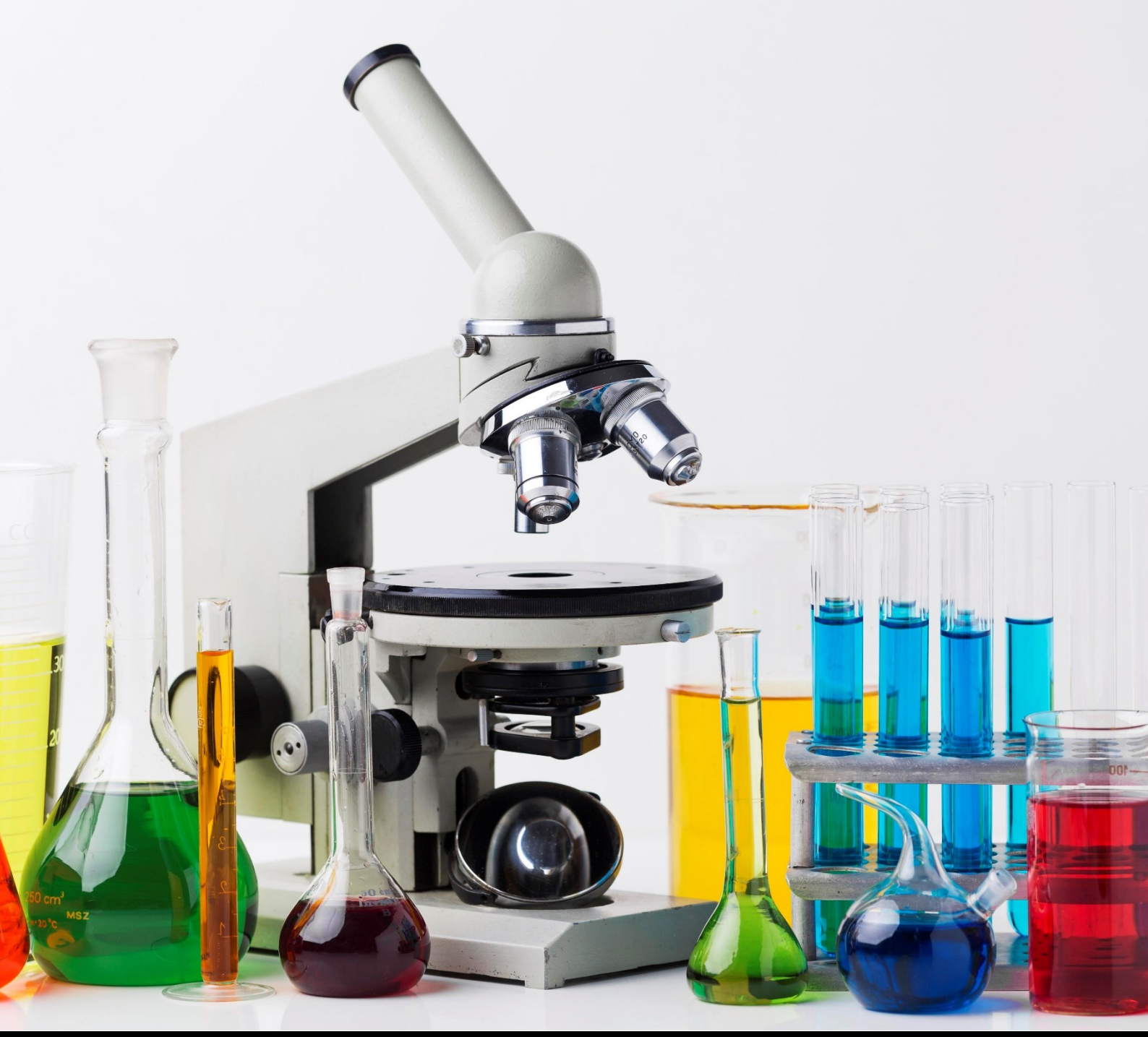

Guardians of Innovation: The Role of Intellectual Property Rights in Biotechnology and Pharmaceuticals

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Introduction

Intellectual property ("**IP**") protection is important for maximizing the value of research and innovations in the biotechnology and pharmaceutical industries. With technological advancements, the role of IP in protecting innovation and investments in these sectors cannot be undermined. It entails the grant of exclusive rights over inventions and discoveries of the IP right owners, thereby enabling an environment for providing solutions to complex health challenges and improving quality of life worldwide.

