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Intellectual Property as the Heartbeat of the Pharmaceutical Industry

by Ademola Adeyolu, ademola@infusionlawyers.com.ng



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Introduction

Generating more than \$333 billion and supporting over \$3.4 million jobs in the US alone, the pharmaceutical industry is considered to be one of the largest and rapidly growing industries on the planet. Apart from making available the drugs and other health products that help to ensure a healthy and productive workforce, the industry also provides quality employment to citizens,



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contributes to the gross domestic product (GDP), and promotes the social wellbeing and quality of life of a nation.¹

Rapidly aging world population, rise in chronic diseases, and higher disposable incomes are driving pharmaceutical consumption. According to Frost and Sullivan, the world pharmaceutical market is currently worth about \$1.6 trillion and is expected to increase by 7.2 percent every year up to 2020.

Located on the West Coast of Africa, Nigeria is the most populous black country on earth. And with a pharmaceutical market that's worth \$1.78bn and the fastest growing economy in Africa, the country's pharmaceutical industry is fairly well developed.

And the industry is still growing.

Analyses show that the Nigerian pharmaceutical market could rise by as much as 9 percent a year over the next ten years to reach \$3.6 billion by 2026, making it as large as the South African market. Over the same period, Nigeria could contribute between \$1.9 billion and \$2.2 billion to pharmaceutical sales growth.² Currently, the industry contributes to nation building with aggregate investments in excess of #300 billion, pays taxes and other tariffs, and employs over 600,000 persons.

Yet, with an estimated size of \$1.78 billion, the Nigerian pharmaceutical industry is less than 0.3 percent of the national GDP and is practically

¹ 'A Strategic Study of the Nigerian Pharmaceutical Sector: Organizational Leadership, Market-share, and Competitive Performance' *International Journal of Business, Humanities and Technology*, Vol 7, No 1, March 2017

² Holt *et al*, 'Winning in Nigeria: Pharma's next frontier', McKinsey, <http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/winning-in-nigeria-pharmas-next-frontier>



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nonexistent in the world pharmaceutical map. Annually, the country loses over \$1.5 billion to the importation of raw materials used in finished pharmaceutical products known as Active Pharmaceutical Ingredients (APIs), and her quest to become self-sufficient in drug production is bleak.

Using the Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis, below is an overall assessment of the Nigerian pharmaceutical sector:

Strengths

- Nigeria—the continent’s most populated country—adds roughly 11,000 newborn to her population every day. With her large population and heavy disease burden, the country’s pharmaceutical spending has been rising at 16 percent compound annual growth rate and the pharmaceutical market has grown significantly over the years. This growth shows no signs of slowing down.
- 60 percent of pharmaceutical production in the ECOWAS countries is domiciled in Nigeria and there is still abundant underutilized manufacturing capacity that can be applied upon demand.
- Technical skills, local expertise and experience, trained manpower, and basic manufacturing infrastructure exist, with more than 150 drug manufacturing companies.

Weaknesses

- Poor infrastructure, high cost of operation, and lack of constant power supply increases the cost of local medicine manufacture and distribution.
- Only 30 percent of the drugs sold in Nigeria are manufactured locally. Even those locally manufactured drugs rely almost exclusively on imported materials both for the active components of the drugs as well as the fillers.



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- With pervasive poverty and extreme inequality, only a small percentage of the population can afford quality health care and quality drugs.
- There is insufficient research and development infrastructure, especially in the areas of analytical equipment like spectroscopic equipment, chromatographic equipment, extraction equipment, animal testing equipment, tissue culture equipment, microbiology and biotechnology equipment, etc. Other inputs like standard drugs and chemicals, solvents and reagents are not readily available locally.³

Opportunities

- Nigeria has a population of over 180 million, and an abundance of human and natural resources. Like any other investment that thrives in population density, investment in the pharmaceutical industry has a high potential of succeeding. Large markets increase the possibility that economies of scale can be achieved in the production process, meaning that essential medicines can be sold at affordable prices. Consequently, the commercial prospects for local drug manufacturing are positive.
- The rise in non-communicable diseases such as diabetes and heart disease is inevitable and spending on drugs and health care is bound to increase.
- Positive economic growth in recent years and macroeconomic stability are helping to reduce poverty and increase purchasing power.⁴
- The increasingly visible and active National Agency for Food and Drug Administration and Control (NAFDAC) and, in particular, its aggressive

