exceptions to patent protection in many countries for pharmaceutical products must be eliminated.

iii. WTO member states must provide patent protection for at least 20 years from the date of filing a patent application

iv. WTO Member States must provide effective judicial enforcement of intellectual property rights.[162]

3.8 Conclusion

A patent is considered a major incentive for technological development, both for being an official document that grants legal protection to the invention and for being the greatest source of information on technological innovation in the world. Since pharmaceutical

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[162] See generally the Agreement on Trade-Related Aspects of Intellectual Property 1995.

industry based on products and processes, have now assumed an increasing importance in the global economy, there is a definite need to globally harmonize policies and procedure in respect of protection of intellectual property rights in view of the fact that enterprises engaged in research will make investment only if strong legal protection is available for the result of their research.

In this chapter, the researcher has been able to examine the inter-relation between patent and pharmaceutical industry. The chapter examined among other things the concept of patent, the criterial for patentability, the application for patent, the rationale for license and the role of the patent corporation treaty in assisting the easy universality of patent right.

The chapter further examined the global institution regulating patent.

CHAPTER FOUR

GENERAL OVERVIEW OF INTELLECTUAL PROPERTY RIGHTS IN THE NIGERIAN PHARMACEUTICAL INDUSTRY

4.0 Introduction

The protection of 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 in 1914.[163]

The essence of the Intellectual Property law is usually to protect inventions especially ones that are new and those that improve on the new ones. In effect, Intellectual Property law confers the right to exclude others, generally, from exercising those rights the law confers on the patentee or right holder. The major beneficiaries of Intellectual Property often include scientists, researchers, authors, pharmacists, engineers, artist, musicians and extendedly the consumers. However, as the task of this work demands, the concentration of this chapter will be on health related inventions. That is, the legal effects of Intellectual Property law on pharmaceuticals or drugs and other edibles in Nigeria.

4.1 Nigerian Governmental Agencies Responsible for Enforcement of Intellectual Property Rights in Nigerian Pharmaceutical Industry

In order to ensure the effective co-ordination and administration of activities relating to intellectual property, various institutions were established to further strengthen the system in Nigeria. The following are the institutions responsible for the enforcement of IPR.

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[163] Victor M. Ibigbami and Christopher Orji. *A Review of the Nigerian System of Intellectual Property. Institutionalization of Intellectual Property Management: Case Studies from four Institutions in Developing Countries* (CAS-IP, Rome, Italy 2009).

4.1.1 Nigerian Copyright Commission

The Commission is established under section 34 of the Copyright Act.[164] The Nigerian Copyright Commission was inaugurated on 19 August 1989, first as the Nigerian Copyright Council. It was elevated to the status of a Commission in April 1996 and this administrative change was confirmed by the Copyright (Amendment) Decree 1999.[165] The Commission is a body corporate with perpetual succession and a common seal and may sue and be sued in its corporate name.[166]

The Commission is the Federal Government agency responsible for all copyright matters in Nigeria including the administration, regulation, enforcement and prosecution under the Copyright Act. Its statutory mandates include:

(a) responsibility for all matters affecting copyright in Nigeria as provided for in the Act;

(b) monitoring and supervising Nigeria's position in relation to international conventions and advising Government thereon;

(c) advising and regulating conditions for the conclusion of bilateral and multilateral agreements between Nigeria and any other country;

(d) enlightening and informing the public on matters relating to copyright;

(e) maintaining an effective data bank on authors and their works;

(f) responsibility for such other matters as relate to copyright in Nigeria as the Minister may, from time to time, direct.[167]

The Commission has the power to grant compulsory licenses in accordance with the provisions of the Fourth Schedule to this Act.[168]

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164 Cap C28, Laws of the Federation of Nigeria, 2004.

165 Supra, n.1

166 34 (2) of the Copyright Act, Cap C28, Laws of the Federation of Nigeria, 2004.

167 Section 34 (3) of the Copyright Act Cap C28, Laws of the Federation of Nigeria, 2004.

168 Section 35 (a) of the Copyright Act Cap C28, Laws of the Federation of Nigeria, 2004.

The Commission is supervised by a Governing Board established under section 36 of the Act and constituted as follows:

(a) a Chairman, who shall be a person knowledgeable in copyright matters, to be appointed by the President on the recommendation of the Minister;

(b) the Director-General of the Commission;

(c) one representative of the Federal Ministry of Justice;

(d) one representative of the Federal Ministry Education;

(e) one representative of the Nigeria Police Force, not below the rank of a Commissioner of Police;

(f) one representative of the Nigeria Customs Service, not below the rank of a Comptroller of Customs;

(g) six other persons, to be appointed by the Minister, who shall represent as far as possible the authors in the following areas– (i) literary works; (ii) artistic works; (iii) musical works; (iv) cinematograph films; (v) sound recordings; and (vi) broadcasts.[169]

The representatives of the Ministries are required to be officers not below the rank of Director and the Board is at liberty to adopt its own rules of procedure and method of operation. The day-to-day administration of the Commission is under a Director General who is designated as the Chief Executive of the Commission.[170]

4.1.2 Nigerian Intellectual Property Office

The Nigerian Intellectual Property Office also known as the Trademarks, Patents and Designs Registry[171] regulates the administration of industrial property in Nigeria and is set up as a

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169 Section 36 of the Copyright Act Cap C28, Laws of the Federation of Nigeria, 2004.

170 Ibid.

171 'Trademarks, Patents and Designs Registry.'

department under the Ministry of Commerce and is responsible for the management of trademarks, patents and designs applications in Nigeria.[172]

Section 28 of the Patents and Designs Act create the office of the registrar, who shall be appointed by the Federal Civil Service Commission.[173]

The registrar may correct any clerical error in an entry in the register, but before doing so he shall give the person to whom the entry relates an opportunity to make representations.[174] Any persons (a) may consult the register free of charge during the prescribed hours; and (b) on payment of the prescribed fee, may obtain a copy of any entry in the register.[175]

A copy of an entry in the register sealed with the registrar's seal shall be admissible as evidence of what is stated therein; and any document purporting to be such a copy shall be presumed, until the contrary is proved, to be what it purports to be. Any person aggrieved by a decision of the registrar in the exercise of his functions under this Act may appeal to the court.[176]

If the Minister so directs, the registrar shall from time to time publish a journal to be known as the Patents and Designs Journal in which shall be published all such matters as are required by this Act to be published or notified and such other matters relating to patents and designs as the registrar thinks fit: Provided that, if there is no such direction in force, any matter required by this Act to be published or notified shall be published by the registrar in the Federal Gazette.[177]

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172 C. Djomga, et al, "A – Z of African Official IP websites No. 38. Nigeria".