Biotechnology is essentially technological application that uses biological systems, living organisms or derivatives thereof to modify products or processes for specific use[1],while Pharmaceuticals involves the research, development, creation, and manufacturing of medicinal drugs.[2] In Nigeria, IP serves to protect innovators and encourages the development of biotechnological and pharmaceutical research, fostering the growth of these sectors. By securing IP rights, researchers and companies are incentivized to invest in the development of new drugs, innovative treatments and medical device. This protection ensures that innovators can reap the financial and moral benefits of their work, which in turn stimulates further research and development. As a result, IP protection plays a pivotal role in the creation of new healthcare solutions that can cure diseases, reduce death rates, and address other critical health challenges.

However, the terrain of IP in biotechnology and pharmaceuticals is not without its challenges. In navigating the global landscape of IP, companies or institutions operating in biotechnology and pharmaceutical sectors are required to comply with various regulatory frameworks. International trade agreements, such as the Trade-Related Aspects of Intellectual Property Rights Agreement ("**TRIPS Agreement**"), adopted in 1994 by the World Trade Organization (WTO), significantly impact access to medicines globally, influencing the landscape of IP protection and technology transfer on a global scale.

Navigating the complexities of these sectors requires more than a commitment to scientific advancements. Companies and institutions must effectively leverage IP rights, such as patents, trademarks, industrial designs and trade secrets and proactively engage with regulatory authorities. This article will explore the relevant IP rights available in the biotechnology and pharmaceutical sectors, discussing their significance, and examining the legal frameworks in Nigeria and internationally. Additionally, we will delve into some of the challenges inherent in enforcing these IP rights and propose recommendations for addressing them.

IP Protection in Nigeria

The relevant IP rights to biotechnology and pharmaceuticals that we would be focusing on are patents, trademark, industrial designs and trade secrets. In Nigeria, these relevant IP rights are legally recognized and protected under the (i) Patents and Design Act, 1971 (the "**PDA**") and (ii) Trademark Act, 1967 (the "**TMA**").

Patent

According to the World Intellectual Property Organization ("**WIPO**"), a patent is an exclusive right granted for an invention, a product or a process that provides a novel solution to a problem. From groundbreaking gene therapies to novel drug formulations, patents play a pivotal role in protecting IP assets, incentivizing research and development efforts. Patent right grants investor exclusive rights to their inventions for a period of time, typically twenty (20) years[3] from the filing date, after which the

[1] Secretariat of the Convention on Biological Diversity, *United Nations Convention on Biological Diversity* (2011) https://www.cbd.int/doc/legal/cbd-en.pdf (last accessed on May 14, 2024).
[2] https://engineeringonline.ucr.edu/blog/pharmaceutical-engineering/ (last accessed on May 20, 2024)
[3] Section 7, PDA.

invention is disclosed to the public. This encourages investment in these high-risk sectors and fuels the engine of innovation and progress in the healthcare sector.

The PDA stipulates the criteria that must be met for a product or process to be patentable. These include: (i) novelty/newness; (ii) inventive step; and (iii) industrial applicability.[4] However, section 1(4) of PDA provides that patents cannot be validly obtained in respect of: (a) plant or animal varieties or biological processes for the production of plants or animals (other than microbiological processes and their products); or (b) an invention where the publication or exploitation would be contrary to public order or morality. Considering (a) above, biotechnological inventions can fall into various categories, such as genes, proteins, antibodies, diagnostic methods, and genetically modified organisms ("**GMOs**"), so long as the invention meets the patentability requirement.

Trademark

A trademark is a recognizable sign, mark, symbol, logo or word that is distinctive and capable of distinguishing one good or service from another. Trademark offers protection in the biotechnology and pharmaceutical industry, serving as a key tool for brand differentiation and providing consumer trust. Counterfeiting is a significant issue in the pharmaceutical industry in Nigeria, as such, having a registered trademark provides legal protection for a brand and guards against counterfeiting. This further helps in building consumer trust and loyalty, which is crucial in such a sector where product safety is paramount.

