Contemporary Challenges in Balancing Patent Protection and Public Interest in Pharmaceutical Patent Law in Nigeria

How the Patents and Designs Act, TRIPS and the Doha Declaration balance innovation with access to essential medicines

A review of the legal framework, the practical obstacles to compulsory licensing and government use, and the reforms needed to reconcile patent protection with access to medicines in Nigeria



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Introduction

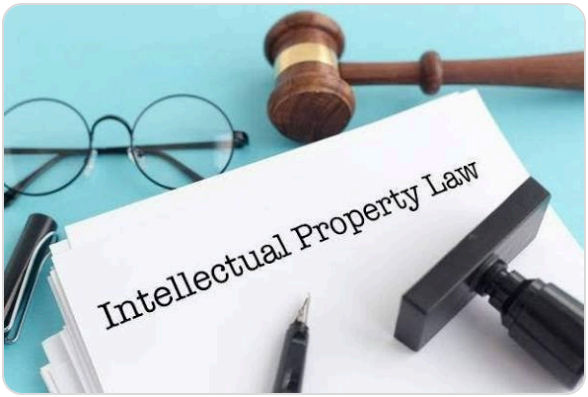


Patent law in Nigeria sits at the intersection of private rights and public welfare. This is most evident in the pharmaceutical sector, where patents incentivise innovation but may restrict access to vital medicines. Nigeria's duty to protect life and health, alongside international obligations, requires balancing these interests. The COVID-19 pandemic and rising disease burdens exposed weaknesses, while heavy reliance on imports demonstrates how fragile this balance remains.

02. The Legal Framework

Patent protection in Nigeria is governed primarily by the Patents and Designs Act (Cap P2 LFN 2004),[1] which grants inventors exclusive rights to make, use, import, or sell their inventions for a term of twenty years from the filing date, subject to payment of annual fees. In the pharmaceutical sector, such protection is justified by the high costs and risks of research and development. At the same time, the Act embeds exceptions and limitations intended to safeguard the public interest. Section 6(3)(a) confines the patentee's rights to acts done for industrial or commercial purposes, which leaves non-commercial and experimental use outside the monopoly.[2] Section 11 gives effect to the First Schedule, under which a court may grant a compulsory licence where a patented invention, being capable of being worked in Nigeria, has not been worked; where the existing degree of working does not meet the demand for the product on reasonable terms; where importation is hindering local working; or where the patentee's refusal to grant licences on reasonable terms prejudices industrial or commercial development.[3] In addition, a Minister may authorise the use of patents for the service of a government agency where the public interest so requires.[4]

1. Patents and Designs Act, Cap P2, Laws of the Federation of Nigeria 2004 (PDA), ss 6(1) and 7. Protection lasts twenty years from the filing date (s 7(1)); the patent lapses if the prescribed annual fees are unpaid, subject to a six-month grace period (s 7(2)).
2. PDA (n 1), s 6(3)(a).
3. PDA (n 1), s 11 and First Schedule, Part I, para 1. See also Doa-Law, 'Compulsory Licensing of Patents in Nigeria' (2020).
4. PDA (n 1), First Schedule, Part II, paras 15 to 16. The Act speaks of "a Minister", not specifically the Minister of Justice.



Nigeria's commitments also extend to the international arena. Under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),[5] states must provide minimum standards of patent protection but are permitted flexibilities such as compulsory licensing and government use. The Doha Declaration on TRIPS and Public Health (2001)[6] reaffirmed that member states retain the right to take measures to protect public health and promote access to medicines. At the continental level, the African Continental Free Trade Area (AfCFTA) Protocol on Intellectual Property Rights, adopted in February 2023, promotes harmonisation of intellectual property rights while recognising the developmental challenges that demand a balanced approach, although it is not yet in force in full.[7] Together, these frameworks reflect a deliberate effort to reconcile private rights with public needs.