173 Section 28(1) of the Patent and Design Act Cap P2 LFN 2004.

174 Section 28(2) of the Patent and Design Act Cap P2 LFN 2004.

175 Section 28 (3) of the Patent and Design Act Cap P2 LFN 2004.

176 Section 28 (5) of the Patent and Design Act Cap P2 LFN 2004.

177 Section 28(8) of the Patent and Design Act Cap P2 LFN 2004.

4.1.3 National Agency for Food and Drug Administration and Control (NAFDAC)

The National Agency for Food and Drug Administration and Control (NAFDAC) is a federal agency under the Federal Ministry of Health that is responsible for regulating and controlling the manufacture, importation, exportation, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, chemicals and packaged water in Nigeria.[178]

Section 1 of the National Agency for Food and Drug Administration and Control (NAFDAC) Act established the National Agency for Food and Drug Administration and Control (NAFDAC) as a body corporate with perpetual succession and a common seal and may sue and be sued in its corporate name.

NAFDAC has various basic functions. According to Section 5 of the NAFDAC Act, the Agency is authorized to:

i. Regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of drugs, cosmetics, medical devices, packaged water and chemicals;

ii. Conduct appropriate tests and ensure compliance with standard specifications designated and approved by the council for the effective control of quality of food, drugs, cosmetics, medical devices, packaged water, and chemicals;

iii. Undertake appropriate investigation into the production premises and raw materials for food, drugs, cosmetics, medical devices, bottled water and chemicals and establish a relevant quality assurance system, including certification of the production sites and of the regulated products;

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[178] Explanatory Memoradum to the National Agency for Food and Drug Administration and Control (NAFDAC) Act

Cap N1 LFN 2004.

iv. Undertake inspection of imported foods, drugs, cosmetics, medical devices, bottled water, and chemicals and establish a relevant quality assurance system, including certification of the production sites and of the regulated products.

v. Compile standard specifications, regulations, and guidelines for the production, importation, exportation, sale and distribution of food, drugs, cosmetics, medical devices, bottled water, and chemicals

vi. Undertake the registration of food, drugs, medical devices, bottled water and chemicals

vii. Control the exportation and issue quality certification of food, drugs, medical devices, bottled water and chemicals intended for export.

NAFDAC and its efficiency in the fight against fake and counterfeiting drugs has improved the manufacture of pharmaceuticals and also given impetus to indigenous participation.[179]

4.1.4 Non-Governmental Organisations (NGOs)

In complementing the role of these Inter-Governmental Organisations, some Non-Governmental Organisations (NGOs) also play very crucial roles in the administration of intellectual property in Nigeria. These are: Copyrights Society of Nigeria (COSON) which is a non-profit making organisation of all owners of copyright or neighbouring rights in musical works and sound recordings. It is a strong force in the fight against copyright infringement and other forms of piracy in Nigeria. However, the legal status of other unregistered collecting societies and associations for musical works (such as the Musical Copyright Society of Nigeria) is currently uncertain in the light of recent litigation regarding same.[180]

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179 T. O. Umahi, "Access to Medicines: The Colonial Impacts on Patent Law in Nigeria", Benson Idahosa University Law Journal, (Sept. 2011), Vol.1, No.1, p.22.

180 J. Umaru, *Intellectual Property Law in Nigeria: An Introduction* (Usmanu Danfodiyo University Press, Sokoto, 2011) 15.

There is also the Reproduction Rights Society of Nigeria (REPRONIG). It was licensed to operate as a collecting society for reprographic rights in late 2003 with funding support from the Reprographic Rights Organisation of Norway (KOPINOR).[181]

Others are Intellectual Property Institute, Nigeria (IPIN) (Ltd/Gte) which is a non-profit organization established to promote the use of intellectual property and intellectual capital as tools for social, technological and economic growth.[182] The Institute also seeks to increase awareness and understanding of the use of intellectual property through activities including intellectual property research, public enlightenment, specialized training and workshops, technical assistance, institution building and consultative forums.[183]

4.1.5 Court

In contemplation of disputes related to intellectual property which are inevitable, dispute resolution institutions are established for administration of justice. The subject matter jurisdiction to hear intellectual property cases is given under the Nigerian Constitution exclusively to the Federal High Court.

Section 251(1) of the Constitution of the Federal Republic of Nigeria 1999 (as Amended 2011) (CFRN) provides that:

> Notwithstanding anything to the contrary contained in this Constitution . . . the Federal High Court shall have and exercise exclusive jurisdiction to the exclusion of any other court in civil causes and matter:
>
> (f) Any Federal enactment relating to copyright, patent, designs, trademarks and passing-off, industrial designs and merchandise marks, business names, commercial and industrial monopolies,

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181 Ibid.

182 Supra, n.1.

183 Umar Abubakar Dubagari and Kabiru Garba Muhammad, 'Legal Regime of Intellectual Property Rights Protection in Nigeria: An Appraisal' (2015) 1 (1) Journal of Political Science, Law and International Relations 13-26.

> combines and trusts, standards of goods and commodities and industrial standards.[184]

It is apparent that any civil matter bordering on intellectual property can only be commenced at the Federal High Court and no other court is permitted by law to entertain such matters. This provision is also substantially similar to the provisions of section 7 of the Federal High Court Act.[185]

Reading the provisions of the Constitution in isolation, it can be imputed that any intellectual property matter that borders on criminal infringement, other courts aside the Federal High Court shall have the jurisdiction to hear such a matter because the Constitution specifically refers to Civil matters. In Nigeria however, this is not the practice. All the intellectual property laws in Nigeria specifically conferred jurisdiction on its subject matter on the Federal High Court both civil or criminal infringement.[186]

Section 46 of the Copyright Act provides that "the Federal High Court shall have exclusive jurisdiction for the trial of offences or disputes under this Act". Section 67 of the Trademarks Act in interpreting "court" as used under the Act states that "'court' means the Federal High Court". The use of the word "means" is restrictive and admits of no other court or further inclusion. Similarly, section 32 of the Nigerian Patents and Designs Act defines court to mean the Federal High Court. Therefore, by these provisions it can safely be concluded that only the Federal High Court is bestowed with the jurisdiction to hear and determine causes and matters, whether criminal or civil, relating to intellectual property in Nigeria.

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184 Section 251 (1) (f) of the Constitution of the Federal Republic of Nigeria 1999 (as Amended 2011)

185 Cap F12 Laws of the Federation of Nigeria (LFN), 2004.

186 Umar Abubakar Dubagari and Kabiru Garba Muhammad, 'Legal Regime of Intellectual Property Rights Protection in Nigeria: An Appraisal' (2015) 1 (1) Journal of Political Science, Law and International Relations 13-26.

4.2 Regulatory Framework on IPL and Nigerian Pharmaceutical Industry

4.2.1 International Instruments

Nigeria, like most countries of the world is a subscriber to international conventions which are intended to set internationally acceptable standards that the domestic legislation on various species of intellectual property must attain as well as to accord intellectual property an international protection.[187] These include: Patent Corporation Treaty and Berne Convention for the protection of literary and artistic works of authors. There is also an agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) affirming the flexibilities available to member states seeking to protect public health.

