The Indian Journal for Research in Law and Management

Open Access Law Journal – Copyright © 2026

Editor-in-Chief – Dr. Muktai Deb Chavan; Publisher – Alden Vas; ISSN: 2583-9896

SKINNY LABELS, SECOND MEDICAL USE PATENTS AND GENERIC MARKET ENTRY: REASSESSING INDIA'S PHARMACEUTICAL PATENT AND REGULATORY FRAMEWORK

~ Piha Birla

ABSTRACT

India relies on substantive patentability standards, rather than regulatory patent-management mechanisms, to govern generic entry into its pharmaceutical market. This approach distinguishes India from the two of the world's leading pharmaceutical jurisdictions, the United States and the European Union. In the United States, patent status is directly linked to drug approval via the Orange Book and Hatch-Waxman's carve-out procedure. The European Union and Canada, in contrast, keep patent status and drug approval formally separate, but still require public disclosure of limited information about protected indications. India separates the two regimes completely and discloses almost nothing between them. India represents a distinct model of pharmaceutical patent regulation, i.e., patent independence without patent transparency. The claim-drafting practice at the Indian Patent Office has widened the gap in the model since 2005. Formulation, combination, and polymorph patents keep bypassing examination even if direct therapeutic use claims would fail under Section 3(i). So generic manufacturers are left with no reliable way to assess their independence to operate in the market. The paper explains how the gap developed and proposes a narrow, linkage-free disclosure to close it.

THE EMERGING DISCONNECT BETWEEN PATENTABILITY AND DRUG REGULATION

Let's start with a question: Why do secondary pharmaceutical patents continue to shape generic entry in India despite a legal framework designed to restrict them? India rejects patent linkage.

This position was settled in the case of Bayer Corp. v. Union of India years ago[1]. It also rejects second medical use claims, whether drafted in the Swiss form or the purpose-limited product claims. Section 3(i) of the Patent Act, 1970, explicitly excludes methods of treatment from patentable subject matter regardless of novelty[2]. Section 3(d) also exists to prevent known molecules from being re-patented through minor modifications[3]. Three doors appear to be closed on paper, and so secondary pharmaceutical patents in India appear to be scarce. But in reality, this is not the case. Formulation, combination, and polymorph patents continue to exist around molecules whose compound patents have already expired. Cases with such patents keep reaching Courts, sometimes with heavy damages attached.

Three models of generic entry emerge once the comparative record is read side by side rather than one jurisdiction at a time. The United States runs on patent linkage: approval and patent status are tied together formally through the Orange Book, and a generic must certify against, or carve around, every listed patent before the FDA will approve it. The European Union and Canada run something closer to patent transparency: approval and patent status stay separate, yet each system still requires information about protected uses to be made public, through the Article 11 carve-out built into EU generics law, or through Canada's Patent Register under the Patented Medicines (Notice of Compliance) Regulations[4].

India runs a third model that is a category of its own, i.e. patent independence. CDSCO approval and Patent Office status are not simply kept apart, as Bayer confirmed. Nothing requires either regulator to put information the other needs into a form anyone can use. India has not failed to build linkage. It has built something none of its usual comparators run, independence without transparency.

Patent independence was a good choice as a policy in 2005, when the worry was limited to import delay into a market built on excessive generic supply. It makes less sense around Section 3(d) and 3(e), because independence without any requirements of disclosure leaves a generic manufacturer with no chance to gain information before committing to production that whether a molecule carries ongoing protection through a patent buried in the Patent Office's records.

[1]Bayer Corp. & Anr. v. Union of India & Ors., L.P.A. No. 443 of 2009 (Del. H.C. Feb. 9, 2010) (upholding the Single Judge's finding that no patent linkage exists between the Drugs and Cosmetics Act, 1940 and the Patents Act, 1970, and that the Central Drugs Standard Control Organisation owes no duty to verify patent status before granting marketing approval).
[2]The Patents Act, No. 39 of 1970, § 3(i) (India).
[3]The Patents Act, No. 39 of 1970, § 3(d) (India), § 3; Novartis AG v. Union of India, (2013) 6 SCC 1.
[4]Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 (Can.).

The assumption that non-linkage costs nothing once the patentability filter is strict enough deserves closer scrutiny than it has received.

