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Patent Law and Access to Medicines in Nigeria: A Legal Bridge or Barrier to Public Health Equity?

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Abstract

The COVID-19 pandemic exposed deep vulnerabilities in Nigeria's access to essential medicines, laying bare the country's heavy reliance on pharmaceutical imports and the rigidity of its patent system. Adopting a doctrinal, analytical and comparative legal research design, this study critically examines how Nigeria's patent regime (rooted in the Patents and Designs Act and shaped by the Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement)), affects the availability and affordability of life-saving drugs. Situated within the field of intellectual property and public health law, the study interrogates the chronic underuse of compulsory licensing, the structural barriers confronting local pharmaceutical production, and the persistent disconnect between intellectual property protection and public health policy. Drawing on statutes, policy documents, secondary literature, comparative reference to India, Brazil, Thailand and South Africa and the empirical record of Nigeria's COVID-19 Vaccines roll-out, the study finds that Nigeria's formally TRIPS-compliant patent framework, including its compulsory licensing and government-use provisions, remains chronically underused because of an outdated statute, weak coordination between health, trade and intellectual property institutions, and a limited political will - a gap illustrated by the destruction of over one million expired COVID-19 vaccine doses in 2021 and the stalled Biovaccines Nigeria Limited manufacturing venture. It concludes that Nigerian patent law currently functions more as a barrier than a bridge to public health equity, not for want of legal tools, but of institutional will to deploy them and. The study offers targeted recommendations such as:- legislative reform of the Patents and Designs Act, systematic use of TRIPS flexibilities, systematic investment in local manufacturing capacity, and closer alignment between patent policy and the right to health in order to reposition Nigeria's intellectual property framework as an instrument of health equity rather than an obstacle to it.

Keywords: Patent law, access to medicine, legal bridge and public health equity

1. Introduction

The COVID-19 pandemic clearly exposed systemic vulnerabilities in Nigeria's access to essential medicines and vaccines. Despite being Africa's most populous nation, Nigeria remains heavily dependent on pharmaceutical imports, a reliance that became a critical bottleneck once international supply chains buckled. While wealthier states secured vaccine doses through advance-purchase agreements, Nigeria and other developing countries were left dependent on donations and expensive procurement arrangements, compounded by border closures and rising medicine prices.[1]

Behind much of this inequity lies the question of intellectual property, and patents in particular, which grant pharmaceutical companies exclusive rights over their innovations for a fixed term, often at the cost of affordability. Nigeria's patent system, governed by the Patents and Designs Act and shaped by the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), was designed to incentivise research and development by guaranteeing market exclusivity. In practice, it frequently privileges intellectual property rights over public health need, delaying the entry of affordable generics and constraining local manufacturing capacity.[2]

The tension is becoming more urgent by the year. With a pharmaceutical industry meeting only around a quarter to a third of national drug demand, and a population exceeding 200 million, patent law sits at a genuine crossroads; it can either enable public health equity through local production and strategic licensing, or entrench inaccessibility through rigid exclusivity.

This article examines that dual character. It investigates the underuse of TRIPS flexibilities such as compulsory licensing, the structural constraints on local pharmaceutical manufacturing, and the

[1] Okeke C and others, 'Essential Health Care Service Disruption due to COVID-19: Lessons for Sustainability in Nigeria' (WHO Regional Office for Africa, AHOP Policy Briefs, 2022) https://iris.who.int/bitstream/handle/10665/363668/9789290234821-eng.pdf accessed 10 June 2025; Emmanuel AN and others, 'Impact of the COVID-19 Pandemic on Consumers' Access to Essential Medicines in Nigeria' (2020) 103(4) American Journal of Tropical Medicine and Hygiene 1630 https://pmc.ncbi.nlm.nih.gov/articles/PMC7543821/ accessed 15 June 2025; Akande-Sholabi W and Adebisi YA, 'The Impact of COVID-19 Pandemic on Medicine Security in Africa: Nigeria as a Case Study' (2020) 35(Suppl 2) Pan African Medical Journal 73 https://pmc.ncbi.nlm.nih.gov/articles/PMC7875805/ accessed 12 May 2025.

[2] Uguru NI and Ogu U, 'Intellectual Property Rights and Access to Essential Medicines in Nigeria: Striking a Balance between Innovation, Public Health, and Affordable Healthcare' (2023) 20(2) Nigerian Journals Online 78.

policy disconnects that undermine equitable access to medicines. Drawing on comparative international experience, it proposes reforms capable of transforming Nigeria's patent regime from a barrier into a bridge supporting both public health and pharmaceutical self-sufficiency.

2. Rethinking the Role of Patent Law in Healthcare Access

The central question confronting any developing country's intellectual property regime, particularly in the health sector, is whether the law serves to protect lives or to protect monopolies. In Nigeria, that question has grown more pressing since the pandemic, high-lighting the need to redefine patent law's social purpose from a purely commercial instrument to a strategic public health tool. This requires re-imagining patent governance not as a passive transposition of TRIPS obligations, but as a flexible, rights-conscious system aligned with national development and health goals.

2.1 Balancing Innovation Incentives with Access Imperatives

Patent law is conventionally justified as a mechanism to incentivise innovation, granting inventors temporary monopolies to recoup investment. In developing economies such as Nigeria, however, most pharmaceutical innovation originates abroad while domestic research and development remains underfunded. Patent monopolies therefore often fail to reward local innovation creating artificial scarcity.[3] A public health-sensitive patent system must strike a delicate balance: encouraging innovation where it is truly warranted, but never at the cost of denying life-saving medicines to the population, particularly for diseases such as HIV/AIDS, tuberculosis, malaria and cancer where patent-protected drugs are frequently priced out of reach.[4]

2.2 A Case for a Public Health-Sensitive Patent Regime

The Doha Declaration on the TRIPS Agreement and Public Health (2001) affirmed that WTO members retain the right to protect public health and promote access to medicines. Nigeria has rarely invoked that right in practice.

[3] Hoen E 't, Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines (Health Action International 2016) https://haiweb.org/storage/2016/07/Private-Patents-Public-Health.pdf accessed 21 June 2025.
[4] Uguru and Ogu (n 2).

A genuinely public health-sensitive regime would clearly define grounds and procedures for compulsory licensing during epidemics; provide explicit statutory grounds for government use of patents in health emergencies; adopt broader patentability exclusions to prevent "evergreening" of drugs lacking real innovation; and encourage utility-model protection for incremental innovation by local manufacturers rather than blanket twenty-year monopolies.