It is to be noted that under international law, a treaty once ratified by a state becomes binding on that state to fulfil all the obligations arising under that treaty. This is in line with the principle of "*pacta sunt servanda"*, which provides that "every treaty in force is binding upon the parties to it and must be performed by them in good faith".[188]

The 1999 Constitution of the Federal Republic of Nigeria provides that "before its enactment into law by the National Assembly, an international treaty has no such force of law as to make its provision justiciable in our courts." So the treaty has to be enacted as municipal law in Nigeria. Where the international treaty is enacted into law by the National assembly and incorporated into municipal or domestic law, like the African Charter on Human and Peoples' Rights (ratification and Enforcement) Act, it becomes binding and our courts must give effect to it like all other laws falling within the judicial powers of the courts. However, if not enacted the country is still bound to honour the treaties provision in its international dealings, because in international law a still cannot plead its municipal law to defeat its international obligations.

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187 B. K. Vanessa and C. Kelley, 'TRIPS, the Doha Declaration and Paragraph 6 Decision: What are the Remaining Steps for Protecting Access to Medicines?'.

188 Article 26 of the Vienna Convention on the Law of Treaties, entered into force on 27 January 1960.

WIPO administers 23 treaties in the field of intellectual property. Fifteen of which are in the field of industrial property and 8 in copyright.[189] However, only few relevant to this present research will be examined.

4.2.1.1 Patent Corporation Treaty[190]

The most important universal treaty in the patent filed at this stage is the Patent Cooperation Treaty (PCT). It establishes a system designed to assist applicants, industry, and patent offices in avoiding a good part of the tremendous duplication of work that is the consequence of individual national procedures for the grant of patents in each country. The PCT allows the filing of a single international patent applications for an invention having effect in a number of designated PCT member countries.[191]

The Patent Cooperation Treaty is divided into six chapters.

The first chapter deals with the international application and search, second chapter deals with the international preliminary examination, chapter three deals with the common provisions such as regional patent treaties, time limits etc. Chapter four is about technical services and chapter five & six is about disputes.

A PCT application (also called international patent application) has two phases. The first phase is the international phase in which patent protection is pending under a single patent application filed with the patent office of a contracting state of the PCT. The second phase is the national and regional phase which follows the international phase in which rights are continued by filing necessary documents with the patent offices of separate contracting states

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189 WIPO, *Summaries of Conventions, Treaties and Agreements Administered by WIPO* (WIPO 2013).

190 Patent Cooperation Treaty (PCT) 1970.

191 WIPO, *Summaries of Conventions, Treaties and Agreements Administered by WIPO* (WIPO 2013).

of the PCT.[192] A PCT application, as such, is not an actual request that a patent be granted, and it is not converted into one unless and until it enters the "national phase".[193]

Filing an International Application

An international application can be filed by any national or resident of a PCT contracting state in most cases with the national office, which will act as PCT receiving office of the international Bureau constituted under Article 55 of the PCT.[194] The same national office can also act as receiving office as an option for nationals and residents of all PCT contracting states. Where a designated state is party to the European Patent Convention, the applicant "my" and in case of Belgium, France, Greece, Ireland, Italy, Monaco and the Nether lands "must" opt for the effect of a European (rather than a national) patent application. When a state is party to the Eurasian Patent Conventions, the applicant may opt for the effect of Eurasion (rather than national) patent. Where a designated state is party to the Harare Protocol, the applicant, and in case of Swaziland, must opt for the effect of ARIPO (rather than a national) patent application. Where a designated state is a member of the African Intellectual Property Organization (OAPI), the effect is that of a regional application field with OAPI.[195]

Standardization and Cost of International Application

The PCT prescribed certain standards for international applications. An international application which is prepared in accordance with these standards will be acceptable, so for as

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192 'PCT Applicant Guide'.

193 *Oxonica Energy Ltd v Neuftec Ltd* (2008) EWHC 2127.

194 WIPO, *Summaries of Conventions, Treaties and Agreements Administered by WIPO* (WIPO 2013).

195 Ibid.

the form and contents of the application are concerned, to all the PCT contracting states, and no subsequent modifications, because of varying national or regional requirements relating to the form or contents of the international application different from or additional to those which are provided by the PCT are acceptable.[196]

Only a single set of fees is incurred for the preparation and filing of the international application and the fees are payable in one currency and at one office, (the receiving office). The national fees become payable much later in the filing of application under PCT than in the traditional Paris Convention route.

The fee payable to the receiving office for an international application consists of three main elements:

1. The transmittal fee – to cover the work of the receiving office;
2. The search fee – to cover the work of the search and examination.
3. The international fee – to cover the work of the international Bureau.

The International Search

The international application is then subjected to what is called an "International Search". That search is carried out by one of the major patent offices. The said search result in an "International search report", that is, a listing of the citations of such published documents that might effect the patentability of the invention claimed in the international application.

The international search report is communicated to the applicant, who may decide to withdraw his application, in particular, where the said report makes the granting of patent unlikely.

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196 'PCT Applicant Guide'.

If the international application is not withdrawn, it is, together with the international search report, published by the international Bureau, and communicated to each designated office.

The International Publication

International publication serves two main purposes:

i. To disclose to the public the invention (i.e. in general, the technological advance made by the inventor) and

ii. To set out the scope of the protection which may ultimately be obtained.

International publication takes place, in general, in 18 months after the priority date of the international publication.[197]

International application is published in the language in which the international application is filed, if that language is Chinese, English, French, German, Japanese, Russian, or Spanish, the international application is published in Chinese, French, German, Japanese, Russian or Spanish, but the little of the invention, the abstract and the international search report, are published in English. If the international application has been filed in any other language, it is translated and published in English.[198]

National and Regional Phases

If the applicant decides to continue with the international application with a view to obtaining national or regional patents, he can wait until the end of the 20 months, after the filing of the international application or, where that application claims the priority of an earlier application, until the end of 20 months after the filing of the earlier application, to commence the national procedure before each designated office by furnishing a translation (where necessary) of the

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197 'PCT Applicant Guide'.

198 Article 22(1); Article 39(1)(a) and all documents submitted must be translated to English.

application in the official language of that office and paying to it the usual fees. This 20 months period is extended by a further 10 months where the application chooses to ask for an "international preliminary report", a report which is prepared by one of the major patent offices and non binding opinion of the patentability of the claimed invention. The applicant is entitled to amend the international application during the international preliminary examination. However, the advantages of international preliminary examination can not be invoked by residents and nationals of, Or in respect of, Spain since Spain chooses not to be bound by the relevant provisions of PCT. The PCT application does not lead to a uniform patent in all designated countries, however each PCT application is treated in each designated state by usual procedure which nationally proceeds the grant of the patent. PCT chapter II is a step in this direction by the international preliminary examination, which should induce the PCT states to adopt in their country the result of the international preliminary examination in their country. In practice however, this is not the case particularly countries with a procedure for substantive examination execute such a procedure nationally, even if an international preliminary examination report exists. Each country loves its national habits. The frustrating result for inventors and industry is significant expenses. In many countries, patent protection is, for many enterprises, not affordable.