Nigerian jurisprudence has also shown early recognition of the need to temper patent exclusivity in pharmaceuticals with considerations of public interest. In *Welcome Foundation Ltd v Lodeka Pharmacy Ltd*,[8] the defendant had supplied a patented drug to government health ministries, and the Federal Commissioner for Health had purported to exempt it from liability under the Patent Rights (Limitation) Decree 1968. Dosunmu J held that the Decree empowered the Commissioner to authorise such supply but not to grant an exemption; that irregularity, however, did not defeat the Decree's evident purpose of protecting those who supply patented articles to government, and the infringement claim was dismissed. The decision affirmed that patent protection, while robust, was not absolute where government measures were directed at safeguarding access to medicines. That position was carried into Part II of the First Schedule to the PDA, yet Adewopo observes that, as at 2021, there were no reported decisions on the use of the government-use provision, even during public health emergencies, including COVID-19.[9] This precedent remains significant in demonstrating that Nigerian law and courts acknowledge public health as a legitimate ground for limiting the enforcement of strict patent rights.

5. Agreement on Trade-Related Aspects of Intellectual Property Rights (Marrakesh Agreement Establishing the World Trade Organization, Annex 1C) (adopted 15 April 1994, in force 1 January 1995) 1869 UNTS 299, arts 8, 30 and 31.

6. World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (adopted 14 November 2001), paras 4 to 5.

7. Protocol to the Agreement Establishing the African Continental Free Trade Area on Intellectual Property Rights (adopted by the African Union Assembly, 19 February 2023), art 21 (local pharmaceutical production in public health emergencies). The Protocol is not yet in force in full.

8. *Welcome Foundation Ltd v Lodeka Pharmacy Ltd & Anor* (Suit No IK/134/67, Lagos High Court, Dosunmu J, 6 September 1971) (1971) All NLR 536; [1971] NGHC 28.

9. Adebambo Adewopo, 'Access to Pharmaceutical Patents in the COVID-19 Emergency: A Case for Government Use in Nigeria' (2021) 65(S2) *Journal of African Law* 259.

03. Contemporary Challenges

Although Nigerian law provides for safeguards such as compulsory licensing and government use, several challenges prevent their effective implementation. A major challenge is the procedural hurdles around compulsory licences. A licence is granted by the court on application, and applicants must wait four years after filing or three years after grant, whichever expires last, a delay that can prove devastating in health emergencies. The additional requirement of first attempting to obtain a voluntary licence on reasonable terms introduces further delay, making the mechanism almost unusable in urgent crises. Paragraph 13 permits earlier licences, including with importation, for products of vital importance to public health, but only by a gazetted ministerial order.[10]

Another difficulty is that a compulsory licence does not permit importation, and the non-working ground applies only where the invention is "capable of being worked in Nigeria."[11] Nigeria lacks the industrial capacity for many medicines, relying on imports for an estimated 60 to 75 per cent of medicines and nearly all active pharmaceutical ingredients. Local plants are reported to operate at roughly 40 to 50 per cent of capacity, making compulsory licensing provisions weak in practice.[12]



10. PDA (n 1), First Schedule, Part I, paras 1, 5 and 13; Constitution of the Federal Republic of Nigeria 1999 (as amended), s 251(1)(f) (exclusive jurisdiction of the Federal High Court over patents).

11. PDA (n 1), First Schedule, Part I, paras 1(a), 6 and 14.

12. KPMG Nigeria, *Repositioning Nigeria's Pharmaceutical Industry* (2026). Published estimates vary by source and year; industry bodies commonly cite import dependence of about 70 per cent and capacity utilisation of around 40 per cent.