³ 'Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries', UNIDO, 2011, 33

⁴ 'Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries', UNIDO, 2011, 33



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campaign against sub-standard health products have shown a positive impact on reducing the counterfeit drugs trade.⁵

Threats

- Very weak purchasing power threatens the scope for marketing health products and encourages the proliferation of informal open markets. These informal markets exist in villages and rural communities where they are the only means of access to medicines.⁶
- Drug price control policy has not yet been articulated by the Federal Government. The current prices of health products in the market are high and most Nigerians cannot afford them.⁷
- Corruption is widespread in most transactions. If not immediately curbed, it may eventually discourage local manufacturing of health products.⁸
- Drug counterfeiting constitutes enormous threat. Frost and Sullivan estimates that nearly 17 percent of essential generic drugs and as high as 30 percent of anti-malarial medicines are routinely faked in Nigeria.⁹

⁵ 'Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries', UNIDO, 2011, 33

⁶ 'Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries', UNIDO, 2011, 33

⁷ 'Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries', UNIDO, 2011, 34

⁸ 'Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries', UNIDO, 2011, 34

⁹ 'Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries', UNIDO, 2011, 34



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The Scope and Relevance of Intellectual Property in the Pharmaceutical Industry

We live in a new age. Science, technology, and globalization have changed—and continue to change—the way we live, interact, and conduct businesses. ‘The world is witnessing a paradigm shift and the economy is shifting towards intangibility.’¹⁰

The value and importance of tangible assets such as stock and real estate have declined, the incredible value surge of intellectual property (IP) has defied the old laws of economics, and basic IP rights such as copyrights, trademarks, trade secrets, and patents now account for almost 80 percent of corporate value.

Intellectual property is now the real deal.¹¹

The race to unlock the secrets of human genome, introduce a new chemical entity or an original drug molecule, and bring the next big thing to the market has produced an explosion of scientific knowledge and spurred the development of new technologies that are altering the economics of drug development.¹² But none of this would be possible ‘without the support of intellectual property protection and the research funding made available from

¹⁰ ‘The Professional-services Profile, Infusion Lawyers – Your partner in Innovation’, 2017, 4, available at www.infusionlawyers.com.ng

¹¹ IP encompasses every original creation of the human mind, from inventions to literary and artistic works, to distinctive signs and designs. These creations are protected by laws that confer exclusive legal rights in their owners for a certain period of time.

¹² Chandra Nath Saha and Sanjib Bhattacharya, ‘Intellectual property rights: An overview and implications in pharmaceutical industry’, *Journal of Advanced Pharmaceutical Technology & Research*, April-June 2011, 2(2), 88–93,

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/>, accessed 1 November 2017



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commercialization or licensing out of such new chemicals or biological entities.¹³

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.¹⁴ Industry estimates 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.

The stakes are feverishly high.

¹³ 'IPR in a Pharmaceutical Company', <http://www.iipta.com/ipr-pharmaceutical-company/>, Indian Institute of Patent and Trademark Attorneys (IIPTA), accessed 1 November 2017

¹⁴ 'Pharmaceutical', Finnegan, <https://www.finnegan.com/en/work/industries/pharmaceutical.html>, accessed 26 October 2017



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Without intellectual property, it would be difficult, if not impossible, for any individual or business to invest in or reap any benefits from their inventions—inventors would not be encouraged to invent; investor would not be enticed to make any investment; and the financial prospect of undertaking research and development would be anything but bright. Millions of people who rely on the pharmaceutical industry for life-saving drugs and treatments would suffer. The economy would suffer. Life as we know it would come to an ill and sick end.

What types of IP do pharmaceutical companies need to protect?

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'.¹⁵

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 trials and approval. 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. I know I wouldn't.

Again, by patenting IP, pharmaceutical companies can make money from their time, efforts, and investments by monetizing their patents through licensing or

¹⁵ 'Intellectual Property Rights for SMEs in the Pharmaceutical Industry', WIPO, http://www.wipo.int/sme/en/documents/ip_pharma_fulltext.html, accessed 2 November 2017



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sale. In case of an infringement, they can also validly sue and demand compensations.

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’.¹⁶

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. 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 through the talents of authors and inventors... Sacrificial days devoted to creative activities deserve rewards commensurate with the services rendered.”¹⁷

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.