If the entry into national or regional phase is not performed within the prescribed time limit, the PCT application generally ceases to have the effect of a national or regional application.[199]

4.2.1.2 Trade Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS Agreement covers the issues of protection of intellectual property in trade-related areas to a significant degree, and is seen as a comprehensive new framework prescribing

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[199] Article 24(1)(iii) PCT.

standards of intellectual property protection. Further, the TRIPS Agreement has the added significance of being the first international agreement concerning all types of intellectual property with numerous substantive provisions.

The TRIPS Agreement is a detailed and expansive agreement consisting of 73 Articles divided into 7 Parts.

Part I consists of general provisions and basic principles. Member countries are obliged to enact domestic legislation to give effect to the provisions of the TRIPS Agreement, which defines "intellectual property" as "all categories of intellectual property that are the subject of Sections 1 through 7 of Part II" of the Agreement, namely copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs (topographies) of integrated circuits, and protection of undisclosed information (trade secrets).[200]

Furthermore, the TRIPS Agreement provides that Members shall comply with their obligations concerning intellectual property rights under existing treaties.[201] These treaties that must be complied with are specified as the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works, the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (Rome Convention) and the Treaty on Intellectual Property in Respect of Integrated Circuits (IPIC Treaty).

In previous treaties concerning intellectual property rights, since there were only provisions establishing national treatment, problems would sometimes arise where persons from specific countries would be awarded greater protection than the Country's own nationals. Although this kind of occurrence was not usual, it was sometimes granted as a tradeoff in return for

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200 Article 1 of the Agreement on Trade-Related Aspects of Intellectual Property 1995.

201 Ibid, Article 2.

other items as a result of bilateral negotiations between countries. Therefore, in the TRIPS Agreement, both national treatment[202] and most-favoured-nation treatment[203] were provided as basic principles. Although most-favoured-nation treatment was stipulated in GATT previously, this applied only to "goods", in other words imported and exported products, whereas in the TRIPS Agreement it came to be applied to "persons" as the holders of intellectual property rights, that is, both natural and legal persons.

Part II of the TRIPS Agreement provides standards concerning the availability, scope and use of intellectual property rights.

4.2.1.3 Patent protection in the TRIPS Agreement

Regarding patentable subject matter, the TRIPS Agreement provides in Article 27(1) that

(1) patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application, and

(2) patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

However, the TRIPS Agreement provides the following exceptions to patentable subject matter: (1) Members may exclude inventions from patentability in order to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment[204] and

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202 Ibid, Article 3.

203 Ibid, Article 4.

204 Ibid, Article 27(2).

(2) Members may also exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals, plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.[205]

The TRIPS Agreement further provides that regarding special plant varieties, Members shall provide for their protection either by patents or by an effective *sui generis* system or by any combination thereof.[206] The TRIPS Agreement prohibits Members from making unreasonable exceptions to patentable subject matter, and apart from limited exceptions it states the principle that any invention, whether a product or process, in all fields of technology, should be granted patent rights if it fulfills the patent requirements. Therefore, provisions excluding inventions in particular fields such as pharmaceuticals, chemicals and foods from patentable subject matter, which in the past had been enacted particularly in the laws of developing countries, now conflict with the TRIPS Agreement, giving rise to the expectation that protection of inventions in developing countries will be improved. Further, the TRIPS Agreement recognizes a period of grace of 10 years for developing countries that did not have a product patent system at the time that the WTO Agreement came into force, to establish a product patent system.[207] However, even in relation to these countries, where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products, they must establish measures equivalent to recognizing patent applications for these inventions from the date of entry into force of the WTO Agreement.[208]

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205 Ibid, Article 27(3).

206 Ibid, Article 27(3).

207 Ibid, Article 65(4).

208 Ibid, Article 70(8).

Further, the TRIPS Agreement contains provisions comprehensively prohibiting discrimination, namely (1) discrimination as to the place of invention, (2) discrimination as to the field of technology, and (3) discrimination as to whether products are imported or locally produced. The prohibition against discrimination as to the place of invention was enacted in light of Article 104 of the former US Patent Law; the prohibition against discrimination as to the field of technology was directed at the state of affairs operating in some countries whereby the conditions of application of compulsory licenses in certain fields were not as strict as in other fields; and the prohibition against discrimination regarding imported versus local produce was included to stop the act of importing patented goods, etc. being regarded as working the patented invention.

With regards to the right confer on the patentee, the TRIPS Agreement provides that a patent shall confer on its owner the following exclusive rights:

(1) where the subject matter of a patent is a product: the acts of making, using, offering for sale, selling, or importing for these purposes that product, and

(2) where the subject matter of a patent is a process: the acts of using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.[209]

The TRIPS Agreement also confirms that patent rights can be assigned or transferred by succession, and the patent owner can conclude licensing contracts.[210] Recognizing that patent rights are exclusive rights conferred in return for making the invention public, from the perspective of maintaining a balance between this and strengthening the protection of patent rights, the TRIPS Agreement provides that regarding a patent owner's obligations, Members

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209 Ibid, Article 28(1).

210 Ibid, Article 28(2).

(1) shall require an applicant to disclose the invention in a sufficient manner when applying for a patent, and

(2) may require the applicant to indicate the best mode for carrying out the invention.[211]

In the case of foreign patent applications the TRIPS Agreement also provides that information must be submitted regarding foreign patent applications.[212]

The TRIPS Agreement allows that members to provide limited exceptions to the rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[213] This provision reflects the patent law provisions in many countries concerning acts such as (1) exploiting a patented invention for the purpose of testing-related research, and (2) dispensing of drugs by doctors.

The TRIPS Agreement sets forth clear and detailed provisions concerning compulsory licenses, which come under other uses without the authorization of the right holder, so that by clarifying the conditions under which these can be established, it is ensured that they are established in appropriate cases.[214]

The TRIPS Agreement provides that there should an available opportunity for judicial review of any decision to revoke or forfeit a patent.[215]

The TRIPS Agreement provides that the term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.[216]

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211 Ibid, Article 29(1).

212 Ibid, Article 29(2).

213 Ibid, Article 30.

214 Ibid, Article 31.

215 Ibid, Article 32.

216 Ibid, Article 33.

Therefore, under the TRIPS Agreement, Member countries must establish a term of protection for patents of at least 20 years from the filing date. There was a conflict of opinions among signatories, with developed countries wanting a term of protection of at least 20 years, and developing countries such as India arguing that this should be left up to each country. In the end, the developed countries' view prevailed.

TRIPS Agreement provided for the onus of proof. Regarding patents of manufacturing processes, it is usually more difficult for the patent owner to prove the particular process than in the case of patented goods. Therefore, regarding the burden of proof in process patent cases, the TRIPS Agreement reduces the onus on the patent owner and provides for adequate protection of process patents by shifting the burden of proof to the defendant, who is the alleged infringer, in cases where certain conditions are met.[217]

4.2.2 Local Legislations

In every country of the world, there is intellectual property local legal regime

4.2.2.1 Copyright Act[218]

This Act makes provisions for the definition, protection, transfer, infringement of and remedy and penalty thereof of the copyright in literary works, musical works, artistic works, cinematograph films, sound recordings, broadcast, and other ancillary matters in Nigeria.