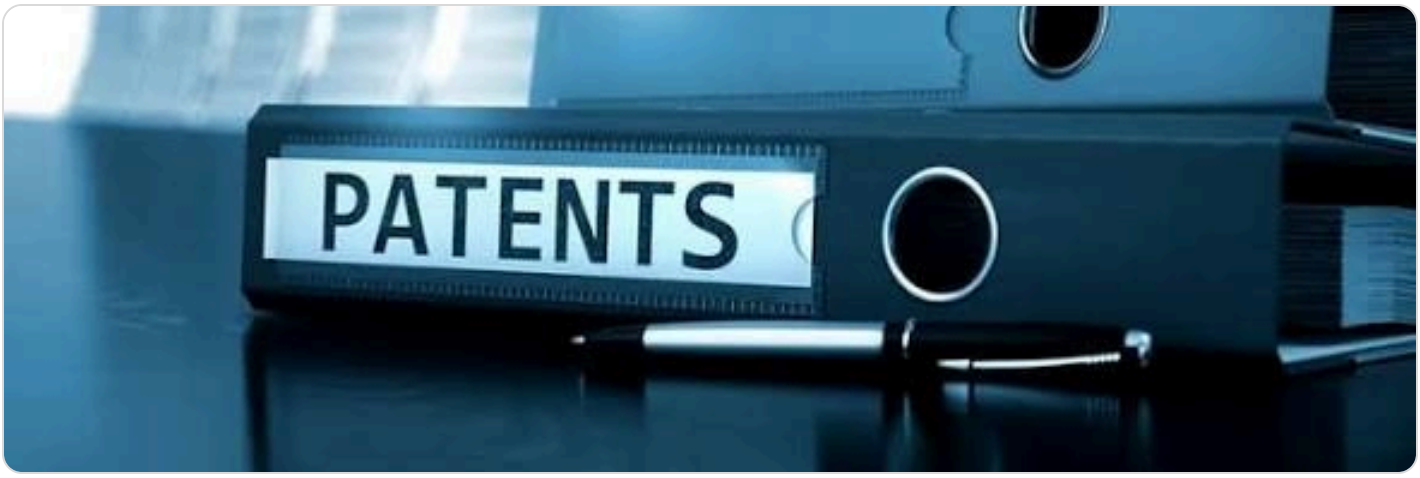
A further obstacle is the vagueness of statutory language. Terms such as "reasonable terms," "demand for the product," "adequate royalties," and "public interest" are not defined with precision, leaving significant scope for interpretation.[13] This legal uncertainty hampers enforcement and deters policymakers from invoking statutory flexibilities for fear of legal disputes. The lack of consistent judicial or administrative guidance compounds the uncertainty. Nigeria also faces external economic and political pressures. Multinational pharmaceutical corporations and developed countries have historically lobbied against or discouraged extensive use of compulsory licences.[14] The threat of trade retaliation or reputational damage may deter Nigeria from exercising its rights under TRIPS, even when public health imperatives justify such action.

Another challenge concerns the determination of adequate remuneration for patentees when compulsory licences or government use are authorised. For compulsory licences, the court fixes "adequate royalties having regard to the extent to which the relevant invention is to be worked," but the Act offers no formula for calculating them. For government use, Part II makes no provision for payment and exempts the Government and its authorised suppliers from liability to pay royalties or otherwise, which sits uneasily with the requirement of adequate remuneration in article 31(h) of TRIPS.[15] This uncertainty creates room for disputes, delays, and arbitrary outcomes. Excessive royalties defeat the purpose of affordability, while inadequate royalties discourage pharmaceutical investment.

The institutional weaknesses of Nigeria's intellectual property system compound these issues. The Patent Registry does not conduct substantive examinations,[16] meaning weak or overbroad patents may be granted. Such patents can block legitimate competition and inhibit the entry of generics. Regulatory institutions also face difficulties in enforcing quality control and patent compliance. Counterfeit and substandard drugs remain prevalent, undermining trust in locally produced medicines and complicating the broader debate over patent protection.

These challenges do not exist in isolation. They are reinforced by wider economic conditions such as high production costs driven by unreliable electricity, poor transport infrastructure, and heavy dependence on foreign exchange for raw material imports. This means that even when the law theoretically opens doors to access, the structural realities keep them closed. In effect, the balance between patent protection and public health remains heavily tilted toward patentees, at significant cost to the Nigerian public.

13. PDA (n 1), First Schedule, Part I, paras 1, 5 and 8; Part II, para 15.
14. The best-known example is the 1998 to 2001 suit by pharmaceutical companies against South Africa over its Medicines and Related Substances Control Amendment Act 1997, withdrawn in April 2001 after sustained international pressure.
15. PDA (n 1), First Schedule, Part I, para 8; Part II, paras 17 and 19; TRIPS (n 5), art 31(h).
16. PDA (n 1), s 4(2) and (4): the Registrar examines for formal compliance only, and patents are granted "at the risk of the patentee and without guarantee of their validity".



04. The Way Forward

If Nigeria is to reconcile patent protection with public interest, both statutory reform and institutional strengthening are needed. Paragraph 13 of Part I of the First Schedule already allows earlier licences, including with importation, for products of vital importance to public health, but only by gazetted ministerial order for each class of product.[17] That power should be operationalised through standing procedures so that compulsory licences can be activated immediately during health emergencies, subject to ministerial certification. This would ensure that lifesaving measures are not delayed by procedural hurdles. Clarity must also be introduced into statutory terms. Definitions of "reasonable terms," "adequate royalties," and "public interest" should be elaborated through regulations or policy guidelines, drawing on international best practices and local health economics.