PATENT LINKAGE SYSTEM IN THE UNITED STATES

By design, the American system links patent status with regulatory approval. Under the Drug Price Competition and Patent Term Restoration Act, 1984, commonly known as the Hatch-Waxman Act, a company with an approved New Drug Application (NDA) must list its relevant patents, and the specific use each one of them covers. They are to be listed in the FDA's Orange Book[5]. A generic applicant filing an Abbreviated New Drug Application (ANDA) must then address those patents through the certification framework under 21 U.S.C. § 355(j)(2)(A)(vii) against each listed patent. Wherever some indicators of a multi-use drug remain protected, while others are not, the generic applicant may file a statement under 21 U.S.C. § 355(j)(2)(A)(viii), carving the protected use out of its own label. What emerges out of this is a skinny label. It means that the generic contains the same active ingredient as the branded drug but is approved only for indications that are outside the remaining patent protection.

The mechanism looks straightforward until the drug actually reaches the market. In GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc., Teva used the section viii carve-out to remove the patented congestive-heart-failure indication from its carvedilol label[6]. The jury still found Teva liable for inducing infringement. It reasoned that the marketing and the language retained on the label led physicians to prescribe the generic for the patented indication. The case exhibits a limitation that removing a patented indication from the label does not necessarily eliminate infringement risk. Disclosure requirements reduce uncertainty, but do not remove it. This distinction is important for India as well. Any reform aimed at improving disclosure and transparency may facilitate generic entry, but it cannot resolve the question of infringement.

INDIA'S STATUTORY FIREWALL

Section 3(d) denies patentability to a new form of a known substance unless that form shows significantly enhanced efficacy[7]. The Novartis AG v. Union of India case gave this standard its real force. For a pharmaceutical invention, only therapeutic efficacy is counted. So,

[5]Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.); see 21 U.S.C. § 355(j)(2)(A)(vii)-(viii).
[6]GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320 (Fed. Cir. 2021).
[7]The Patents Act, No. 39 of 1970, § 3(d) (India).

improvements in bioavailability, stability, or flow properties do not satisfy the requirement[8]. Novartis therefore lost its patent for the beta-crystalline form of imatinib mesylate even after showing a thirty percent increase in bioavailability, because bioavailability was not the right kind of gain.

Section 3(e) addresses a different issue. It bars a substance obtained by mere admixture that only aggregates the properties of its components[9]. The pharmaceutical examination guidelines, 2014, however, read this to allow combination claims where the components interact to produce an effect greater than the sum of their parts, what is described as synergy[10]. Section 3(i) creates a separate exclusion altogether. It bars any claim directed towards a method of treating the human body, regardless of how it was drafted. This is why Swiss-type and purpose-limited product claims familiar from European practice cannot be used in India to obtain protection for a therapeutic use since it would fall within the Section 3(i) exclusion.

The next two provisions deserve more attention than they usually receive. Section 48 sets out what a patent offers, the rights conferred, including the exclusive right to prevent others from making, using, offering for sale, selling, or importing the patented product.[11]. Once a secondary patent clears the filters under Section 3(d) and 3(e), its claims carry the same enforcement force as a primary compound patent. Indian law does not reduce that force merely because the patent is limited to a particular indication. Unlike jurisdictions which use a formal code to calibrate infringement, India has no such mechanism.

Section 84 operates at the opposite end of this framework. Although it does not directly address the problem, it is relevant because it provides a mechanism for compulsory licensing. It lets a third party apply for a compulsory licence three years after grant where the patented invention's reasonable requirements are not met, it is unavailable at a reasonably affordable price, or it is not worked in India[12]. The Controller's decision in Natco Pharma Ltd. v Bayer Corp. for granting a compulsory licence over Bayer's sorafenib patent to Natco Pharma and upheld on appeal, remains the only one India has issued under Section 84 to date[13], which says as much about how rarely the section is used as about its availability in principle.

[8]Novartis AG v. Union of India, (2013) 6 SCC 1.
[9]The Patents Act, No. 39 of 1970, § 3(e) (India).
[10]Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, Office of the Controller General of Patents, Designs & Trade Marks, ¶ 6 (Oct. 2014).
[11]The Patents Act, No. 39 of 1970, § 48 (India).
[12]The Patents Act, No. 39 of 1970, § 84 (India).
[13]Natco Pharma Ltd. v. Bayer Corp., Compulsory Licence Application No. 1 of 2011 (Controller of Patents, Mar. 9, 2012), aff'd on appeal by the Intellectual Property Appellate Board and, subsequently, the Bombay High Court.