The primary legislation governing trademarks in Nigeria is the TMA. The Trademarks, Patents and Designs Registry oversees the registration and enforcement of trademarks in Nigeria. The National Agency for Food and Drug Administration and Control ("**NAFDAC**")[5] requires evidence of the pharmaceutical product's registration as a trademark in the name of the trademark/brand name owner before it can be registered with the agency. However, before a mark can be registered, it must be distinctive and capable of being distinguished from different goods and services.[6]

The advantages of trademarks become more appreciated when the invention becomes available in the market. This allows the proprietor to exclusively use the word, logo, sign or symbol and to take legal action in case of infringement.[7] Additionally, trademarks facilitate the commercialization of new biotechnological and pharmaceutical products by providing a recognizable brand that can be marketed to consumers and healthcare providers.

Industrial Designs

Industrial Design protection is essential in the biotechnology and pharmaceutical sectors, where the design of medical devices, packaging, and even the distinctive appearance of pharmaceutical products are valuable. Well-designed and effective packaged medical devices can significantly improve patient's health and ensure patient's safety by improving the ease of use and functionality.

In a competitive market, the design of pharmaceutical products and their packaging can serve as a critical differentiator. Unique designs help companies establish brand identity, making their products easily recognizable to consumers and healthcare professionals. Moreover, properly designed pharmaceutical products and packaging helps to comply with regulatory requirements and safety standards.[8]

Industrial design protection is governed by the PDA. The PDA provides a legal basis for the protection of industrial designs, which can include the shape, configuration, pattern, or ornamentation applied

[4] Section 1.PDA.
[5] Para. 3.1.4, NAFDAC Guidelines for registration of drug products made in Nigeria.
[6] Section 9(1), TMA.
[7] Section 5, TMA.
[8] For instance, in Nigeria, compliance with section 5 of the Food and Drugs Act, 1976.

to an article, giving it a unique visual appearance. To qualify for protection, a design must be new and must not be contrary to public order or morality.[9]

Trade secret

A trade secret is any type of information that holds inherent economic value to a company or individual because the information is not publicly known or readily available. It provides a means of protecting valuable proprietary information that cannot be patented or needs to remain confidential for competitive advantage.[10] In the pharmaceutical industry, trade secrets can protect formulas, manufacturing processes, and methods that a company uses in the production of their products. Trade secrets can also safeguard research data, experimental results, and unpublished scientific discoveries that are important to a biotechnology company.

While patents can provide relatively comprehensive protection for certain IP, they cannot be obtained to protect all of the confidential information which a biotechnology company or institution may want to keep from the hands of competitors. This is due to its restricted coverage and the unavoidable requirement for sufficient disclosure in the patent application which will then be published to the public.

Trade secrets as an Intellectual Property Right generally do not require any form of registration. In Nigeria particularly, there is no governing statute with respect to trade secrets. However, the TRIPS Agreement to which Nigeria is a party has provided a general standard for the protection of trade secrets. Trade secrets are also protected under various common law principles, including contract law, tort law, and employment law. Companies often rely on non-disclosure agreements and confidentiality clauses within employment contracts to protect trade secrets.

Often, a company's trade secrets will enhance its patent rights. Thus, when a trade secret is utilized and adequately protected, it provides a meaningful advantage against competition.

International agreements and treaties

Patent Cooperation Treaty, 1970 (the "PCT")

The PCT (a) assists applicants in seeking patent protection internationally for their inventions; (b) helps patent offices with their patent granting decisions; and (c) facilitates public access to a wealth of technical information relating to those inventions. By filing one international patent application under the PCT, applicants can simultaneously seek protection for an invention in about 157 countries including Nigeria (the "**Contracting States**").[11] The PCT has essentially made the filing of patent easier for inventors and such filing is done electronically. Under the PCT, A single patent application can be submitted in any recognized language to one patent office within twelve (12) months from the date of the earliest patent application for the same invention. This single PCT application has the same legal effect as filing separate patent applications in the Contracting States.[12]

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure, 1977 (the "Budapest Treaty")

The Budapest Treaty provides that all contracting states which allows or requires the deposit of microorganisms for patent procedure must recognize, for such purposes, the deposit of a microorganism with any International Depositary Authority ("**IDA**"), regardless of whether the authority is within or outside the territory of the said state. It further mandates contracting states to recognize microorganisms deposited as part of the patent procedure, irrespective of the location of

[9] Section 13, PDA.
[10] https://www.citma.org.uk/trade-marks-ip/what-is-a-trade-secret.html (last accessed May 12, 2024, at 9am).
[11] https://www.wipo.int/pct/en/ (last accessed May 8, 2024, at 10pm).
[12] Ibid.

the IDA. This essentially eliminates the need to submit microorganisms to each national authority where patent protection is sought.