Equally vital is investment in pharmaceutical capacity. Policy should incentivise API production, reduce tariffs on raw materials, and provide infrastructure support such as electricity and transport to raise capacity and ensure competitive pricing. Nigeria's pharmaceutical industry can be transformed into a regional hub if such measures are sustained. To achieve this, Nigeria must also encourage partnerships between universities, research institutes, and private companies, creating innovation clusters focused on diseases most relevant to African populations.

17. PDA (n 1), First Schedule, Part I, para 13.

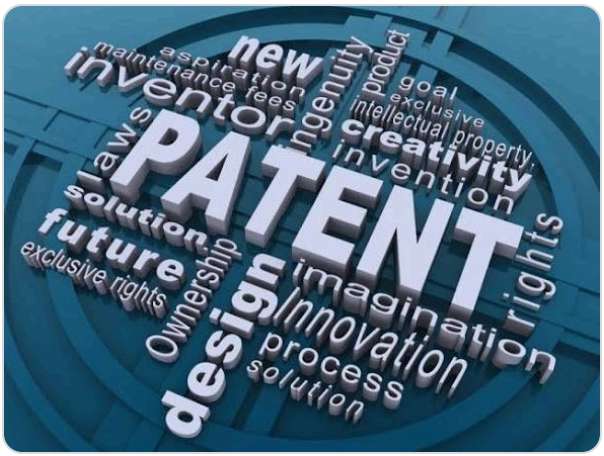
The patent office should evolve into a substantive examining body, ensuring that only genuinely novel inventions receive protection. This will prevent weak patents from blocking generics and free up competition. Regulatory agencies must also be resourced to combat counterfeit medicines and ensure the quality of locally produced generics, thereby strengthening public confidence. Transparency in royalty guidelines, possibly benchmarked against international models such as Canada's formula-based royalty for export licences under its Access to Medicines Regime,[18] would help balance fairness with affordability.

At the diplomatic level, Nigeria must confidently assert its rights under TRIPS and the Doha Declaration, using compulsory licences when public health demands. Trade negotiations should be approached with health security as a non-negotiable priority. By doing so, Nigeria will not only protect its population but also send a strong message that intellectual property cannot be elevated above the right to health, which Nigeria has domesticated through article 16 of the African Charter on Human and Peoples' Rights.[19] In the long term, aligning trade policy with health priorities will enhance Nigeria's bargaining power regionally and globally.



18. Patent Act, RSC 1985, c P-4, ss 21.01 to 21.2; Use of Patented Products for International Humanitarian Purposes Regulations, SOR/2005-143, reg 8. The royalty is calculated by a formula tied to the importing country's rank on the UN Human Development Index and cannot exceed 4 per cent of the contract value. The regime governs licences for export, so it is a model of method rather than a direct analogue.
19. African Charter on Human and Peoples' Rights (Ratification and Enforcement) Act, Cap A9, Laws of the Federation of Nigeria 2004, art 16.

05. Conclusion



The Nigerian legal framework already contains the seeds of balance between patent protection and public health. The Patents and Designs Act, TRIPS, and the Doha Declaration all provide avenues for securing access while rewarding innovation. Yet these safeguards often fail in practice due to procedural delays, weak local capacity, ambiguous statutory terms, external pressures, and institutional inefficiencies. The future of pharmaceutical patent law in Nigeria must therefore focus on reforms that enhance speed, clarity, and industrial capacity. By removing barriers, empowering institutions, and asserting its rights internationally, Nigeria can build a patent system that rewards research while safeguarding the health of its people. Ultimately, the measure of success lies not only in protecting innovation but in ensuring that no Nigerian is denied essential medicines because of legal or structural inadequacies.

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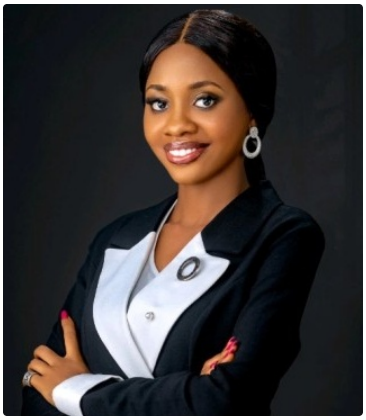
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