This approach is not without precedent. India's Patents Act, section 3(d), excludes new forms of known substances from patentability, a significant enhancement in therapeutic efficacy, curbing evergreening while sustaining a robust generic industry. The provision, affirmed in *Novartis AG v Union of India*, helped cut the price of the cancer drug Glivec from roughly ₹150,000 to ₹6,000 per month while restraining abusive patenting practice.[5]

2.3 Aligning Patent Law with National Drug Policy

A significant weakness in Nigeria's health governance is the disconnect between intellectual property law and drug policy. The National Drug Policy (2015, revised 2021) emphasizes access to affordable essential medicines and local manufacturing capacity, yet patent rules operate largely in isolation, at times contradicting these public health goals.[6] Reform must ensure that Intellectual Property (IP) policies are embedded within broader national objectives, universal health coverage, pharmaceutical self-reliance, and reduced out-of-pocket expenditure. The Draft Patents and Designs (Repeal and Re-enactment) Bill, 2021 should not merely modernise terminology in line with TRIPS, but actively support the National Drug Policy by facilitating public procurement of generics, enabling technology-transfer agreements without fear of IP retaliation, and encouraging voluntary licensing for local production.[7]

2.4 The Human Rights Dimension

A transformative approach to intellectual property must place human rights at its core. Access to essential medicines falls within Article 12 of the International Covenant on Economic, Social and

[5] Sinha M, 'The Evolution of Patent Law in the Pharmaceutical Industry — India' (*Mondaq*, 15 July 2024) https://www.mondaq.com/india/intellectual-property/1492956 accessed 20 June 2025; Chukwuma-Agbodike C, 'Access to Essential Medicine: A Legal Analysis' (2024) 1(2) NAUJOPL Journal.
[6] Federal Ministry of Health, Nigeria, *National Drug Policy* (3rd edn, 2021).
[7] Uguru and Ogu (n 2).

Cultural Rights, guaranteeing the right to the highest attainable standard of health; the UN Committee on Economic, Social and Cultural Rights has emphasised that states must prevent IP regimes from becoming barriers to that right.[8] Nigeria's Constitution does not explicitly recognise health as a justiciable right, but it protects human dignity (section 34) and social welfare (section 17), which can anchor rights-based IP reform. South Africa's framing of access to medicines as a constitutional right, particularly in the HIV/AIDS context, offers Nigeria a precedent worth following.[9] Rooting patent policy in human rights obligations would allow Nigeria to justify compulsory licensing, price controls and government use on principled grounds, not merely economic ones.

3. Nigeria's Patent Regime and International Obligations

Nigeria's patent system is governed by the Patents and Designs Act, originally enacted in 1971 and consolidated as Cap P2, LFN 2004.[10] The Act confers on a patentee the exclusive right to make, use or sell an invention for twenty years from filing, operates on a first-to-file basis, and is enforceable against unauthorised manufacture, importation, sale or distribution.[11] As a WTO member, Nigeria is bound by the TRIPS Agreement, which mandates a minimum twenty-year patent term across all fields of technology, including medicines, and Nigeria has formally notified the Act as part of its TRIPS compliance.[12]

TRIPS nonetheless preserves flexibilities allowing states to protect public health: compulsory licensing, parallel importation and government use, permitting authorised use of a patent without the holder's consent during emergencies.[13] The Patents and Designs Act incorporates some of

[8] UN Committee on Economic, Social and Cultural Rights, *General Comment No 14: The Right to the Highest Attainable Standard of Health* (2000).
[9] Mike JH, 'A Re-Evaluation of the Framework for the Protection of Patents, Women's Health in Nigeria and the Issue of Accessing Pharmaceutical Innovation in Africa' (2019) 22(3–4) Journal of World Intellectual Property 162 https://online library.wiley.com/doi/abs/10.1111/jwip.12123 accessed 22 June 2025.
[10] Patents and Designs Act, Cap P2, Laws of the Federation of Nigeria 2004 https://nairametrics.com/wp-content/uploads/2012/01/patents.and_.designs.act_.pdf accessed 12 May 2025.
[11] Patents and Designs Act, ch 344 https://ictpolicyafrica.org/pt/document/bzst7k778ii accessed 12 May 2025.
[12] World Trade Organization, Notification of Nigeria's Patents and Designs Act under Article 63.2 of TRIPS https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?Open=True&filename=Q:/IP/N/1NGAI1.PDF accessed 12 May 2025; Patents and Designs Act, ch 344, Laws of the Federation of Nigeria 1990 https://lawsofnigeria.placng.org/laws/P2.pdf accessed 12 May 2025.
[13] World Intellectual Property Organization, *Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities* (Durban, 29–31 January 2013)

these mechanisms, notably around compulsory licences and official use under section 11.[14] Despite this, Nigeria's actual use of TRIPS flexibilities remains marginal, for five interlocking reasons.

First, the Act is outdated: unamended in any substantial way for over fifty years, it lacks provision for data exclusivity, biotechnology patents, a "*Bolar*" regulatory-approval exception, (which allows generic manufacturers to begin regulatory testing on a patented drug before the patent expires)[15], or clear public-interest exceptions, leaving Nigeria without the legal tools that other jurisdictions use to enable swift generic entry after patent expiry.[16] Second, institutional capacity is weak: patent administration sits with the under-resourced Trademarks, Patents and Designs Registry, which lacks a searchable online database, causing delays and undermining transparency. Third, local participation in patent activity is minimal: Nigerian residents filed only 410 patent applications in 2020. This figure is against a global average of nearly 18,880 per country, reflecting limited R&D investment and weak innovation incentives compared with peers such as India and Brazil.[17] Fourth, despite the section 11 compulsory-licensing power, its use has been hampered by diplomatic pressure from multinational pharmaceutical interests and Nigeria's dependence on foreign aid and trade partnerships, compounded by low IP literacy among policymakers and fragmented coordination between the Ministries of Health, Industry and

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https://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_dur_13/wipo_ip_dur_13_ref_t5d.pdf accessed 15 June 2023.

[14] Nigerian Legislation Database, Patents and Designs Act, ch 344 https://www.commonlii.org/ng/legis/num_act/pada195/ accessed 15 May 2025.

[15] Named after the US case Roche Products v Bolar Pharmaceutical (1984), in which Bolar's early testing of a patented drug for FDA approval purposes was initially found to infringe Roche's patent, a "Bolar" exception (also called a regulatory review exception or early-working exception) is a provision in patent law that allows a generic drug manufacturer to use a patented invention without the patent holder's permission, for the purpose of generating the data needed to seek regulatory approval, before the patent expires. Without this exception, a generic manufacturer would have to wait until the patent expires before it could even begin the (often lengthy) process of testing, clinical trials, and regulatory submission needed to get its generic version approved. That would effectively extend the originator's market monopoly by however many years the approval process takes, sometimes 2-3 additional years, even after the patent itself has legally expired. The Bolar exception closes that gap and generic manufacturers can do the preparatory regulatory work during the patent term, so their product is ready to launch the moment the patent expires.