Section 107A provides a Bolar-type research exemption, which permits a generic manufacturer to make, use, or sell a patented invention solely to generate the data for regulatory approval, before the patent expires[14]. This allows an Indian generic to complete the regulatory process early and enter the market right after the patent protection lapses. This provision rests on the assumption that the manufacturer is aware when the protection is ending. This assumption holds when the protection lies in a compound patent with a fixed and publicly ascertainable term. But when additional protection is claimed through formulation or combination patents, the assumption fails because such public records are rarely available that tell what part of the patent remains enforceable past the patent's expiry. Section 107A facilitates regulatory preparation for generic entry, but it says nothing about the question of how a generic manufacturer may determine when the market entry actually opens.

Then how do these formulation and combination claims actually survive examination, given the bar under Section 3(d)? The answer lies in how the provision is applied in practice. The 2014 pharmaceutical examination guidelines set out the requirements of enhanced efficacy and the synergy standard, but leave much of its application to the judgement of individual examiners. They do not lay down a unform approach or a binding precedent that every examiner must follow. As a result, the practice varies across the four patent offices in Delhi, Mumbai, Chennai, and Kolkata, as well as between controllers within same office. This does not indicate bad faith or deliberate inconsistency. Rather it reflects the difficulty of applying a fact-based standard across an examination system without sufficient centralized and binding guidance. The problem is not the rule itself but the difficulty is ensuring the consistent application across the patent system.

THE QUIET SURVIVAL OF SECOND MEDICAL USE PROTECTION THROUGH CLAIM DRAFTING

The decisions of the Patent Office show a pattern when grouped by claim type. It shows how protection linked to a particular indication can survive the Section 3(d) barrier.

Salt and polymorph claims face greater difficulty when they lack comparative data. In the application for a thermodynamically stable tosylate salt form of sorafenib, the Controller refused the claims because the specification did not provide examples or relevant data showing

[14]The Patents Act, No. 39 of 1970, § 107A (India).

an inventive step or enhanced efficacy over the known compound[15]. In contrast, the application for a polymorphic form of rifaximin was granted despite a 3(d) objection because the applicant showed the polymorph's in vivo absorption ran roughly a hundred times lower than the earlier form, producing a corresponding drop in toxicity, a pharmacological fact rather than a formulation convenience[16].

Isomer and enantiomer claims survive on the same logic, one level more technical. The chiral resolution application for tofacitinib was initially rejected for lack of comparative efficacy data against the parent racemic compound, but the Intellectual Property Appellate Board reversed on affidavit evidence showing the isolated enantiomer was four to six times more potent, a difference the Board treated as biologically and statistically meaningful[17]. Combination and drug-delivery claims are examined under Section 3(e) rather than 3(d). They can clear the bar once the applicant shows the combined formulation outperforms the simple addition of its parts. This happened with a granted application for a drug-delivery system administering a water-soluble cationic and amphiphilic active substance[18].

Taken together, these examples show how the statutory framework operates in practice. Section 3(d) and 3(e) do not examine whether a claim describes a new therapeutic use because Section 3(i) has already excluded such claims. Instead, they ask whether a physical, chemical, or pharmacokinetic change in the product produces enhanced efficacy or a synergy, supported by evidence[19]. An applicant cannot claim the new use directly. But protection may still be obtained through a salt, a polymorph, an isomer, or a combination, where statutory requirements are satisfied and supported by adequate data. Resultant is a system that restricts the form of the claim rather than its commercial purpose, allowing claim drafting to adapt to securing protection. Second medical use protection survives in India under other names: a molecule can look open, its compound patent expired and its therapeutic use unpatentable under Section 3(i), while a narrower claim from one of these categories still stands. The difficulty is that it is

[15]In re Application No. 1960/DELNP/2007 (Thermodynamically Stable Form of a Tosylate Salt) (Indian Patent Office, Controller's Decision).
[16]In re Application No. 106/DELNP/2008 (Polymorphic Forms of Rifaximin, Process for their Production and Use thereof in Medicinal Preparations) (Indian Patent Office).
[17]In re Application No. 991/MUMNP/2003 (Chiral Salt Resolution), Order No. OA/2/2016/PT/MUM/3482 (Intellectual Property Appellate Board) (leading to grant of Indian Patent No. 352215).
[18]In re Application No. 2343/KOLNP/2010 (Indian Patent Office) (drug delivery system for administration of a water-soluble cationic and amphiphilic pharmaceutically active substance).
[19]Saipriya Balasubramanian, Patenting 'Second Medical Use' Inventions in India, Zacco Insights (2023).

discoverable only by searching records, and the law does not oblige a generic to search exhaustively before production.

