





From Lab to Global Market

Navigating Legal Risks and Cross-Border Patent Challenges in Licensing Life Sciences Intellectual Property

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22nd September 2025

Introduction

The journey of a life sciences invention from laboratory discovery to global commercialization is fraught with both opportunities and risks. From pharmaceuticals and biotechnology to medical devices, the life sciences sector is one of the most heavily regulated and globally integrated industries.



Life sciences innovations move across borders, but so do legal and regulatory hurdles.

Effective IP licensing helps businesses and universities balance commercialization opportunities with compliance challenges.

As innovations cross borders, so do the legal complexities surrounding intellectual property (IP) rights, regulatory approvals, licensing formalities, and technology transfer restrictions. For businesses, universities, and multinational corporations, understanding and managing these

challenges is crucial to ensuring effective commercialization and risk mitigation. This article explores the critical legal and regulatory issues that shape the licensing of life sciences IP, with a focus on Nigeria as a case study.

Regulatory Approval as a Licensing Barrier

Approval timelines and requirements differ widely across jurisdictions, affecting when licensed products can enter the market.

In Nigeria, no pharmaceutical or medical product can be commercialized without NAFDAC authorization, making it a critical factor in cross-border IP licensing.

One of the most immediate challenges in cross-border IP licensing in life sciences is the disparity in regulatory timelines and requirements. Before a product can be sold or distributed in any market, it must undergo a rigorous review process by local regulatory authorities. These processes vary significantly across jurisdictions in terms of the duration, data requirements, and procedural steps. For instance, while the U.S. Food and Drug Administration (FDA) may take 6 to 12 months to review a drug application, other countries may have longer or more complex procedures.

In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) plays a central role in regulating the importation, manufacturing, distribution, and sale of pharmaceuticals and medical products. All such products require market authorization from NAFDAC, without which commercial activity is prohibited. For foreign companies licensing IP to Nigerian pharmaceutical companies, this means that commercialization is contingent upon obtaining NAFDAC approval, thereby impacting the timing and financial projections under licensing agreements.



Advertising Restrictions and Compliance

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Beyond market authorization, licensees must also navigate a complex regulatory landscape governing the advertising of pharmaceutical products. In Nigeria, such marketing activities are subject to multiple regulatory instruments, including the National Agency for Food and Drug Administration and Control Act (NAFDAC Act), under which several subsidiary regulations such as the NAFDAC Guidelines for the Advertisement of Drugs and Related Products have been issued. Additionally, the Federal

Competition and Consumer Protection Act (FCCPA) imposes consumer-focused obligations on pharmaceutical advertisers, particularly regarding misleading or deceptive claims. Furthermore, the Advertising Regulatory Council of Nigeria (ARCON) Act, alongside the Nigerian Code of Advertising Practice, sets sector-wide standards to ensure that all advertisements, including those for pharmaceuticals, are legal, decent, honest, and respectful of public health considerations.



These laws would be briefly discussed below:

NAFDAC Subsidiary Regulations

NAFDAC is Nigeria's lead agency for regulating pharmaceuticals, under the NAFDAC Act Cap N1, LFN 2004. It issues and enforces subsidiary regulations governing advertising and labeling of food, drugs, and related products. For instance, The Drug and Related Products Advertisement Regulations, 2021, outlines the particulars that must accompany any application for advertisement approval, including product labelling, intended audience, and evidence of NAFDAC registration.¹ Furthermore, advertisements are

prohibited for certain categories of pharmaceutical products. For instance, the regulation prohibits the advertisement of prescription drugs for diseases listed in the Schedule to the Regulations, covering diseases such as; cancer, hypertension, and diabetes,² it also limits the duration of advertisement approvals to one year, after which re-approval must be sought, while the Regulation mandates that advertisements for Over-The-Counter (OTC) medications must warn users not to exceed prescribed dosage.³ Regarding

labeling, the Food and Drug Products Labelling Regulations 2005 (as amended) require that labels must include generic and brand names, manufacturing and expiry dates, active ingredients, dosage, warnings, and NAFDAC number.⁴ It also mandates that all labels be in English and in clear, readable format.⁵ The Counterfeit and Fake Drugs (Miscellaneous Provisions) Act also penalizes mislabeling or false packaging, linking labeling compliance directly with consumer safety and criminal sanctions.