[16] Watal J, '"Bolar" Exception to Patent Rights: Some Economic Implications' (WIPO SCP Seminar on Exceptions and Limitations to Patent Rights, 3 November 2014) https://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_ref_watal.pdf accessed 15 May 2025.

[17] Index Mundi, 'Nigeria - Patent Applications' https://www.indexmundi.com/facts/nigeria/patent-applications accessed 11 May 2025; TheGlobalEconomy.com, 'Nigeria Patent Applications by Residents' https://www.theglobaleconomy.com/Nigeria/Patent_applications_by_residents/ accessed 15 May 2025.

Justice.[18] In sum, Nigeria's patent framework is formally in place but functionally ill-suited to its public health realities. Without reform, it will continue to entrench exclusivity over equitable access.

4. Patent Law in Practice: Evidence from the Pharmaceutical Sector

The real test of any legal framework lies in its implementation. While Nigeria's patent law formally guarantees rights and exceptions, its application in the pharmaceutical sector reveals a troubling gap between legal text and public health outcome.

4.1 Local Production: Promise Undermined by Policy Gaps

Nigeria has the largest pharmaceutical manufacturing base in West Africa, with over 115 registered local manufacturers including *Emzor, Fidson Healthcare, May & Baker and Swiss Pharma Nigeria*. Yet this industrial footprint meets only around a quarter to a third of national demand, with the remainder imported chiefly from India and China.[19] The gap reflects the absence of technology-transfer mechanisms, weak patent-pooling arrangements, unreliable power supply, high import duties on raw materials and thin state support for pharmaceutical innovation. Many local firms cannot access patented active pharmaceutical ingredients because global patent holders are either unwilling to license them or demand royalties beyond indigenous firms' means. Without stronger state negotiation and legal safeguards such as compulsory licensing, local producers are largely confined to manufacturing basic, off-patent drugs - a structural constraint that patent law alone cannot fix, but that it currently does little to relieve.

4.2 Patent Law as a Barrier to Equitable Access

Patent protection, though designed to reward innovation, often functions as a significant barrier to public health equity in Nigeria. With out-of-pocket spending accounting for over 70% of total health expenditure, the high cost of patented medicines renders many essential drugs unaffordable

[18] Nwafor G, 'Policy Instability, FX Crisis as Bane of Pharmaceutical Sector' *The Guardian* (Lagos, 26 July 2024) https://guardian.ng/business-services/policy-instability-fx-crisis-as-bane-of-pharmaceutical-sector/ accessed 17 June 2025.

[19] Okereke M and others, 'Why Nigeria Must Strengthen Its Local Pharmaceutical Manufacturing Capacity' (2021) Pan African Medical Journal https://pmc.ncbi.nlm.nih.gov/articles/PMC9401367/ accessed 11 July 2026.

for ordinary Nigerians.[20] Twenty years of market exclusivity allows originator companies to block cheaper generic competitors, inflating prices and constraining supply for the population that can least absorb the cost.[21] Because roughly 70% of Nigeria's drug supply is imported, and local manufacturers typically cannot navigate the patent landscape or afford licensing arrangements, patent restrictions compound rather than offset the country's dependence on volatile international pricing.[22]

The trajectory of antiretroviral therapy (ART) illustrates this point. ART was priced above ₦400,000 per patient per year in the early 2000s until global advocacy and donor programmes such as the 2003 US President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund brought generic versions within reach, not because Nigeria itself invoked compulsory licensing, but because it relied on external charity to solve what was, in substance, a statutory accessibility problem. The broader tension between intellectual property and access to medicines is well documented: patents can spur research, but where unregulated they restrict access and worsen health outcomes, particularly for HIV/AIDS, tuberculosis and malaria, where timely, affordable treatment is essential.[23]

4.3 Case Studies: Antiretrovirals, COVID-19 Vaccines and Missed TRIPS Opportunities

Despite the WHO Essential Medicines List including most ARVs, patent protection has historically limited the availability of affordable generics in Nigeria, and only a fraction of people living with HIV have secured consistent access, with severe consequences for morbidity and mortality.[24] The COVID-19 pandemic repeated the pattern at a larger scale. Nigeria relied overwhelmingly on vaccine imports through COVAX, bilateral donations and commercial purchase rather than pursuing domestic or regional production via TRIPS flexibilities. COVAX

[20] Attaran A, 'How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?' (2004) 23(3) Health Affairs 155 https://pubmed.ncbi.nlm.nih.gov/15160813/ accessed 15 June 2025.
[21] Uguru and Ogu (n 2).
[22] Chukwuma-Agbodike C, 'Access to Essential Medicine: A Legal Analysis' (2024) 1(1) Nnamdi Azikiwe University Journal of Public Law 34 https://ezenwaohaetorc.org/journals/index.php/Naujopl/article/view/2970 accessed 15 June 2025.
[23] Obembe O, Adeyemi T and Eze C, 'Impact of Regulatory Policy Changes on Access to Medicine in Nigeria' (2022) 8(4) International Journal of Science and Research Archive 112.
[24] Chukwuma-Agbodike (n 21).

delivered nearly four million AstraZeneca doses by March 2021, with cumulative COVAX contributions eventually reaching an estimated 65.8 million doses - over 95% of Nigeria's vaccine imports during the early rollout.[25]

When India and South Africa led the push at the WTO for a temporary TRIPS waiver on COVID-19 intellectual property, Nigeria supported the call diplomatically but did not itself invoke compulsory licensing, patent exemptions or government-use provisions to support local manufacturing, even though Article 31 of TRIPS and the Doha Declaration permitted it. While South Africa and India pursued vaccine technology-transfer initiatives, Nigeria remained on the sidelines, lacking both the manufacturing base and the political mobilisation to act. Similar constraints continue to limit access to patented treatments for cancer, diabetes and hypertension.[26] COVID-19 presented a rare opportunity to assert public health priorities over foreign patent monopolies and build domestic capacity; Nigeria's hesitancy revealed a deeper inertia in integrating IP flexibility into national health policy - a gap that continues to hinder long-term resilience.

