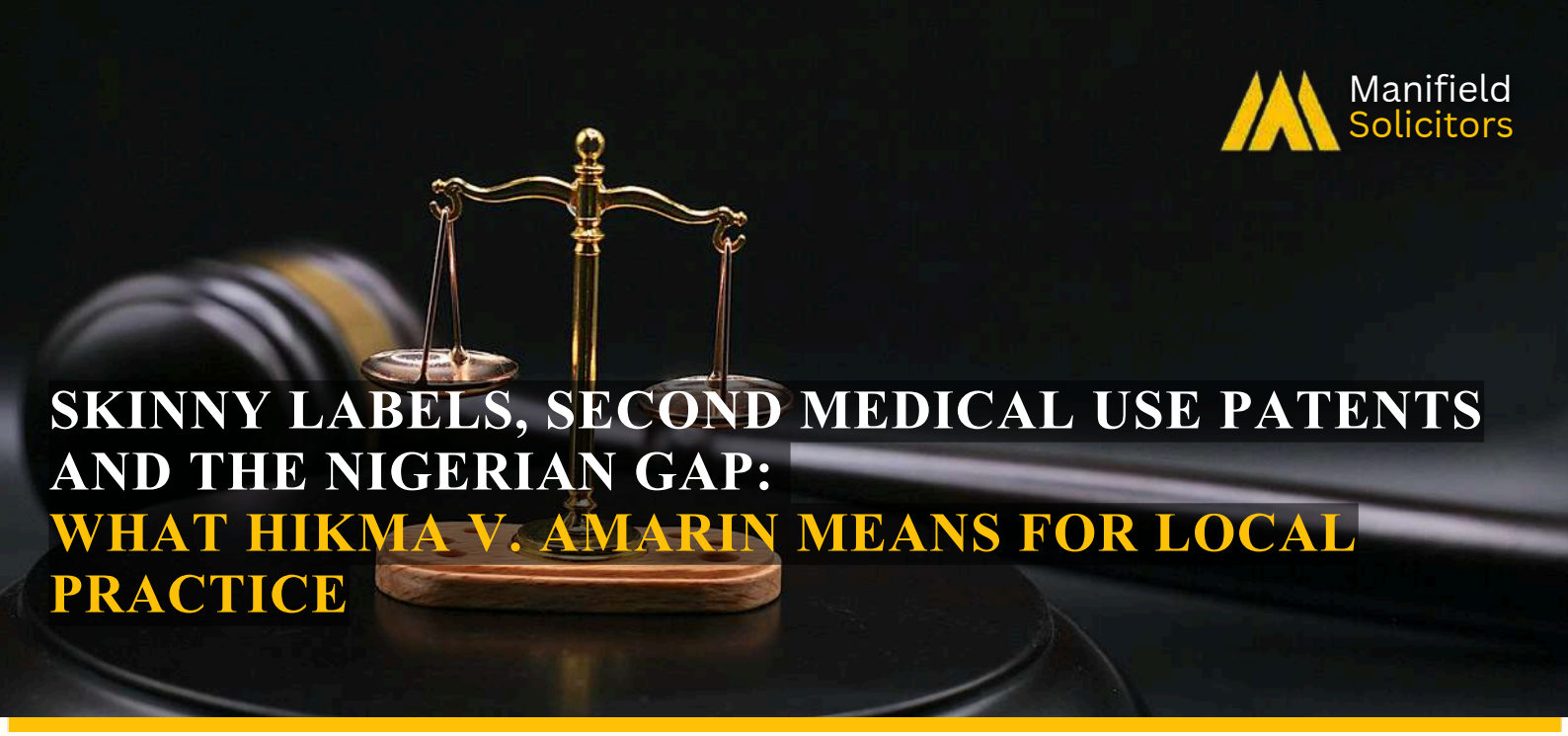

SKINNY LABELS, SECOND MEDICAL USE PATENTS AND THE NIGERIAN GAP: WHAT HIKMA V. AMARIN MEANS FOR LOCAL PRACTICE

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INTRODUCTION

Every so often a patent dispute over a single drug ends up reshaping the rules for an entire industry. Back in June, the US Supreme Court delivered one of those decisions. Although the case itself is American, the question underneath it is one Nigerian pharmaceutical patent practice will eventually have to confront, and with considerably less law to work from than either the US or the UK currently has.

In Hikma Pharmaceuticals USA Inc v Amarin Pharma Inc (2026), a unanimous Court sided with the generic drugmaker. It held that Hikma's marketing of its version of the cardiovascular drug Vascepa did not amount to induced patent infringement, even though Amarin still held patents covering the drug's most commercially important use. For an industry that had spent the past few years bracing for the opposite outcome, the ruling was a significant relief. The UK, as it happens, has never fully settled the same question either. Nigeria, as the final part of this piece sets out, has barely begun to ask it.