Section 1(1) of the Copyright Act provides for works protected by copyright which include;

(a) Literary works

(b) Musical works

(c) Artistic works

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217 Ibid, Article 34.

218 Copyright Act Cap 28 LFN 2004.

(d) Cinematograph films

(e) Sound recordings

(f) Broadcasts

It is important to note that copyright does not protect ideas unless it original and fixed. According to section 1(2), a literary, musical or artistic work must satisfy the twin requirements of originality and fixation.

Copyright in literary, musical or artistic works other than photographs last until seventy (70) years following the death of the author. In the case where the work is owned by a government or corporate body, the copyright in the literary, musical or artistic work will expire seventy (70) years after the work was first published. Copyright in films and photographs lasts 50 years after the year the work was first published. Copyright in sound recordings also lasts 50 years after the recording was first published. Performance rights subsist until the end of the period of fifty years from the end of the year in which the performance first took place.

4.2.2.2 Patent Act and Design Act[219]

The Act makes comprehensive provisions for the registration and proprietorship of Patents and Designs in Nigeria and other matters ancillary thereto. Section 1 of the Patent and Design Act sets out the requirement of a patentable invention (a) If it is new, results from inventive activity and is capable of industrial application; or (b) If it constitutes an improvement upon a patented invention and also is new, results from inventive activity and is capable of industrial application.

Section 1 (4), (5) provides for the exceptions to patentability. These include plants or animal varieties, or essentially biological processes for the production of plants or animals.

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219 Patent and Design Act Cap P2 LFN 2004.

Inventions the publication of which will be contrary to public order and morality are also excluded, so also are principles of a scientific nature.

Section 13(1) of the Patent and Designs Act 1990 provides that an industrial design is registrable if;

(a) it is new

(b) it is not contrary to public order or morality.

The lifespan of the patent lasts for 20 years provided the annual renewal fees are paid for the duration of its potential life. Where the patentee defaults in the payment of the annual renewal fee, the patent lapses, after a 6 months period of grace, if still not be renewed and cannot be revived again.

4.2.2.3 Trademark Act[220]

The Trademark Act makes provision for the registration of trademark and other matters ancillary thereto. Section 9 of the Trademark Act CAP T13 LFN 2004 provides that in order for a trademark to be registrable under part A, the mark must contain one of the following:

i. The name of a company, individual, or firm represented in a special or particular manner;

ii. The signature of the applicant for registration or some predecessor in his business;

iii. an invented word or invented words;

iv. A word or words having no direct reference to the character or quality of the goods, and not being according to its ordinary signification a geographical name or surname;

v. Any other distinctive mark.

To be registrable under part B, the mark has to be capable of being distinctive.

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220 Trademark Act Cap T13 LFN 2004.

4.3 Intellectual Property Monetization Strategies a Pharmaceutical Company Can Deploy

4.3.1 Own Use

Innovative pharmaceutical companies all over the world pour millions of dollars into research and development activities to generate intellectual property. The ability to produce a better or a customized product, especially when competitors do not have such an advantage, is one of the key commercial advantages of IP. This enables the owner of the IP asset to sell a higher volume of products, achieve greater profits and maintain customer interest over time.[221] Capitalizing on the "first-mover" advantage is a great way to gain competitive edge, recoup expenses, and make some profits.[222]

4.3.2 Licensing

Licensing is the sharing or the renting of IP through a legally binding contract that specifies certain conditions with another company the licensee in exchange for the payment of royalties.[223] Strategic licensing is especially good for pharmaceutical companies that intend to make additional income from IP assets that have been transcended by recent developments. Also, where a company has IP assets that have no intrinsic value, it can license them to other companies who may still find those assets extremely useful.[224]

4.3.3 Strategic Alliances

Businesses often form alliances to achieve jointly what is difficult to achieve separately. A fledgling pharmaceutical company may forge alliances with big companies and willing

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221 'IP Asset Development and Management A Key Strategy for Economic Growth', WIPO, 34.

222 Ibid.

223 Ibid.

224 Ademola Adeyoju, Intellectual Property as the Heartbeat of the Pharmaceutical Industry.

investors. This is necessary where the small-sized company does not have the adequate resources and funding to develop or manufacture a new discovery.[225] Old dogs, having realized that patents protection last only for so long and that pursuing the next blockbuster is an overrated adventure, are increasingly looking for new tricks.

4.3.4 Sale

A pharmaceutical company that possesses redundant and useless items in their IP portfolio can choose to sell out. This approach may be especially desirable where the company has valuable IP that is currently outside its current commercial focus. For example, an alliance of technology giants bought Nortel's patents for $4.5 billion, and Google bought Motorola's patents for $12.5 billion.[226]

4.3.5 IP Rights Enforcement

Enforcing IP rights has become a business model on its own. A pharmaceutical company that owns any IP must keep vigilant watch on the market and take swift enforcement action against suspected infringers. 5 May 2014, Samsung was ordered to pay Apple nearly $120 million in damages for infringing on Apples patents.[227]

4.4 Civil Remedies for Intellectual Property Rights Infringement in the Nigerian Pharmaceutical Industry

All the intellectual property laws allow for civil action against infringers. Thus there are remedies the right holder can seek from the court to redress the harm done to him or to stop the impending harm to be done to him. According to section 25 of the Patent act, a patentee,

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225 Ibid.

226 'Monetizing Intellectual Property to Improve Financial Performance',Venable LLP White Paper, November 11, 3.

227 Ademola Adeyoju, Intellectual Property as the Heartbeat of the Pharmaceutical Industry.

whose patent has been infringed shall be entitled to the remedies of damages, injunction and accounts.[228] These remedies are briefly discussed hereunder.

4.4.1 Injunctions

Injunctions are equitable remedies. The order of injunction is granted based on trite principles which the applicant must prove to the satisfaction of the court.[229] Where the IPR owner becomes aware of any or perceived infringement, they ought to act fast so as to forestall further damage to their rights. However, before an injunction is granted, the applicant must undertake that if in the end their action fails, they will compensate the defendant for the interference to the defendant's business affected by the injunction.[230] Thus, there are several kinds of injunctions that can be sought at various stages of IPR enforcement from the courts. Interlocutory injunction will often be granted by the court in order to preserve the status quo until the determination of the suit.[231] Thus, instead of waiting till the end of the trial before actions can be taken, the court may be asked to act at once, and to grant at the outset an injunction against infringement lasting until the trial of the action.[232] Unless the evidence fails to disclose that the plaintiff has any real prospect of success at the trial, the court will consider whether the balance of convenience lies in favour of granting or refusing an interlocutory injunction. An important consideration in weighing the balance of convenience is whether the plaintiff or the defendant will be adequately compensated in damages if an

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228 Similar provisions are contained in the Copyright Act and the Trademark Act.