4.4 Effects on Marginalised and Vulnerable Populations

The burden of stringent patent enforcement falls disproportionately on low-income individuals, rural communities and people with chronic illness, who lack the means to afford patented medicines and consequently experience worse health outcomes.[27] The resulting affordability gap also drives some patients toward substandard or counterfeit drugs, a problem the Nigerian health system already struggles to contain and one that patent-driven market restriction compounds rather than relieves.[28] In sum, while patent protection remains essential to fostering innovation, its current

[25] UNICEF, 'Nigeria Marks One-Year Anniversary of First COVID-19 Vaccine Shipment' (2 March 2022) https://www.unicef.org/nigeria/press-releases/nigeria-marks-one-year-anniversary-first-covid-19-vaccine-shipment accessed 2 July 2025; UNICEF, 'COVID-19 Vaccines Shipped by COVAX Arrive in Nigeria' (2 March 2021) https://www.unicef.org/wca/press-releases/covid-19-vaccines-shipped-covax-arrive-nigeria accessed 2 July 2025.
[26] Uguru and Ogu (n 2).
[27] Attaran A, 'Patent Rights and Essential Medicines in Developing Countries: Is Access Compromised for Innovation in Nigeria?' (2004) 12(3) International Journal of Intellectual Property 145.
[28] Obembe, Adeyemi and Eze (n 22).

application in Nigeria too often functions as a legal barrier to the medicines that vulnerable populations need most.[29]

4.5 Multinational Corporations: Exclusivity and Pricing Power

Multinational pharmaceutical corporations continue to shape Nigeria's medicine supply chain through patent-backed exclusivity and strategic market control, distributing drugs such as O*seltamivir (Tamiflu)* and *Remdesivir* at price points unaffordable to most Nigerians.[30] A 2023 Al Jazeera investigation reported that following the withdrawal of the multinational pharmaceutical company, *GlaxoSmithKline* (GSK) from local manufacturing, the price of asthma inhalers such as Ventolin doubled from N3,500 to N7,500.[31] Nigeria's National Agency for Food, Drug Administration and Control (NAFDAC) data suggest that 70-80% of prescription medicines are imported, often as patented branded products, while local production, sourced from fewer than 150 domestic manufacturer, accounts for only 20–30%.[32] Through 2023-2024, GSK and *Sanofi* (a French multi-national pharmaceutical company) formally exited local manufacturing in favour of third-party distribution, citing foreign-exchange shortages and rising operating costs; the resulting import surge (up 68% in the third quarter of 2023) drove prices for some essential medicines up by as much as 1,000%.[33]

By contrast, India and Brazil have used compulsory licensing and rigorous patent examination to check exploitative pricing. India's first compulsory licence, granted to Natco Pharma in 2012 under section 84 of its Patents Act, addressed the inaccessible pricing of Bayer's cancer drug

[29] Uguru and Ogu (n 2).
[30] The Guardian Nigeria, 'FX Challenges, High OPEX Force GSK's Exit from Nigeria' (4 August 2023) https://guardian.ng/news/nigeria/fx-challenges-high-opex-force-gsks-exit-from-nigeria/ accessed 15 June 2025.
[31] Al Jazeera, 'As Big Pharma Exits Nigeria, Asthma Patients Face Spiralling Costs' (19 June 2024) https://www.aljazeera.com/features/2024/6/19/as-big-pharma-exits-nigeria-asthma-patients-face-spiralling-costs accessed 15 June 2025.
[32] AllAfrica, 'Nigeria: Unlocking the Value Chain in Motion — Testing Nigeria's Bold Bet on Local Pharmaceutical Manufacturing' (9 April 2025) https://allafrica.com/stories/202504100068.html accessed 15 June 2025; National Agency for Food and Drug Administration and Control, 'Imperatives for National Drug Security' (23 June 2018) https://nafdac.gov.ng/imperatives-for-national-drug-security/ accessed 15 June 2025.
[33] Ezeagu CN, Omoleke SA and Kanmodi KK, 'The Impact of the Exodus of Big Pharmaceutical Companies from Nigeria on Antimicrobial Resistance in the West African Subregion' (2024) 2 BMC Global Public Health 35 https://doi.org/10.1186/s44263-024-00068-z accessed 2 July 2025; Muanya C and Oji H, 'FX Challenges, High OPEX Force GSK's Exit from Nigeria' *The Guardian Nigeria* (4 August 2023) https://guardian.ng/news/nigeria/fx-challenges-high-opex-force-gsks-exit-from-nigeria/ accessed 4 July 2025.

Sorafenib.[34] Brazil issued a compulsory licence for *Efavirenz* in 2007 under its Industrial Property Law, cutting prices by roughly 60% and strengthening domestic generic manufacturing.[35] Nigeria's patent law, by comparison, remains largely passive, giving foreign patent holders continued latitude to set prices unchecked even during public health emergencies.

5. Practical Impacts: What Nigeria's COVID-19 Response Reveals

The COVID-19 pandemic did not merely expose Nigeria's patent-policy weaknesses in the abstract; it produced concrete, documented episodes in which the absence of coordination between patent law and health policy translated directly into wasted resources, stalled local production, and market chaos. Three episodes illustrate the point, and together they form the practical case for the reforms this article proposes.

5.1 The Vaccine-Wastage Crisis: When Donation Replaces Production

On 22 December 2021, Nigerian authorities bulldozed 1,066,214 doses of *AstraZeneca* vaccine at a dumpsite in Abuja after the doses expired before they could be administered.[36] The doses had arrived through *COVAX* and bilateral donation with only weeks of shelf life remaining, and Faisal Shuaib, head of the National Primary Health Care Development Agency, stated bluntly that developed countries had procured and hoarded such vaccines before offering them for donation once they neared expiry.[37] This episode is a direct consequence of the absence of any domestic or regional manufacturing capacity that patent law, deployed strategically, might have helped build. Nigeria was structurally unable to convert a global supply glut into local stock, or to negotiate the

[34] Shukla N, 'Compulsory Licensing in India' (*Mondaq*, 18 January 2019) https://www.mondaq.com/india/patent/772644/compulsory-licensing-in-india/ accessed 29 June 2025; Estavillo M, 'India Grants First Compulsory Licence, for Bayer Cancer Drug' (*Intellectual Property Watch*, 12 March 2012) http://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-licence-for-bayer-cancer-drug/ accessed 29 June 2025.

[35] Chaudhary V, 'Emerging IP Regime in Pharma Industry: A Challenge in Balancing the Interest of Developing Nations' (*The Amikus Qriae*) https://theamikusqriae.com/emerging-ip-regime-in-pharma-industry-a-challenge-in-balancing-the-interest-of-developing-nations/ accessed 29 June 2025.