THE SKINNY LABEL WORKAROUND

Drug patents do not only protect a chemical compound. They can also protect a specific medical use of that compound, through what is known as a method-of-use, or "second medical use," patent. That lets a company retain exclusive rights over one application of a drug even after the underlying compound patent, and the drug's original approved use, have expired.

This creates a genuine problem for generic manufacturers. If a drug has several approved uses and only some of them remain patented, how does a generic company enter the market at all without risking infringement? Regulators' answer, at least in the United States, is the "skinny label": an abbreviated product label that omits the still-patented indications and lists only the ones that are free and clear. The generic drug itself is chemically identical to the branded version. It is the paperwork, not the pill, that has been slimmed down.

The trouble is that doctors are free to prescribe medicines off-label. Nothing stops a physician from prescribing a skinny-labelled generic for the exact use its label leaves out, and that raises an uncomfortable question for brand-name manufacturers: can they hold the generic company responsible for what doctors do next?

HOW VASCEPA ENDED UP IN COURT

Amarin's drug Vascepa (icosapent ethyl) was first approved in 2012 to treat severe hypertriglyceridemia, a condition marked by very high blood fat levels. Seven years later the US Food and Drug Administration approved a second, far more common use: reducing cardiovascular risk in patients with elevated triglycerides who are already taking statins. Amarin patented that cardiovascular indication, and it quickly became the commercial heart of the Vascepa franchise (Hikma Pharmaceuticals USA Inc v Amarin Pharma Inc, 2026).

When Hikma won approval for a generic version in 2020, it did so under a skinny label covering only the original, unpatented indication. On paper that should have kept Hikma clear of Amarin's patents. Amarin disagreed. It argued that Hikma's skinny label, patient leaflet, website .

and press releases, which described the product simply as a “generic version” of Vascepa, together added up to active encouragement of the still-patented cardiovascular use. Legally, that is a claim of induced infringement.

A district court threw the case out. The Federal Circuit brought it back to life, ruling that it was at least plausible a physician could read Hikma’s statements as encouragement to prescribe off-label. That decision unsettled the generics industry, because it implied that routine, government-mandated marketing language might itself be enough to trigger liability, which would make skinny labels far less useful than they were designed to be (Hikma Pharmaceuticals USA Inc v Amarin Pharma Inc, 2026).

WHAT THE SUPREME COURT ACTUALLY DECIDED

On 4 June 2026 the Supreme Court disagreed and reinstated the dismissal. Writing for a unanimous bench, Justice Ketanji Brown Jackson framed the real question as whether Amarin had plausibly alleged that Hikma actively encouraged the infringing use, not simply whether a doctor could have read Hikma’s materials that way (Hikma Pharmaceuticals USA Inc v Amarin Pharma Inc, 2026).

That is a meaningfully higher bar. Statements that merely could be understood as encouragement do not clear it. A patent owner has to show the generic company’s conduct was aimed at prompting the infringing use. The Court left room for that encouragement to be implicit rather than explicit, so a skinny label is not an automatic shield in every future case. But describing a generic as the equivalent of its brand-name counterpart, without more, is ordinary industry practice rather than evidence of intent to induce infringement

For generic manufacturers that is a substantial win. Complying with the skinny-label pathway, plus standard marketing language, will generally not expose them to liability on its own. For originator companies it narrows the options for policing off-label use once a skinny-labelled competitor reaches the market.

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THE VIEW FROM THE UK

The UK matters here for more than comparison's sake. Nigerian patent law traces directly back to English patent practice, and Nigerian courts routinely reach for English authority where local precedent is thin, which on this question it is. British courts, however, have never fully resolved the point themselves.

The leading case, Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) [2018] UKSC 56, concerned Lyrica (pregabalin). Once its underlying compound patent expired, epilepsy and anxiety treatment opened up to generics, while a separate patent specifically covering pregabalin's use for neuropathic pain remained in force. Generic manufacturers launched skinny-labelled versions covering only the unpatented uses, and Warner-Lambert sued regardless.

By the time the case reached the UK Supreme Court in 2018, the underlying pain patent had already been found invalid for lack of sufficient disclosure, so the justices did not strictly need to rule on infringement at all. They did so anyway, across four separate opinions, and landed roughly 2:2:1

(Warner-Lambert Company LLC v Generics (UK) Ltd, 2018). Two justices, Lord Sumption and Lord Reed, said the manufacturer's state intent-based evidence entirely in unusual cases.of mind does not matter at all: what the product looks like on the outside, packaging included, is what counts. Two more, Lord Hodge and Lord Briggs, said intent is exactly what matters, and can be proven through conduct, including marketing and even silence, even without an explicit admission. The fifth, Lord Mance, landed mostly with the first camp but stopped short of ruling out

Tellingly, all five judges agreed on the actual result. On these specific facts the generic manufacturer's conduct would not have infringed even if the patent had been valid. The disagreement was over which test should govern future cases, not over how this one came out, which is a more reassuring signal for generics than "the law is unsettled" alone suggests.