The Budapest Treaty enhances the patent system of contracting states by providing significant advantages to depositors, especially those applying for patents in multiple contracting states. The deposit of a microorganism under the procedures provided for in the Budapest Treaty saves the depositor money and increases security.[13] It reduces costs because the depositor needs to make only one deposit with one IDA, instead of depositing the microorganism in each contracting state where a patent application is filed. The Budapest Treaty increases security for the depositor by establishing a uniform system for the deposit, recognition and furnishing of samples of microorganisms.

As of January 1, 2009, there are seventy-two (72) contracting parties to the Budapest Treaty and 37 IDA in 22 different countries[14]. However, Nigeria has yet to sign the Budapest Treaty.

TRIPS Agreement

The TRIPS Agreement provides for not only the minimum substantive standards of protection that should be provided for in each area of IP, but also the procedures and remedies that should be available so that rights holders can enforce their rights effectively. The TRIPS Agreement's objectives and principles[15] impact biotechnology and pharmaceutical companies by promoting innovation through IP protection, facilitating technology transfer, and balancing rights and obligations to support social and economic welfare. It allows for measures to protect public health and nutrition, potentially limiting exclusive rights to ensure broader access to essential medicines.

Furthermore, the TRIPS Agreements [16] stipulates that patent protection must be available for any inventions whether a product or a process in all fields of technology provided that they are (i) new; (ii) involve an inventive step; and (iii) are susceptible of industrial application. Hence, biotechnological inventions are considered in the same light as other technical inventions as they have the same patentability requirement, same rights, same exceptions and limitations as any other technology. Nigeria is a signatory to the TRIPS Agreement.

Debates over the patentability of biological discoveries often lead to dilemmas, raising questions about access to essential healthcare technologies and the balance between fostering innovation and maintaining exclusivity. Striking a balance between protecting IP and ensuring equitable access to life-saving medications remains a pressing concern for industry stakeholders. For example, the provision of Article 31 of the TRIPS Agreement allows the use of a patented invention during the patent term without consent of the patent holder for purposes of developing information to obtain market approval and facilitates market entry by competitors immediately after the patent term expires hence ensuring early access to generic medicines. This may be a drawback to innovators knowing that their invention will become publicly available.

Madrid Agreement, 1891

The Madrid Agreement provides a centralised protection of trademarks by providing internal registration. By filing a single application with the International Bureau of the WIPO, trademark owners can protect their marks in their chosen states that are party to the agreement. [17]

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[13] World Intellectual Property Organization. https://www.wipo.int/treaties/en/registration/budapest/summary_budapest.html (last accessed May 7 2024 at 11pm).
[14] Budapest Treaty https://www.uspto.gov/ip-policy/patent-policy/budapest-treaty (last accessed May 22, 2024).
[15] Article 7 and 8, TRIPS Agreement.
[16] Article 27, TRIPS Agreement 1994.
[17] World Intellectual Property Organization website https://www.wipo.int/treaties/en/registration/madrid/ (accesses May 10, 2024).

The international registration in a contracting party has the same effect as if the mark was registered directly in the trademark registration office of the contracting party. Similar to the advantages of the Budapest Treaty, the Madrid Agreement reduces the time and money spent on filing separate national applications in each country of interest.

Although Nigeria is not a party to the Madrid Agreement, considering the advantages and ease it offers trademark owners, Nigeria's buy-in would be a laudable step for the protection of trademark owners working on expanding their goods and services to global markets.

Challenges and Recommendations in Enforcing IP Rights in Biotechnology and Pharmaceutical Sector in Nigeria

Despite the robust frameworks, enforcing IP rights in the biotechnology and pharmaceutical sectors faces several challenges. Some of the challenges include the high cost of enforcement, territorial protection of IP rights, the complexity of patent eligibility and claims, biopiracy, compulsory licensing and issues related to cross-border enforcement of IP rights.

The cost of enforcing IP rights can be problematic, especially for smaller companies and startups, potentially leading to a reluctance to pursue litigation against infringers. Additionally, the territorial applicability of most IP rights such as Trademark, patents and industrial designs, poses a challenge to inventors and developers. They often face the burden of filing multiple applications to secure broad protection for their IP rights. Cross-border enforcement issues also arise due to the global nature of the biotechnology and pharmaceutical industries. For instance, a patent granted in one country may not be recognized in another, leading to potential disputes and enforcement difficulties.