[36] CBC News/Associated Press, 'Nigeria Destroys 1 Million Expired Doses of COVID-19 Vaccine' (22 December 2021) https://www.cbc.ca/news/health/nigeria-destroys-expired-covid-vaccines-1.6295131 accessed 11 July 2026; Al Jazeera, 'Nigeria Destroys More Than 1 Million Expired COVID Vaccines' (22 December 2021) https://www.aljazeera.com/news/2021/12/22/nigeria-destroys-more-than-1-million-expired-covid-vaccines accessed 11 July 2026.

[37] CBC News/Associated Press, 'Nigeria Destroys 1 Million Expired Doses of COVID-19 Vaccine' (22 December 2021) https://www.cbc.ca/news/health/nigeria-destroys-expired-covid-vaccines-1.6295131 accessed 11 July 2026; Al Jazeera, 'Nigeria Destroys More Than 1 Million Expired COVID Vaccines' (22 December 2021) https://www.aljazeera.com/news/2021/12/22/nigeria-destroys-more-than-1-million-expired-covid-vaccines accessed 11 July 2026.

technology transfer that would have let it manufacture booster or replacement doses on its own timeline. The sight of vaccines destined for Nigerian arms being crushed into landfill, at a moment when barely 2% of the population was fully vaccinated, is among the clearest illustrations of this article's central argument. Without functioning TRIPS flexibilities and local production capacity, patent-dependent supply chains fail the very populations that need them most.

5.2 Biovaccines Nigeria Limited: A Local Manufacturing Plan Stalled by Technology-Transfer Bottlenecks

Nigeria's most concrete attempt to translate pandemic urgency into domestic production illustrates the same failure from a different angle. Biovaccines Nigeria Limited, a joint venture between the Federal Government and May & Baker Nigeria Plc conceived to revive the defunct National Vaccine Production Laboratory in Yaba, Lagos, was selected in 2021 by the WHO as Nigeria's designated recipient of mRNA technology under the global mRNA technology-transfer programme, placing it alongside counterparts in Senegal, South Africa, Egypt and Kenya.[38] Yet years after the pandemic began, Biovaccines had still not commenced vaccine production. The Federal Government's N10 billion in seed funding, announced in January 2021, was delayed for over fifteen months before release, and industry figures pointed to lingering bottlenecks in agreements on intellectual property and technology transfer as a central obstacle to construction of the manufacturing facility.[39] Biovaccines' own board chairman, virologist Oyewale Tomori, publicly acknowledged in 2022 that Nigeria was "not ready" for local manufacture, even as other African states advanced toward production.[40] A review of the above cases reveals one thing: Nigeria's patent and technology-transfer framework offers no clear statutory pathway to compel or incentivise the licensing arrangements that local production of a patented vaccine requires, leaving

[38] The Guardian Nigeria, 'Efforts to Restart Local Manufacture of Vaccines Suffer Setbacks' (29 April 2022) https://guardian.ng/features/efforts-to-restart-local-manufacture-of-vaccines-suffer-setbacks/ accessed 11 July 2026; BusinessDay NG, 'How Nigeria Failed to Lead Vaccine Production in Africa' (26 January 2022) https://businessday.ng/health/article/how-nigeria-failed-to-lead-vaccine-production-in-africa/ accessed 11 July 2026.

[39] The Guardian Nigeria, 'Nigeria Not Ready for Local Vaccine Manufacture Two Years after COVID-19' (23 February 2022) https://guardian.ng/features/nigeria-not-ready-for-local-vaccine-manufacture-two-years-after-covid-19/ accessed 11 July 2026.

[40] The Guardian Nigeria, 'Nigeria Not Ready for Local Vaccine Manufacture Two Years after COVID-19' (23 February 2022) https://guardian.ng/features/nigeria-not-ready-for-local-vaccine-manufacture-two-years-after-covid-19/ accessed 11 July 2026.

even a state-backed venture dependent on the goodwill of foreign patent holders rather than on any enforceable legal right.

5.3 Chloroquine Hoarding, Price Gouging and Counterfeit Medicines

A third, more immediate impact struck Nigerian households directly. In March and April 2020, following unverified international claims about chloroquine's efficacy against COVID-19, community pharmacies across Nigeria reported the price of chloroquine and hydroxychloroquine rising by as much as 350% within weeks, as panic-buying stripped shelves bare.[41]The Federal Competition and Consumer Protection Commission was compelled to issue a formal public notice condemning unreasonable, arbitrary price increases and warning against panic-buying,[42] Separately, NAFDAC reported seizing dozens of falsified medicines and medical products, including counterfeit chloroquine and hand sanitisers, as opportunistic actors exploited the resulting shortages.[43]Nigeria's reliance on imported active pharmaceutical ingredients meant the country had no buffer of locally manufactured stock to absorb the demand spike, and no compulsory-licensing or emergency-production mechanism ready to authorise rapid domestic manufacture of a medicine that was, in any event, already off-patent. The episode shows that import dependence and thin local production capacity create vulnerabilities even for generic, off-patent drugs, let alone the patented therapeutics and vaccines at the centre of this article's broader argument.

5.4 Synthesis

Taken together, these three episodes - vaccines destroyed for want of local production capacity, a state-backed manufacturing venture stalled by unresolved technology-transfer and IP bottlenecks, and a public health emergency in essential medicines triggered by import dependence- are not

[41] Folorunsho-Francis A, 'Demand for Chloroquine, Hydroxychloroquine Shoots Up Price by 350%' *PUNCH Healthwise*https://healthwise.punchng.com/demand-for-chloroquine-hydroxycholoroquine-shoots-up-price-by-350/ accessed 11 July 2026.

[42] Federal Competition and Consumer Protection Commission, 'Price Gouging, Unreasonable Arbitrary Increases in Prices of Hygiene Products and Certain Medications, Panic-Buying on Account of Coronavirus (COVID-19) Concerns' (23 March 2020) https://fccpc.gov.ng/price-gouging-unreasonable-arbitrary-increases-in-prices-of-hygiene-products-and-certain-medications-panic-buying-on-account-of-coronavirus-covid-19-concerns/ accessed 11 July 2026.

[43] UNODC Country Office Nigeria, 'Falsified Medicines in the Wake of COVID-19: An Emerging Threat for Security and Public Health in Nigeria' https://www.unodc.org/conig/en/stories/falsified-medicines-in-the-wake-of-covid-19_-an-emerging-threat-for-security-and-public-health-in-nigeria.html accessed 11 July 2026.

isolated administrative failures. They are the practical, observable consequences of the legal and institutional gaps identified in Sections 3 and 4: an outdated Patents and Designs Act, chronic underuse of TRIPS flexibilities, and the absence of coordination between Nigeria's health, trade and intellectual property institutions. It is precisely because these consequences were so visible, and so avoidable, that this article argues for urgent legislative and institutional reform rather than further incremental policy statements.