229 Nkem Itanyi, 'Enforcing Intellectual Property Rights in Nigerian Courts' (2018) 11(2) Law and Development Review 627–645.

230 Ibid.

231 *Hoftman-La Roche & Co. AG v. Secretary of State for Trade and Industry* [1975] AC 295.

232 Ibid.

interlocutory injunction is either wrongfully refused or wrongfully granted.[233] Lord Wilberforce in *Hoftman-La Roche & Co. AG v. Secretary of State for Trade and Industry*[234] said that "the object of this injunction is to prevent a litigant who must necessarily suffer the law's delay from losing by that delay the fruit of his litigation." The whole idea is to freeze the situation before damages can flow, pending a subsequent trial on the merits.[235] In *American Cyanamid Co. v. Ethicon Ltd*.[236] the plaintiffs were the holders of a patent for absorbable surgical sutures and they were displeased when they realized that the defendants were proposing to put in the market a similar and allegedly infringing product. The House of Lords granted the interlocutory injunction to plaintiff thereby preventing the defendant from proceeding with their plans.

Perpetual Injunction is granted at the end of the trial in which the infringement of the plaintiff's right is established. This injunction protects the proprietary rights or interest of the plaintiff *ad infinituum.*[237]

The Mareva injunction is available to a right holder. It is a freezing order, sought and granted *ex parte*, restraining a defendant from removing the assets from jurisdiction. This ensures that the fruit of the judgment is not tampered with or destroyed.[238] This is a heady remedy in enforcement of IPR infringement. This injunction may be granted pending the determination

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233 White, Jacob & Davies*, Patents Trademarks, Copyright and Industrial Designs* (2nd edn, London: Sweet & Maxwell, 1978) 6 -7.

234 [1975] AC 295 at 355.

235 G. I. Uloko, 'A Critical Appraisal of the Remedies in Intellectual Property Litigations in Nigeria' 1 (1) Nigerian Journal of Public Law 270.

236 [1975] AC 396, [1975] 1 All ER 504.

237 Nkem Itanyi, 'Enforcing Intellectual Property Rights in Nigerian Courts' (2018) 11(2) Law and Development Review 627–645.

238 *Third Chandris Shopping Corporation v Uniamarine SA* [1979] 2 All ER 592.

of the infringement action in court. It is sometimes combined with the Anton Piller order for effectiveness.

Anton Piller injunction emerged from the case of *Anton Piller KG v. Manufacturing Processes Ltd.*[239] The purpose of this injunction is to restrain the defendant from destroying material evidence in his possession and which is valuable to the success of an action. It is granted where the applicant believes or has reasonable cause to believe that an infringement activity is ongoing inside particular premises.[240] The applicant must be in the company of a police officer not below the rank of Assistant Superintendent of Police (ASP) to search the premises.

4.4.2 Damages or Account of Profits

The usual procedure in any action for infringement is that the issue of liability is decided first. The issue of how much compensation the defendant must pay will only arise if the plaintiff wins. The plaintiff may decide to pursue his claim in damages or account of profits.

Damages refers to a primary remedy for infringement and it is a pecuniary monetary satisfaction awarded by the court to the plaintiff for his financial loss occasioned by the infringement of his rights. Damages are presumed as the natural consequence of the defendant's action. Thus, proof of actual or special damages is not absolutely necessary. There is no standard for the assessment of damages in intellectual property law cases,[241] although the court may follow the general standard of awarding damages in tort.

Where an action of infringement of copyright is proved or admitted, the court may award additional damages if it is satisfied that effective relief would not otherwise be available to

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239 [1976] Ch. 55 at 61.

240 *Ferodo v Unibros Stores* [1980] FSR 499.

241 G. I. Uloko, 'A Critical Appraisal of the Remedies in Intellectual Property Litigations in Nigeria' 1 (1) Nigerian Journal of Public Law 270.

the plaintiff, having regard (apart from all other factors) to the flagrancy of the infringement, and any benefit shown to have accrued to the defendant by reason of the infringement.[242] This was applied by the Court in *Peter Obe v Grapevine Communications Ltd.*[243] in increasing the plaintiff's damages from the Five Million Naira (₦5,000,000) sought to Ten Million Naira (₦10,000,000). As to the measure of damages, so many factors are considered by the court including lost royalties.[244] Thus, the plaintiff is entitled to exact compensation for any monetary damage he has actually suffered that can be fairly attributed to the infringement.

The primary aim of the remedy of accounts of profits is to prevent unjust enrichment and it is not available to a plaintiff who has otherwise been adequately compensated in damages for the infringement, the general principle being that an account of profits is a condonation of the alleged infringement.[245] Where a defendant raises a defence of innocent infringement under section 16(3) Copyright Act, the plaintiff will not be entitled to damages but can be granted an order for account of profits. The defendant is thus ordered to render account and pay over to the plaintiff all profits realized from the exploitation of the IPR. It is the infringer's profits that matter not the plaintiff's loss and this will be a guide to the court regarding the measure of damages to award.

Delivery up can also be ordered against the defendant to hand over all infringement articles to the plaintiff. These may be destroyed, forfeited or converted for the plaintiff's use. This is known as conversion right under section 18 Copyright Act.[246]

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242 Section 16(4) Copyright Act.

243 [2003-2007] 5 IPLR; 40 NIPJD [FHC 1997] 1244/1997.

244 *Beddings Holdings Ltd v INEC & 5 Ors* Suit No. FHC/ABJ/CS/816/2010.

245 *Potton Ltd. V Yorkdose Ltd* [1990] FSR 11.

246 *Haritz Ibezim Okilo v Dick Francis & Anor* [2003- 2007] 5 IPLR 230.

4.5 Challenges to Effective Intellectual Property Rights System in the Nigerian Pharmaceutical Industry

4.5.1 Lack of Expert Patent Examiners

Possibly one of the biggest challenges with regard to patent rights in Nigeria is that fact that patent examiners are not experts in the fields of science, engineering and technology. They are not required to have advanced degrees or trainings in the above fields.[247] The effect of this lack of expertise is that patent examiners in Nigeria are unable to perform more than a cursory search of the registry records in order to locate prior art and as such there is no substantive examination of the specifications and drawings that are submitted for filings. This is potentially dangerous because the average person finds it difficult to read and understand patent specifications and drawings and therefore increasing the possibility of patents being registered when there are prior patents covered by the new registration.

In addition to the lack of expertise of the patent examiners, there are very few training modules or patent examination guidelines that have been developed to educate patent examiners in Nigeria.

4.5.2 Counterfeiters are Getting Better at Producing Fakes

The sad reality is that just as technology is evolving and companies developing sophisticated anti-counterfeiting techniques, counterfeiters are equally getting better at producing fakes. The World Health Organization (WHO) estimates that fake anti-malaria drugs alone kill approximately 100,000 Africans a year and these counterfeit medicines deprive governments of 2.5%-5% of their revenue.[248]

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247 'Patent Strategies – Doing Business in Nigeria.