¹ Drug and Related Products Advertisement Regulations 2021, reg 6

² Drug and Related Products Advertisement Regulations 2021, reg 21

³ Drug and Related Products Advertisement Regulations 2021, reg 5, 6, 12, 17

⁴ Food and Drug Products Labelling Regulations 2005 (as amended), s 6&7

⁵ Food and Drug Products Labelling Regulations 2005 (as amended), s 5.

Federal Competition and Consumer Protection Act, 2018 (FCCPA)

The FCCPA 2018 is Nigeria's primary legislation for consumer protection and fair competition. It applies across all sectors and provides comprehensive rules against misleading marketing practices. The Act mandates that goods, including drugs, must be marketed in a manner that is not misleading or deceptive.⁶ It also prohibits false representation as to the composition, characteristics, or

effectiveness of a product.⁷ Misleading price or promotional offers, which can affect pharmaceutical advertisement claiming guaranteed results, discounts or cures, are specifically prohibited under the Act.⁸ In addition, the Act empowers the Federal Competition and Consumer Protection Commission (FCCPC) to issue compliance orders, seize offending products, and impose administrative

penalties on violators.⁹ Moreover, the FCCPA complements ARCON by ensuring that advertising practices do not undermine public health, particularly by penalizing false health claims or marketing practices that can exploit vulnerable consumers.



⁶ Federal Competition and Consumer Protection Act 2018, s 114.

⁷ Federal Competition and Consumer Protection Act 2018, s 114, s 123.

⁸ *ibid*, s 124(1)(a)–(b)

⁹ *ibid*, s 125.

The Advertising Regulatory Council of Nigeria (ARCON) Act and Nigerian Code of Advertising

The Advertising Regulatory Council of Nigeria (ARCON), created by the ARCON Act 2022, is the statutory body for regulating advertising in Nigeria. ARCON succeeded the Advertising Practitioners Council of Nigeria (APCON) and has broader enforcement powers. Under the ARCON Act, ARCON is empowered to regulate, control, and enforce advertising standards across all media.¹⁰ It prohibits any advertisement unless it has been vetted and approved by ARCON, particularly for sensitive products like pharmaceuticals.¹¹

The Nigerian Code of Advertising Practice requires that advertisements for drugs must not be deceptive or exploitative, the regulation prohibits false claims, unverified testimonials, and

guarantee of cures. Advertisements must also contain the product's NAFDAC registration number, ingredient listing, dosage, and appropriate health warnings.¹² Additionally, the Code outlines diseases and conditions (e.g., cancer, STDs, infertility) for which advertising to the general public is restricted or prohibited, ensuring that such matters remain under professional medical control.¹³

From the analysis of the laws discussed above, it is clear that the Nigerian legal framework governing pharmaceutical advertising and labeling is multifaceted and strict. The ARCON Act, FCCPA, and NAFDAC Regulations collectively ensure that consumers are protected from false claims, unregulated

promotions, and unsafe usage. Advertisers must comply with ARCON's pre-approval processes, the FCCPA's transparency requirements, and NAFDAC's technical and procedural standards for both labeling and advertising. Failure to do so may result in bans, penalties, or criminal prosecution.

The likely justification for the restrictions posed by these regulations lies in public health protection, limiting the promotion of potent medications for serious conditions helps prevent self-medication and misuse, thereby reducing risks to consumers and ensuring that medical interventions remain under professional supervision.

¹⁰ Advertising Regulatory Council of Nigeria Act 2022, ss 3

¹¹ Advertising Regulatory Council of Nigeria Act 2022, ss 3 and 9.