6. Patent Law as a Bridge to Public Health Equity

Strategically implemented, patent law can serve as a bridge to equitable access rather than a barrier to it. Central to that potential are the TRIPS flexibilities to wit: compulsory licensing, parallel importation and government use, which give member states, including Nigeria, legal tools to balance patent rights against public health need.

6.1 TRIPS Flexibilities in Practice

Compulsory licensing allows government authorization of the production or importation of generic versions of a patented medicine without the patent holder's consent, typically in cases of national emergency, public non-commercial use, or anti-competitive conduct.[44] Nigeria's Patents and Designs Act contains the necessary provision, but its practical use has been rare: Thailand, by contrast, issued compulsory licences for *efavirenz* in 2007, cutting costs by over 60%, while Nigeria, facing a comparable HIV burden, did not follow suit.[45] Parallel importation permits the import of patented medicines that have been legitimately sold elsewhere, without the patent holder's separate permission, opening access to lower-priced versions from other markets.[46] Government use allows the state to use a patented invention for public, non-commercial purposes without authorisation from the rights-holder, a mechanism particularly relevant during health emergencies such as COVID-19.[47] Research exceptions and patent-opposition procedures offer

[44] World Intellectual Property Organization (n 13).
[45] Babyar J, 'Trade, Intellectual Property, and the Public Health Bearing' (2022) 12(1) Health Systems (Basingstoke) 123 https://pmc.ncbi.nlm.nih.gov/articles/PMC10013560/ accessed 16 June 2025.
[46] Oloko TO, 'Legal Implication of the Effect of the TRIPS Agreement on the Trade Marks Law in Nigeria' (2016) 12(10) European Scientific Journal 140 http://dx.doi.org/10.19044/esj.2016.v12n10p140 accessed 15 June 2023.
[47] Waklek A, 'The TRIPS Agreement and Development: A Review of Nigeria's Patent Law' (2021) 9(2) International Journal of Humanities & Social Studies <www.theijhss.com> accessed 15 June 2023.

further tools for challenging weak or overly broad patents. Collectively, these flexibilities exist to prevent patent protection from becoming an insurmountable barrier to essential medicines, yet in Nigeria they remain underused for want of legal literacy, enforcement capacity and political will.

6.2 Why Nigeria Underuses These Flexibilities

Four factors explain the gap between legal entitlement and practical use. The Patents and Designs Act of 1970 has not been comprehensively updated to integrate TRIPS flexibilities, leaving legal ambiguity and procedural uncertainty.[48] Awareness among policymakers, health officials and legal practitioners of the strategic scope of these tools remains limited, though a 2024 national workshop on TRIPS, organised jointly with the WTO, represents a step toward closing that gap.[49] Political and economic pressure, to wit:- concerns about trade relations, foreign investment and pharmaceutical lobbying- continues to discourage the use of compulsory licensing despite its legitimacy under international law.[50] Furthermore, bureaucratic complexities within Nigeria's institutions hampers the timely issuance and enforcement of compulsory licences or government-use orders.[51]

6.3 Potential for Local Pharmaceutical Development and Self-Sufficiency

Effectively leveraged, patent law and TRIPS flexibilities can promote local manufacturing and reduce import dependency, strengthening Nigeria's public health resilience. Strategic use of compulsory licensing and government-use provisions can facilitate technology transfer and stimulate innovation tailored to national health priorities,[52] while flexible patentability criteria and stricter examination standards can prevent evergreening and the patent abuses that delay generic

[48] Nkomo M, 'The Under-Utilization of TRIPS Flexibilities by Developing Countries: The Case of Africa' (WTO Colloquium Papers, 2010) https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2010/chapter_11_2010_e.pdf accessed 17 June 2025.
[49] Adams & Adams, 'Nigerian National Workshop on TRIPS' (2024) https://www.adams.africa/adams-news/nigerian-national-workshop-on-trips/ accessed 17 June 2025.
[50] World Intellectual Property Organization (n 13).
[51] Nkomo (n 39).
[52] Yauri SA, 'The Patent System in Nigeria' (2012) 34(3) World Patent Information 213 https://doi.org/10.1016/j.wpi.2012.04.00 accessed 17 June 2025.

competition.[53] Aligning patent law reform with industrial policy would allow Nigeria to create the enabling conditions under which domestic pharmaceutical firms can thrive.

7. Structural Barriers to Local Production and Innovation

Nigeria's aspiration to pharmaceutical self-sufficiency is constrained by barriers that operate independently of, but interact with patent law.

Regulatory fragmentation. Pharmaceutical regulation is split across agencies with overlapping mandates: NAFDAC on drug safety, the Ministry of Health on policy, and the Trademarks, Patents and Designs Registry on patents. This fragmentation weakens the implementation of exceptions such as compulsory licensing, which requires coordinated action between health officials and IP administrators; the absence of a central coordinating body, long proposed under the dormant Industrial Property Commission Bill, leaves the regulatory ecosystem slow to respond to emergencies.[54]

Infrastructure deficits. Even where legal pathways exist to work around patent restrictions, unreliable power supply, poor transport networks and weak water and sanitation systems raise production costs and disrupt supply chains, leaving local manufacturing less competitive than imports.[55] Most local firms operate at small scale and cannot produce complex active pharmaceutical ingredients, which continue to be sourced from India and China; the 2023 exit of GSK and Sanofi from local production further exposed how fragile domestic manufacturing capacity remains.

Limited finance and skills. High interest rates and thin credit facilities restrict investment in modern equipment and R&D,[56] while a persistent shortage of specialised technical expertise constrains quality assurance and regulatory compliance.[57] Nigeria's national Research and

[53] McGivern L, 'Trade-Related Aspects of Intellectual Property Rights Flexibilities and Public Health: Implementation of Compulsory Licensing Provisions into National Patent Legislation' (2023) 101(4) Milbank Quarterly 1280.
[54] Nwafor (n 17); Anagor-Ewuzie A, 'Nigeria's Supply Chain Report Exposes Challenges to Pharmaceutical Industry' *BusinessDay* (24 July 2024) https://businessday.ng/maritime/article/nigerias-supply-chain-report-exposes-challenges-to-pharmaceutical-industry/ accessed 17 June 2025.
[55] NESG Health Policy Commission, *Enhancing Local Production of Medicines and Vaccines in Nigeria* (May 2022) https://nesgroup.org/download_resource_documents/WHITE%20PAPER%20ON%20ENHANCING%20LOCAL%20PRODUCTION%20OF%20MEDICINES%20AND%20VACCINES%20IN%20NIGERIA.pdf accessed 17 June 2025.
[56] NESG Health Policy Commission (n 46).
[57] Anagor-Ewuzie (n 45).