Still, no single test commands a majority, so the next UK case to squarely confront the issue could go either way. A conduct-based test would land close to the US Supreme Court's active-encouragement standard from Hikma. A pure outward-presentation test would be considerably more forgiving of generics, since a press release calling the product equivalent to the branded drug would not matter as long as the label itself stayed compliant.

WHAT ABOUT NIGERIA?

Neither the US position nor the UK's unsettled one transplants cleanly onto Nigerian law, and the reasons are worth setting out properly rather than assumed away.

Start with whether the underlying patent would even be valid subject matter. The Patents and Designs Act, Cap P2, Laws of the Federation of Nigeria 2004, Nigeria's principal patent statute since 1971, excludes a method of medical treatment or diagnosis from patentable subject matter, alongside the more familiar exclusions for discoveries and plant and animal varieties (Federal Republic of Nigeria, 2004). That exclusion sits squarely across claims like Amarin's: a patent on a method of reducing cardiovascular risk using a known compound.

Whether a Swiss-form claim, drafted as the use of a substance in the manufacture of a medicament for a stated purpose rather than as a method of treatment outright, would escape that exclusion is genuinely untested here. It escapes the equivalent exclusion in Europe only because the European Patent Office built a specific doctrinal workaround for it over decades of case law. Nigerian law has built no such thing, and no reported Nigerian decision has tested whether a court here would extend the same courtesy.

Then there is the fact that grant is not conditioned on examination. The Patents and Designs Act does not require the Patents Registry to conduct substantive examination before a patent is granted. An application proceeds to registration once the formalities, being the specification, the claims and the fee, are in order; the Act does not require the Registry to examine whether the claimed subject matter is patentable under Section 1 (Federal Republic of Nigeria, 2004).

One consequence of that statutory design is that a second-medical-use patent could, in principle, be registered even where it may not meet the patentability requirements of Section 1. That does not leave such a patent immune from challenge. Section 9 of the Act provides a nullity action, and where a patent's subject matter falls within a statutory exclusion as clearly worded as the medical-treatment exclusion, that is a straightforward ground on which validity could be tested. What it does mean is that, absent such a challenge, a granted patent remains on the register and available to be relied upon, including as the basis for an infringement claim, until its validity is tested.

The regulatory hook that turns a skinny label into a formal, defined artefact in the US does not exist here either. The American system ties drug approval directly to patent status: a generic applicant must certify against the originator's listed patents, and it is that certification that produces a skinny label as a specific regulatory filing. NAFDAC's registration process has no counterpart to any of this.

It assesses safety, quality, manufacturing compliance and, for generics, bioequivalence. It does not check, list or certify against patents at all (National Agency for Food and Drug Administration and Control, 2025). A generic manufacturer can secure NAFDAC approval regardless of what patents cover which indications, and nothing in that process obliges anyone to carve anything out of a Nigerian label. Any skinny labelling that happens in the Nigerian market is a voluntary commercial and litigation-risk decision, not a step in a regulatory pathway. That also means there is no approved document a Nigerian court could point to as the objectively compliant version of events, the way both the Hikma Court and the Warner-Lambert justices could.

The infringement provision itself is thin on exactly this point too. Section 25 of the Act makes it an infringement to do, or cause to be done, any act reserved to the patentee (Federal Republic of Nigeria, 2004). That "cause to be done" language is the only real statutory hook for anything resembling induced infringement. There is no Nigerian equivalent to the American inducement standard, no developed case law on specific intent or active steps and nothing addressing marketing language, off-label prescribing or pharmacist substitution in this context. A Nigerian court asked whether calling a product a generic equivalent amounts to inducement would be working from close to a blank slate. Given the Act's roots in English patent practice, Warner-Lambert is the more natural persuasive authority to reach for than Hikma, but no Nigerian court has yet had occasion to reach for either.

The practical upshot is less a rule to follow than an exposure to manage. For an originator client, a method-of-use patent may well register despite the Section 1 exclusion, but enforcing it against a skinny-labelled generic means litigating validity and infringement at the same time, with no local precedent on either question. For a generic client, the absence of a regulatory skinny-label pathway cuts both ways. There is more freedom to label as commercial judgment dictates, but also no official safe harbour document to point to if a dispute arises. Nigeria's National Intellectual Property Policy and Strategy, approved in late 2025,

signals that reform is finally on the agenda, but it has not yet reached these specific questions (European Commission Intellectual Property Helpdesk, 2026). Until the Federal High Court gets a case that squarely raises them, this remains genuinely open ground in a market too large for the silence to last indefinitely.