248 Mitchell Ogisi, Fake Medicine Common in Many Sub Saharan African Countries, 2011, Gallup World.

This problem is certainly not limited to Nigeria and other developing countries. In the U.S. for example, counterfeiters cost businesses an estimated $200 billion a year.[249] One major problem that may result from a company's goods being counterfeited in Nigeria is that when word gets out to the market that some of the goods are fakes, consumers tend to avoid purchasing that brand, which often leads to loss of millions of Naira.

In order to combat counterfeiting and stay steps ahead of counterfeiters in Nigeria, companies such as GlaxoSmithKline (GSK) have in collaboration with Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), piloted innovative approaches that are aimed at protecting patents in Nigeria from counterfeit medicines. What GSK and NAFDAC have done is to take advantage of the fact that in the area of telecoms, Nigeria is one of Africa's largest markets with close to 100 million mobile phones.[250]

Using mobile phones, GSK began a six-month pilot anti-counterfeiting program in February 2011, in relation to its antibiotic, AmpicloxTM. The company placed a scratch-off code on the back of the Ampiclox antibiotic pack. Using this code, consumers would send a text message to a central NAFDAC toll-free phone number for verification; the mobile service looks up the code and sends a verification text back to consumers.[251]

An October 2011 report by GALLUP showed that about 83% of Nigerians claimed to have encountered a counterfeit drug.[252]

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249 Lan, ' Understanding Word-of-Mouth in Counterfeiting' 2012 .

250 <https://nairametrics.com/2019/07/16/nigeria-ranks-7th-country-with-highest-number-of-internet-users-in-the-world/>.

251 'Patent Strategies – Doing Business in Nigeria'<http://ssrn.com/abstract=1801883>.

252 Mitchell Ogisi, 'Fake Medicine Common in Many SubSaharan African Countries' <http://www.gallup.co m/poll/ 149942/fake-medicine-common-sub-saharan-african-countries.aspx >.

4.5.3 Failure to Revise the Patents & Designs Act

Since the enactment of the Patent Act in 1971, there has been no significant amendment to it. This lack of revision/failure to amend has certainly been a challenge in view of the fast pace in which technology is advancing in Nigeria and also worldwide.[253] Countries like China that equally have markets comparable with the Nigerian Market have made several significant amendments to their patent laws. For example in 2009, the Chinese government made its third revision to the Chinese patent law and in 2010, new regulations was issued. Although Nigeria currently has a proposed IP Bill, that incorporates some of the trends that are now globally acceptable with regard to patents, the Bill is still currently pending and as such what continues to be operational is the 1971 Act.

4.5.4 Lack of Criminal Sanctions for Patent Infringement.

Unlike the U.S. where patent infringers receive criminal sanctions for infringement of existing patents, there is currently no criminal law sanction for patent infringement in Nigeria. In cases of patent infringement in Nigeria, the patent owner may sue in civil proceedings for damages, injunction and accounts.[254]

Nigeria's proposed Intellectual Property Bill, titled: A Bill for an Act to provide for the Establishment of the IP Commission of Nigeria, Repeal of Trademarks Act CAP T13 LFN 2004 and Patent and Designs Act, CAP P2 LFN 2004 and make comprehensive provisions for the registration and protection of trademarks, patents and designs, plant varieties, animal breeders and farmers rights' and for other related matters, however provides for criminal sanctions for patent infringement.

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253 'Patent Strategies – Doing Business in Nigeria'<http://ssrn.com/abstract=1801883> Accessed 28 January 2021.

254 Section 25(1) &(2) Patent and Designs Act, CAP P2 LFN 2004 .

Under Article 161 and 162 of the Bill, it is a criminal offence to use a patent without the consent of the patent owner and to counterfeit or imitate a patented article in the course of business.

The Bill makes it a criminal offence punishable with 1 year imprisonment and/or a fine of N300,000.

In addition, the proposed Bill makes it a criminal offence to make false claims or representations of patent and provides for judicial orders for injunction, evidence discovery of patent and preservation. However, the Bill did not finally see the light of day.

4.5.5 Poor Patenting Culture Amongst Nigerian Researchers

Universities and research institutions play a key role in national innovation systems. Studies have shown that Nigerian universities and research institutions generate some inventions, however only a few of those inventions are patented.[255] Some of the reasons for the failure to patent inventions by Nigerian researchers include: lack of awareness of the procedure for patenting; Information gap; large portion of the research that lead to inventions are sponsored by the government, early publication of research in journal articles, poor culture of patenting, and lack of a specific law on IP creation and management at research institutions and universities in Nigeria.

4.6 Conclusion

Nigeria's Intellectual Property System is fairly young and is still evolving in terms of content and effective protection remedies. While there are some challenges, the current IPS presents

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[255] A.A.Oyewale, W. O. Siyanbola, A. D. Dada and M. Sanni, 'Understanding of patent issues among Nigeria's Researchers: A Baseline Study. Presented at the International Conference on Regional and National Innovation Systems for Development, Competitiveness and Welfare: the government, academia, industry, partnership (theory, problems, practice and prospects). Saratov, Volga Region, Russia, September 19-23, 2007.

opportunities operating within the country, especially as Nigerian consumers are ravenously seeking technological innovations.

This chapter has been able to critically examine the institutional and regulatory framework on Intellectual Property Rights in the pharmaceutical industry in Nigeria. The chapter further examined the remedies available to Intellectual Property Rights holder, whose right has been infringed upon. Lastly the chapter examined the challenges to effective intellectual property rights system in the Nigerian pharmaceutical industry.

CHAPTER FIVE

SUMMARY, RECOMMENDATIONS AND CONCLUSION

5.0 Summary

This Chapter is the finishing section of this work. It is envisioned to provide a wide-ranging over view of the work. This will be done with a view to examining the findings of this research, drawing conclusions from the observations made in the course of the research and finally stating the main recommendations of the work.

Intellectual property is all about the results of human creativity. Its subject matter is formed from new ideas generated by man. In the area of pharmaceutical industry, there have been innovative drug treatments which have offered cures from illnesses previously considered life threatening, and have improved lifestyles and diminished the effects of ageing on those fortunate enough to be able to afford treatment. Therefore, it has been come necessary for pharmaceutical industries to implore the aid of intellectual property law.

This work is structured into five parts.

Chapter one provided the background to the study and the importance of the study. In this chapter the history and the evolution of the protection of intellectual property was examined. This was done in three phases, the territory, international and the global area and it was observed that from an early point in the development of intellectual property regulations, countries retained the flexibility to customize intellectual property policy and laws to meet specific national priorities including transfer of technology, developing certain industrial sectors and attracting foreign direct investment. It further examines the extent to which safeguards have historically been used in patent laws to safeguard public interest and how both developed and developing countries have made use of exceptions to patent rights to meet policy objectives.