Development (R&D) budget remains below 1% of GDP, well short of the African Union's 2% target, and academic-industry partnerships in drug development remain rare, meaning patent law has little innovation pipeline left to protect.

Weak technology transfer and import dependence. Multinational patent holders are often reluctant to share proprietary know-how, and Nigeria lacks robust frameworks to compel or incentivise technology-transfer agreements; most active pharmaceutical ingredients and excipients are imported, exposing manufacturers to currency volatility and supply disruption.[58]

Absent political will. Vawda and Shozi's 2020 study found that many African states, Nigeria included, possess reasonably robust legal frameworks but lack the political momentum to apply TRIPS flexibilities, a gap that was particularly visible during the COVID-19 pandemic.[59] Unlike India and Brazil, Nigeria invoked no emergency IP mechanism even amid vaccine and antiviral shortages - evidence that public health has rarely driven Nigerian IP policy in practice.

Patent law's interaction with local innovation is therefore double-edged: well-designed protection can incentivise domestic R&D by guaranteeing exclusive commercialisation rights,[60] but overly broad or poorly examined patents can entrench evergreening and block the follow-on on research that generic competition depends on.[61] Addressing these barriers requires a whole-of-government response - legislative reform, regulatory restructuring, R&D investment and sustained public health advocacy - coordinated with the ongoing review of the Draft Patents and Designs (Repeal and Re-enactment) Bill, 2021 and Nigeria's participation in the African Medicines Agency.

8. Comparative Perspectives and International Best Practices

Several countries have developed strategies for balancing IP protection with equitable access that offer instructive lessons for Nigeria.

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[58] Vanni A, 'The Participation of Pharmaceutical Drug Industry in Patent Governance and Law-Making: A Case Study of India and Nigeria' (14 March 2021) https://ssrn.com/abstract=5183653 accessed 17 June 2025.

[59] Yousuf AV and Shozi B, 'Eighteen Years after Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa' (South Centre Research Paper 103, February 2020) https://www.southcentre.int/research-paper-103-february-2020/ accessed 13 July 2025.

[60] Egboh-Nwachukwu C, Olukokun K and Ishola H, *Guardians of Innovation: The Role of Intellectual Property Rights in Biotechnology and Pharmaceuticals* (G Elias) https://www.gelias.com/images/IP_ROLE_IN_BIOTECHNOLOGY_AND_PHARMACEUTICALS_11062024.pdf accessed 18 June 2025.

[61] Agbasi MN, 'An Analysis of the Effect of Pharmaceutical Patent Laws on Access to Medical Care' (2019) 7(1) ABUAD Law Journal 70 https://journals.abuad.edu.ng/index.php/alj/article/view/182 accessed 18 June 2025.

India has used TRIPS flexibilities, particularly compulsory licensing and strict patentability criteria, to build the world's leading generic pharmaceutical industry, supplying low-cost antiretrovirals and other essential medicines both domestically and globally.[62]Brazilhas combined price negotiation with compulsory licensing to secure universal access to antiretroviral therapy, contributing to a marked decline in HIV/AIDS mortality.[63]Thailand issued compulsory licences for antiretrovirals and cancer medicines after unsuccessful price negotiations, demonstrating the practical utility of TRIPS flexibilities in a middle-income setting.[64]SouthAfrica's "Fix the Patent Laws" campaign has driven legislative reform toward substantive patent examination and evergreening prevention, aligning patent protection with the constitutional right to health.[65] At the multilateral level, the World Health Organization (WHO), World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) have established trilateral cooperation to help states align IP policy with health equity goals, emphasising TRIPS flexibilities, voluntary licensing and technology transfer.[66]

Four lessons emerge for Nigeria. The first is that TRIPS flexibilities should be explicitly integrated into domestic law, removing the ambiguity that currently discourages their use, alongside a shift to substantive patent examination to curb weak or duplicate patents.[67] As a follow up, local production should be actively promoted through technology-transfer incentives, R&D grants and distributed manufacturing modelled on the Indian and Brazilian experience.[68] Third, regulatory and institutional capacity needs strengthening: a modernised, digitised patent office, better-trained examiners, and judicial expertise capable of resolving IP disputes efficiently. Finally, reform should be pursued through multi-stakeholder's engagement, drawing in civil society, patient

[62] Patents (Amendment) Act 2005 (India), s 3(d); *Novartis AG v Union of India* (2013) 6 SCC 1.
[63] Lei de Propriedade Industrial (Industrial Property Law) No 9.279/96 (Brazil).
[64] Babyar (n 36).
[65] Section27, 'Fix the Patent Laws Campaign Supports Efforts to Increase Access to Medicines through Intellectual Property Reforms at International and Domestic Levels' (2022) https://section27.org.za/2022/06/ftpl-patent-law-reform-june-2022/ accessed 12 June 2025.
[66] Sharma A, 'Patent Law and Vaccination Policy: Balancing Innovation with Global Health Equity' (Center for Study and Research in Intellectual Property Rights, NUSRL) https://csriprnusrl.wordpress.com/2025/07/04/patent-law-and-vaccination-policy-balancing-innovation-with-global-health-equity/ accessed 27 June 2025.
[67] Section27 (n 56).
[68] World Intellectual Property Organization, 'Bridging the Gap: The Role of Finance and IP in MedTech Innovation and Access' (2024) https://www.wipo.int/en/web/global-health/w/news/2024/news_0015 accessed 27 June 2025.

groups and industry, supported by technical assistance from WHO, WIPO and WTO and by regional cooperation to harmonise patent laws and pool procurement across Africa.[69]

International experience shows that balancing IP protection with health equity is both possible and achievable, provided TRIPS flexibilities are embedded in domestic law, local production is promoted, and policy development remains inclusive. For Nigeria, adapting these practices is the clearest route from patent law as barrier to patent law as bridge.