The most significant stage in applying for a patent is arguably drafting the actual application, as such drafting an application can be cumbersome. For instance, determining whether biotechnological inventions such as genes, proteins, antibodies, diagnostic methods and GMOs qualify as patentable subject matter can be complex. Some jurisdictions have stricter criteria for patenting genes or naturally occurring sequences, especially after landmark cases like *Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013) where the U.S. Supreme Court held that naturally occurring DNA sequences as against the synthetically generated DNA cannot be patented because they are products of nature.* Moreso, the legal protection for an innovation includes the ability to restrict others from using it, but this is only effective if the patent claims are properly worded.[18] In Nigeria, many patent applications are rejected due to the poorly drafted patent claims.

Biopiracy on another hand, is the unauthorised access and exploitation of biological material and using it for commercial goals, as well as gaining exclusive monopoly rights over biological material. This unauthorized exploitation of biological materials without proper authorization or compensation, is another significant challenge to IP protection for biotechnology and pharmaceuticals, particularly in countries rich in biodiversity.[19] This issue arises when companies or researchers extract valuable genetic resources and traditional knowledge from indigenous communities without providing fair compensation or obtaining proper consent. These actions not only violate the rights of the indigenous populations but also lead to the loss of potential economic benefits for the host countries.[20] Biopiracy undermines trust and collaboration between local communities and external researchers or companies, which can stifle scientific innovation and thwart IP protection.

[18] Abou Naja Intellectual property' Top 10 Intellectual Property Challenges Businesses Face in 2022" https://abounaja.com/blogs/intellectual-property-challenges (accessed May 11, 2024 at 3;00pm).
[19] https://unacademy.com/content/neet-ug/study-material/biology/what-is-biopiracy/ (last accessed May 28, 2024, at 9:16am)
[20] Dutfield, G. (2004). *Intellectual Property, Biogenetic Resources and Traditional Knowledge*. Earthscan

Compulsory licensing is another challenge to the growth of refers to the granting of licenses for the use or production of a patented invention without the permission of the patent holder.[21] Section 11 and first schedule of the PDA provides for instances when compulsory licenses will be granted. Also, Article 31 of the TRIPS Agreement allows for the exploitation of patented subject matter through government authorization without the patent holder's consent, for reason of national emergency and public non-commercial use. In 2012, the Indian government granted a compulsory license to Natco Pharma for the cancer drug Nexavar, which was patented by Bayer and Weickmann.[22] The license aimed to increase access to the medication by reducing its cost and making it available to a larger population. However, it is important to note that in Nigeria there has not been any publicly reported cases of compulsory licensing of patents although there is provision for it under the PDA.

To address these issues, it is essential to harmonize and strengthen IP laws and frameworks globally to ensure uniformity and ease of enforcement. Countries should accede to international treaties like the Budapest Treaty and Madrid agreement to benefit from the protection available under these treaties. Companies are also encouraged to collaborate with governments, regulatory bodies, and other stakeholders to address issues related to biopiracy and cross-border enforcement. Enhancing public awareness about the importance of IP rights and the implications of IP infringements would help prevent biopiracy issues and foster growth in the Biotechnology and Pharmaceutical Sector.

Conclusion

Patents, trademarks, designs and trade secrets are crucial IP rights that enable biotechnology and pharmaceutical companies to safeguard their inventions and maintain competitive advantages. The regulatory frameworks in Nigeria and internationally ensure the protection and enforcement of these IP rights, promoting the growth and sustainability of these industries. However, challenges remain in enforcing IP rights, necessitating continued efforts to strengthen IP frameworks, enhance collaboration, and support stakeholders. By addressing these challenges and leveraging IP rights effectively, the biotechnology and pharmaceutical sectors can continue to thrive, contributing to global health and economic development.

[21]First schedule, PDA

[22] Bonadio, Enrico. "India Grants a Compulsory Licence of Bayer's Patented Cancer Drug: The Issue of Local Working Requirement." *European Journal of Risk Regulation* 3, no. 2 (2012): 247–50. http://www.jstor.org/stable/24323223. (last accessed May 28, 2024 at 9:16am)

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