The chapter then traces efforts by industry in developed countries to increase the level of intellectual property protection and enforcement in the 1970s and 1980s culminating in the inclusion of intellectual property to the Uruguay trade round and the creation of the Agreement on Trade Related Aspects of Intellectual Property rights (TRIPS) which made it a requirement for every World Trade Organization (WTO) Member to apply minimum standards on intellectual property.

The chapter further examined the history and evolution of intellectual property right protection in pharmaceutical industry. It was noted that at the earlier stage of intellectual property right protection, pharmaceutical industry and medicine were usually excluded but later on especially in the 20th century, countries started extending intellectual property right protection to pharmaceutical industry and medicine.

This chapter also examined the Intellectual Property Rights stakeholders, which include government, Intellectual Property Rights offices, firms and customers.

Lastly, the chapter examined the legislation on Intellectual Property Rights protection in Nigeria. It was observed that there are three main legislations on IPR in Nigeria. The three main statutes governing the intellectual property Law in Nigeria are the Copyright Act, the Patents and Designs Act, and the Trademarks Act.

The second chapter examined the nature of the pharmaceutical industry, the types of pharmaceutical industry. It was observed that there are two major types of pharmaceutical industry, they are generic pharmaceutical industry and research pharmaceutical industry. Generic pharmaceutical companies are low-cost, low-margin and low-risk businesses while the research pharmaceutical industries are innovative pharmaceutical companies that bring the new pharmaceuticals to the market.

The stages in the production of drugs by pharmaceutical industry were also examined. It was observed that the production of drugs starts with drug discovery which is a process which

aims at identifying a compound therapeutically useful in curing and treating disease. This process involves the identification of candidates, synthesis, characterization, validation, optimization, screening and assays for therapeutic efficacy. Once a compound has shown its significance in these investigations, it will initiate the process of drug development earlier to clinical trials. New drug development process must continue through several stages in order to make a medicine that is safe, effective, and has approved all regulatory requirements.

It further examined the type of intellectual property rights that a pharmaceutical industry needs to protect. Lastly the economic importance of pharmaceutical industry was discussed.

Chapter three examined the inter-relation between patent and pharmaceutical industry. The chapter examined among other things the concept of patent, the criteria for patentability, the application for patent, the rationale for licenses and the role of the patent corporation treaty in assisting the easy universality of patent right.

Chapter four examined the importance of patent and the global institution regulating patent.

In this chapter the institutional and regulatory framework on Intellectual Property Rights in the pharmaceutical industry in Nigeria were examined. The chapter further examined the remedies available to Intellectual Property Rights holder, whose right has been infringed upon. Lastly the chapter examines the challenges to effective intellectual property rights system in the Nigerian pharmaceutical industry.

5.1 Recommendations

Based on the foregoing discussion, this work will be concluded by proffering some recommendations.

1. Policy Reform

Unlike the U.S. where patent infringers receive criminal sanctions for infringement of existing patents, there is currently no criminal law sanction for patent infringement in Nigeria.

In cases of patent infringement in Nigeria, the patent owner may sue in civil proceedings for damages, injunction and accounts.

Therefore, there is an urgent need to put in place the necessary machineries to amend the existing laws so as to have new laws that will really protect the interest of the patentee.

2. Turning Infringers into Licensees

When a company discovers that its patent is being infringed in Nigeria, one way it can avoid the high costs and length of the litigation process is through licensing, which can be extremely profitable and a great source of revenue to the company. The company's strategy here will be to turn an infringer or a competitor into an ally. This can prove extremely valuable in cases where the infringing company/competitor did not infringe the patent intentionally, already has an established market and is exploiting the patent in products and services that it sells.

3. Focus not only on trademarks and design filings but also on patent filings

While no one can undermine the importance of registering trademarks and designs in Nigeria, successful IP strategies usually combine the various forms of protection available (depending on whether the subject matter is covered by the available protection). The idea is to weave a tight mesh of rights in the invention, creating a recognizable bond and therefore providing the most effective form of protection. Thus, nothing stops a company that has invented new computerized software from getting a trademark, filing a patent and design application and claiming copyright on the same software.

4. Educate Potential Inventors and Employees about the Necessity of Patent Protection

Educating pharmaceutical inventors about the research and development process and the need for patent protection enables them think differently about how they work. It also teaches them to look for opportunities to create IP that are aligned with the pharmaceutical company's business objectives. Because of the pace at which the consumer market is developing in Nigeria, it is essential to ensure that all employees of a pharmaceutical company doing business in Nigeria are fully aware of intellectual property rights issues generally and that company is able to formulate and implement a consistent patent strategy.

5. Increase Compensation for Employees' Inventors

Under Nigerian law, patents on employees' inventions are automatically assigned to the company. The usual practice is for companies to reward its employees who have come up with useful inventions and patented them. Compensation is usually monetary. The problem with this strategy is that such employees are often not compensated for subsequent use of the patent on the grounds that the employee made use of the companies data, the research and development conducted by the company has led to the new inventions and the initial filing were all carried out within the scope of the employee's employment. The rationale, which companies rely on, is that any additional compensation would amount to paying the employee for work, which they would ordinarily be required to do.

The importance of compensating employees should not be underestimated. Technology and the flow of information have changed the way people think and their expectations. In the past, employee/inventors were compensated by the company putting their name on the patent. However, this may no longer be seen as an adequate reward. It is highly important that additional corporate incentives be made available in order to motivate more research and to

get patents that will be valued worldwide. Such compensation will also discourage the employee from revealing the trade secrets to the company's competitors.

5.2 Conclusion

Nigeria's Intellectual Property System (IPS) is fairly young and is still evolving in terms of content and effective protection remedies. While there are some challenges, the current IPS presents opportunities operating within the country, especially as Nigerian consumers are ravenously seeking technological innovations.

Intellectual property rights (IPR) have been defined as ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property. IPR provide certain exclusive rights to the inventors or creators of that property, in order to enable them to reap commercial benefits from their creative efforts or reputation. There are several types of intellectual property protection like patent, copyright, trademark, etc. Patent is a recognition for an invention, which satisfies the criteria of global novelty, non-obviousness, and industrial application. IPR is prerequisite for better identification, planning, commercialization, rendering, and thereby protection of invention or creativity. Each industry should evolve its own IPR policies, management style, strategies, and so on depending on its area of specialty. Pharmaceutical industry currently has an evolving IPR strategy requiring a better focus and approach in the coming era.

The pharmaceutical industry is one of the evergreen industries in the world. No matter what happens, whether the economy is on its most stable behaviour or in recession mode. Any day a person can fall sick or might require his supplement pills. Basically the products are used 24/7.

Innovation drives the pharmaceutical industry. Innovation also differentiates research-based pharmaceutical companies from generic drug companies. Pharmaceutical companies heavily

invest in lengthy and costly research and development processes to remain relevant in the market.

Intellectual property rights, especially patent rights, are the foundation of the pharmaceutical industry. The industry heavily depends on the future profits which innovation (and as a result, exclusivity) enable.

This paper concludes and makes salient recommendations which if implemented could successfully enhance the utilization of Intellectual Property Rights in pharmaceutical industry.

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