9. Recent Policy Developments

Nigeria has recently taken several steps that suggest a growing, if still incomplete, recognition of the need to align patent law with public health goals. The revised National Drug Policy (2021) emphasises self-sufficiency and local production, aligning with the National Health Act 2014 and the National Strategic Health Development Plan.[70] The Draft Patents and Designs (Repeal and Re-enactment) Bill, 2021, introduced in April 2021 and endorsed for second reading by the House of Representatives in May 2021, proposes to replace the 1971 Act with a modern statute incorporating utility-model certificates, clearer compulsory-licensing grounds covering public interest, national emergency and anti-competitive conduct, and enhanced enforcement mechanisms.[71] Nigeria's National Intellectual Property Policy and Strategy, developed with WIPO and validated in September 2022, calls for strengthened IP administration, improved technology transfer, and a deliberate balance between IP protection and public interest, including access to medicines.[72] In 2024, an Inter-Ministerial Committee spanning Trade, Health and Justice was convened to review and update this policy, signalling political intent to overhaul the framework,

[69] World Intellectual Property Organization (n 59).
[70] Federal Ministry of Health, Nigeria (with World Health Organization), *National Drug Policy* (3rd edn, 2021) https://policyvault.africa/wp-content/uploads/policy/NGA1477.pdf accessed 22 June 2025.
[71] Nigerian Tribune, 'Reps Support Bill on Protection of Intellectual Property, Innovation' (20 May 2021) https://tribuneonlineng.com/reps-support-bill-on-protection-of-intellectual-property-innovation/ accessed 12 July 2025; Vanguard, 'Reps Repeal Patents, Designs Act to Effectively Protect Intellectual Properties' (21 May 2021) https://www.vanguardngr.com/2021/05/reps-repeal-patents-designs-act-to-effectively-protect-intellectual-properties/ accessed 12 July 2025.
[72] World Intellectual Property Organization, 'Nigeria Validates National IP Policy and Strategy (NIPPS)' (2022) https://www.wipo.int/web/office-nigeria/w/news/2022/news_0002 accessed 12 July 2025.

though implementation remains pending.[73] Regionally, the African Medicines Agency (AMA), ratified by fifteen African Union member states and in force since November 2021, aims to harmonise medicines regulation across the continent, support local pharmaceutical production under the AU's Pharmaceutical Manufacturing Plan for Africa, and coordinate joint clinical trial and product reviews.[74] For Nigeria, active participation in AMA offers a route to faster regulatory approval and reduced dependence on imports from multinational suppliers, provided domestic patent law is aligned to support rather than obstruct that continental effort.[75] Each of these initiatives, however, is only as effective as its implementation; policy pronouncements alone have not yet translated into measurable gains in medicine access.

10. Policy Recommendations: Building a Bridge, Not a Barrier

1. Mordenize the Patents and Designs Act: Nigeria should replace the outdated 1971 Act with a statute containing clear, flexible provisions for compulsory licensing and government use during public health emergencies, explicit safeguards against evergreening, and defined patentability criteria that prevent minor reformulations of existing drugs from receiving fresh twenty-year monopolies.
2. **Operationalising TRIPS flexibilities and local production.** Nigeria must actively use its TRIPS flexibilities, streamlining procedures for compulsory licensing and government use to build legal confidence in their application, needed to invoke them promptly during public health emergencies. This should be paired with investment in pharmaceutical R&D, tax incentives and public-private partnerships to support local manufacturing, and stronger technology-transfer frameworks to build sustainable domestic production capacity.

[73] The Guardian Nigeria, 'FG Kick-Starts Review of National Intellectual Property Policy and Strategy' (2 June 2024) https://guardian.ng/news/fg-kick-starts-review-of-national-intellectual-property-policy-and-strategy/ accessed 12 July 2025.

[74] BusinessDay NG, Anyakora C, 'Establishment of African Medicines Agency: A Critical Step in Achieving Health Security' (26 July 2022) https://businessday.ng/columnist/article/establishment-of-african-medicines-agency-a-critical-step-in-achieving-health-security/ accessed 13 July 2025; African Union, 'Frequently Asked Questions (FAQs) on the African Medicines Agency (AMA)' (7 December 2021) https://au.int/en/documents/20211207/frequently-asked-questions-faqs-african-medicines-agency-ama accessed 13 July 2025.

[75] AUDA-NEPAD, 'African Medicines Agency (AMA)' https://www.nepad.org/microsite/african-medicines-agency-ama accessed 13 July 2025.

3. **Anchor patent policy in the right to health: R**eform should expressly recognise the right to health as a guiding principle of patent administration, drawing on Article 12 of the International Covenant on Economic, Social and Cultural Rights and comparable constitutional protections, so that access to essential medicines is treated as a legal priority rather than a discretionary concession.
4. **Invest in local pharmaceutical manufacturing:** Government should back investment in pharmaceutical research and development, offer targeted tax incentives and public-private partnerships, and build binding technology-transfer frameworks that give domestic manufacturers a legal pathway to access patented active pharmaceutical ingredients and vaccine platforms; addressing directly the stalled experience of ventures such as Biovaccines Nigeria Limited.
5. **Strengthen institutional capacity:** Government capacity requires reinforcement through stronger regulatory institutions. The Trademarks, Patents and Designs Registry needs more skilled patent examiners, digitised and searchable records, and formal coordination mechanisms linking it with the Federal Ministry of Health, NAFDAC and the Ministry of Trade, so that health emergencies trigger rapid, coordinated intellectual property responses rather than fragmented ones.
6. **Deepen regional cooperation:** Nigeria should deepen regional cooperation through the African Continental Free Trade Area, ECOWAS and the African Medicines Agency to harmonise patent laws, pool procurement, and facilitate cross-border technology transfer, reducing the country's exposure to single-source import shocks. We must at the same time, train judges, policymakers and regulators, and engaging civil society, patient groups, academia and industry in an inclusive, pragmatic reform process that strengthens accountability and sustains progress toward equitable medicine access.
7. **Pursue inclusive, multi-stakeholder reform:** Legislative and institutional change should be developed through sustained engagement with civil society, patient advocacy groups,

academia and industry, and supported by training for judges, legislators and regulators, so that reforms are both technically sound and publicly accountable.

11. Conclusion

Patent law occupies a genuinely pivotal position in Nigeria's public health landscape, functioning simultaneously as bridge and barrier. It incentivises pharmaceutical innovation and the development of new treatments, yet when rigidly enforced without regard to public health imperatives, it restricts the availability and affordability of life-saving medicines, disproportionately harming marginalised populations. The COVID-19 pandemic exposed this tension starkly, underscoring the need for a pragmatic recalibration that balances patent holders' legitimate interests against the fundamental right to health.

How do we go about this? The answer is co-ordinated action: policymakers must embed TRIPS flexibilities clearly into domestic law; the judiciary and legal profession must be equipped to interpret patent law in ways that uphold public health priorities; and public health stakeholders must continue to advocate for policies that prioritise equitable access and domestic manufacturing capacity. Strengthening local production, improving regulatory frameworks and deepening international and regional partnerships are not merely desirable: they are expedient for building resilience against the next public health emergency.

Patent law, misapplied, limits the very development it is meant to serve. For Nigeria, the question is no longer whether to maintain a patent regime, but how to wield it so that innovation and access reinforce rather than undermine one another. Nigeria already possesses the legal framework required to make that shift. What remains is the political will to use it.