¹² Nigerian Code of Advertising Practice 2023, Part 5, paras 24–25.

¹³ *ibid*, Sch 3.

Intellectual Property Licensing Formalities and Enforceability Risks

Legal formalities surrounding the recordal of licensing agreements presents another layer of complexity. Under Nigerian law and with regard to registered patents, once a license is granted, it must be recorded with the Patent Registry for it to be enforceable against third parties. Patents and Designs Act¹⁴ provides that a license agreement has no legal effect against third parties until it is registered and the requisite fee paid. The case of ***Arewa Textiles Plc. v. Finetex Ltd***¹⁵ illustrates the legal risks of failing to comply with this requirement, as unrecorded licenses may be deemed ineffective in court. Besides the risk of jeopardizing legal enforceability, failure to record a license agreement may also

result in tax complications or raise antitrust concerns, especially in cases where exclusive licenses may distort market competition. Thus, both licensors and licensees must prioritize proper documentation and registration of licensing agreements.

In the case of trade mark licensing, NAFDAC may require documentary proof of trademark ownership or a registered licensing arrangement as a condition for product registration and importation. This makes it critical for parties to ensure that licensing agreements are not only executed but also properly recorded to comply with both IP and regulatory frameworks.

With respect to copyright, particularly

in cases involving software embedded in medical devices, marketing materials, product literature, or packaging designs, licensing arrangements should also be clearly documented. While the Nigerian Copyright Commission (NCC) does not require registration for enforceability, a properly documented copyright licence can be vital in asserting rights in the event of infringement or in commercial disputes. For multinational pharmaceutical firms operating through local distributors, clear copyright licensing terms can help mitigate risks of unauthorized reproduction or misuse of branding elements and proprietary documentation.

¹⁴ Patents and Designs Act CAP P2 LFN 2004 S. 23(2)
¹⁵ (2003) 7 NWLR (Pt. 819) 322

Technology Transfer Restrictions and NOTAP Compliance

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A distinctive feature of Nigeria's legal landscape is the role of the National Office for Technology Acquisition and Promotion (NOTAP). All agreements involving the transfer of foreign technology including patent licenses, know-how, and proprietary drug formulations must be registered with NOTAP.¹⁶ Without this registration, royalty payments to foreign licensors cannot be processed by the Central Bank of Nigeria (CBN).

This requirement is particularly critical for multinational pharmaceutical companies licensing technologies to Nigerian partners. Even when licensing involves local Research and Development (R&D) collaboration or clinical trials, NOTAP approval is a mandatory prerequisite for repatriating earnings. Furthermore, NOTAP scrutinizes agreements to ensure they comply with local content policies, fair royalty rates, and clauses promoting capacity-building and knowledge transfer. Agreements that do not meet these standards may be denied registration.

¹⁶ Section 4(d) of the NOTAP Act empowers NOTAP to monitor the execution of contracts or agreements entered into by any person in Nigeria with any person outside Nigeria for the transfer of foreign technology to Nigerian parties and to ensure their registration in accordance with the provisions of this Act

Conclusion

Licensing life sciences intellectual property on a cross-border basis presents significant legal, regulatory, and administrative challenges. From navigating divergent regulatory approvals and advertising restrictions to ensuring proper license registration and compliance with technology transfer laws, the pathway from lab to market requires strategic foresight and rigorous legal due diligence.

In Nigeria, the regulatory requirements of NAFDAC, NOTAP, the NCC, the Patent and Trade Marks Registry highlights the importance of a multi-pronged compliance approach. As the global demand for pharmaceutical and biotech innovation grows, stakeholders must be proactive in addressing these legal risks to fully realize the commercial potential of life sciences inventions.



About Stren & Blan Partners

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for anticipating our client's business needs and surpassing their expectations, and we do this with an uncompromising commitment to Client service and legal excellence.

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