ALIGNING WITH THE INTERNATIONAL COMMUNITY

None of the gaps above are reasons for despair. Several are reasons for deliberate choice, and at least one of them already has a live template close to home.

Examination is the most tractable fix, and Nigeria would not have to build it alone. South Africa has run the same non-examining, depository-style system as Nigeria for decades, and is now moving, through a forthcoming Patents Bill, toward a phased substantive search and examination model, starting in technical fields where examiner capacity already exists rather than attempting full examination everywhere at once (Chambers and Partners, 2026).

It is a realistic template to adapt rather than a distant aspiration, and it answers the paper-patent problem described above directly. Nigeria's membership of the Patent Cooperation Treaty, in force since 2005

adds a second and cheaper lever (World Intellectual Property Organization, 2005). Many lightly resourced patent offices already lean on the search and examination reports produced during a PCT application's international phase as a substitute for full local capacity. Doing the same for applications that arrive via the PCT route would import a layer of substantive scrutiny without Nigeria having to fund a full examination corps immediately.

On second medical use claims specifically, Nigeria needs a position more than it needs a particular answer. The exclusion of methods of medical treatment from patentability is not, by itself, a point of international non-alignment. Article 27.3(a) of the TRIPS Agreement expressly permits World Trade Organization members to exclude therapeutic and diagnostic methods, and Nigeria's exclusion sits comfortably within that flexibility (World Trade Organization, 1994).

The real gap is narrower. Nigeria has never said whether a Swiss-form or purpose-limited claim escapes that exclusion the way it does at the European Patent Office, or whether it should be treated as the same prohibited subject matter by another name, the way India's Section 3(d) treats a great deal of secondary pharmaceutical patenting (Novartis AG v Union of India, 2013). Both are internationally recognised, defensible positions, and they pull in different directions. One favours the innovation incentives that keep originator research flowing into new uses of old molecules.

The other favours faster, cheaper generic access for a country with Nigeria's public health burden and a domestic generics industry worth protecting.

What Nigeria cannot indefinitely do is leave the question unanswered and let it be settled by accident, whenever the first contested case happens to reach the Federal High Court.

Regionally, Nigeria is already more engaged than its patent law reflects. It has ratified the underlying AfCFTA Agreement and was the first State Party to complete parliamentary ratification of the AfCFTA Protocol on Digital Trade (Diplomatic Times Online, 2026). Yet Nigeria sits outside both ARIPO and OAPI, the continent's two regional patent systems (Spoor & Fisher, 2022), and the AfCFTA Protocol on Intellectual Property Rights, adopted in 2023, is still short of the ratifications it needs to take effect (tralac, 2023).

That combination looks like a genuine strategic choice rather than an oversight, since Nigeria is large enough to run its own national system instead of defaulting to a regional one. But it means any reform to

the Patents and Designs Act is a chance to build in compatibility with the IP Protocol now, ahead of its entry into force, rather than retrofitting national law to continental obligations under time pressure later.

Finally, Section 25 needs somewhere to go. Whether that comes from a legislative amendment spelling out an inducement standard, or from Nigerian courts building the doctrine incrementally through case law the way the United States built its own active-steps test across Metro-Goldwyn-Mayer Studios Inc v Grokster Ltd (2005) and Global-Tech Appliances Inc v SEB SA (2011) and now Hikma over two decades, either path beats the current position, in which the statute has the words but no test behind them. The National Intellectual Property Policy and Strategy adopted in late 2025 is the natural vehicle for the legislative route, if the political will follows the paperwork.

THE TAKEAWAY FOR NIGERIAN PRACTICE

Hikma v Amarin and Warner-Lambert both show mature patent systems still working out exactly where a fair skinny label ends and active inducement begins, after decades of litigation and, in the American case, a trip to the Supreme Court. Nigeria has not had that conversation yet, in court, in the Registry or in the reform process now underway. That is not a reason for alarm, but it is a reason for care on both sides of a Nigerian pharma dispute. Originator clients should not assume a method-of-use patent is safe just because it registered, and generic clients should not assume a skinny label protects them just because nothing in Nigerian law formally requires or polices one. Until the Federal High Court, the Registry or the legislature says otherwise, the soundest advice is also the most oldfashioned kind: careful patent drafting, cautious marketing, and close attention to a reform conversation that Nigeria, for once, still has the chance to get ahead of rather than merely react to.

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