¹⁶ Section 7 of the Patents and Designs Act, Chapter 344, Laws of the Federation of Nigeria (LFN) 2004

¹⁷ *Mazer v Stein*, 347 US 201 (1954) per Justice Stanley F. Reed



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Trademark

A trademark is a sign capable of distinguishing the goods and services produced or provided by one enterprise from those of other enterprises.¹⁸ 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 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'¹⁹ When doing this, they should be extremely careful 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.'²⁰

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 only assist healthcare professionals in limiting common mistakes when forced to choose from among

¹⁸ 'Intellectual Property Rights for SMEs in the Pharmaceutical Industry', WIPO, http://www.wipo.int/sme/en/documents/ip_pharma_fulltext.html, accessed 3 November 2017

¹⁹ 'IPR in a Pharmaceutical Company', <http://www.iipta.com/ipr-pharmaceutical-company/>, Indian Institute of Patent and Trademark Attorneys (IIPTA), accessed 1 November 2017

²⁰ Helika Jurgenson, 'Drug Innovation through Better Enforcement: IPR Protection in the Pharmaceutical Industry in China', <https://www.youripinsider.eu/drug-innovation-enforcement-ipr-protection-pharmaceutical-industry/>, accessed 3 November 2017



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a large number of medical products with similar names, it also increases the ability of consumers to rapidly identify the drug of their choice.²¹

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

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. 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.

To some businesses, trade-secrets protection is preferred to patent because trade secrets last indefinitely, involve no registration cost, and do not require compliance with formalities such as compulsory disclosure to any government agencies. But one big disadvantage of trade secrets in Nigeria is that Nigerians 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. The cabal at the Coca-Cola Company has been using this form of IP for decades now.

²¹ 'Creating strong pharmaceutical trademarks ,
<https://www.lexology.com/library/detail.aspx?g=58e4a4ca-29ec-4b98-a1e2-b0d6c28d6429>,
accessed 4 November 2017



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IP Monetization Strategies a Pharmaceutical Company Can Deploy

Once upon a time, Disney bought Marvel Comics for \$4 billion based mostly on its copyright-protected comics and movies and trademarked cast of characters. An alliance of technology giants bought Nortel's patents for \$4.5 billion, and Google bought Motorola's patents for \$12.5 billion.²² Not long ago, a US-based Abbott Laboratories acquired Primal Health Care for \$3.7 billion. It is believed that the price was so high because of Primal's most valuable asset — its IP.

Here's the point of my narrative—Innovative companies can get so much value from their IP. But monetizing IP requires skillful management. A company can adopt any or a combination of the following methods.

- **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.²³ Capitalizing on the 'first-mover' advantage is a great way to gain competitive edge, recoup expenses, and make some profits.

²² 'Monetizing Intellectual Property to Improve Financial Performance', Venable LLP White Paper, November 2011, 3

²³ 'IP Asset Development and Management: A Key Strategy for Economic Growth', WIPO,



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- **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.²⁴ 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.²⁵

- **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 Apple’s patents.

- **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 investors. This is necessary where the small-sized company does not have the adequate resources and funding to develop or manufacture a new discovery. 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.

²⁴ ‘IP Asset Development and Management: A Key Strategy for Economic Growth’, WIPO, 34

²⁵ Every year, IBM generates well over \$1.5 billion in licensing revenues, all without making a single product.



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- **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.’²⁶

Conclusion

The competitiveness and commercial success of any pharmaceutical firm is tied to more than just an innovative idea—superior IP strategy and management, IP monitoring and valuation, and IP exploitation are all necessary tools. Creating, obtaining, and exploiting IP must become a corporate activity in the same manner as the raising of resources and funding. ‘In today’s exceedingly competitive markets, the use and protection of IP is often the difference between continued success or impending failure of an enterprise in {the} pharmaceutical industry.’²⁷

Ademola Adeyaju is a Graduate Legal Intern at Infusion Lawyers. Infusion Lawyers is an IP & IT law firm that helps today’s entrepreneurs, startups, and companies protect and exploit their innovations in a knowledge economy.

²⁶ ‘Leveraging your biotech intellectual property’, Bioentrepreneur, <https://www.nature.com/bioent/2008/080401/full/bioe.2008.5.html>, accessed 5 November 2017

²⁷ ‘Leveraging your biotech intellectual property’, Bioentrepreneur, <https://www.nature.com/bioent/2008/080401/full/bioe.2008.5.html>, accessed 5 November 2017



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Email: info@infusionlawyers.com.ng

Phone: +234(0)816 995 1792

Website: www.infusionlawyers.com.ng