PATENT THICKETS AND THE ECONOMICS OF EVERGREENING

At first glance, a jurisdiction running one of the strictest anti-evergreening tests in the world should have little scope for patent thickets. But India shows that this is not necessarily the case. Patent thickets are usually associated with jurisdictions that recognise second medical use patents, particularly where purpose-limited claims can protect a new therapeutic indication. India does not permit such claims. Yet multiple narrow patents can still accumulate around the same molecule through formulations, combinations, polymorphs, and other permissible categories. Each patent may independently satisfy the requirements of patentability, while their combined effect creates a thicket around the product. This matters, because the problem cannot be addressed by imposing a stricter efficacy standard. India's thicket problem lies in the cumulative effect of multiple narrow claims, something that a patentability test generally assesses claim by claim rather than as a whole.

A molecule whose compound patent expires in twelve years may still be protected by formulation or combination protection until later. This is not because any single secondary patent achieves broad coverage but because multiple narrower patents filed at different stages can collectively extend protection over commercially relevant forms of the product.

The Delhi High Court's willingness to grant secondary and follow-on patents gives the thicket problem a commercial weight. In F. Hoffmann-La Roche Ltd. v. Cipla Ltd., the court held that Cipla's generic product infringed Roche's compound patent, years after the Single Judge had refused an interim injunction on grounds of public interest[20]. Similarly, in Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals Ltd., the court reversed the refusal of interim relief and held that Merck's patent on sitagliptin and its pharmaceutically acceptable salts covered Glenmark's salt formation[21]. Neither of the cases involved a second medical use patent as barred by Section 3(i). Both covered claims that were broad or specific enough to cover the generic product in question. This is evergreening without technically breaching Section 3(d). These cases show how exclusivity can extend beyond the life of the original compound patent through multiple follow-on claims, enforced via litigation rather than through any registry.

[20]F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 2015 SCC OnLine Del 13619 (Div. Bench).
[21]Merck Sharp & Dohme Corp. v. Glenmark Pharms. Ltd., 2015 SCC OnLine Del 8227 (Del. H.C. Mar. 20, 2015).

GENERIC ENTRY IN A NON-LINKAGE SYSTEM

Bayer Corp. v. Union of India settled the linkage question directly. Bayer wanted the Delhi High Court to read Section 156, Patents Act together with the Drugs and Cosmetics Act so the regulator would refuse Cipla's application for a sorafenib-based product while Bayer's patent stood[22]. Both the Single Judge and the Division Bench rejected this stating that the two statutes serve different purposes. The Patents Act creates no positive duty on the government to protect a patent from infringement, and the DCGI may grant approval regardless of pending litigation, leaving the patentee to its ordinary remedy. Cipla's generic, priced at roughly a tenth of Bayer's product, reached patients while the infringement suit ran its own course.

Read on its own, Bayer looks like a clean access-to-medicine result. CDSCO approves only safety and efficacy. Patent disputes are litigated separately, with courts weighing public interest and pricing at the injunction stage, exactly as the Single Judge did for Roche's erlotinib patent before the Division Bench later reversed on the merits. Generic entry is not held hostage to a certification-and-stay process the way it can be in the United States. That is a genuine and undisputed advantage.

The advantage carries a cost that only becomes visible once secondary patents enter the picture. Where a molecule's compound patent has expired but a formulation or combination patent remains live, CDSCO's approval process draws no distinction between an indication that is genuinely open and one a live secondary patent still covers. A generic manufacturer applies for, and receives, approval for the complete label, launches on that basis, and discovers whether it infringed only when a patentee sues, sometimes years into commercial sale, as both Roche's and Merck's generic counterparties learned. No registry exists against which the manufacturer could even attempt an indication-specific carve-out, because India runs no use-code system of any kind. Non-linkage, in this narrower sense, leaves an Indian generic with less room to manage risk than a skinny-label regime gives an American ANDA filer, not more. Teva could at least attempt a section viii carve-out and argue about its adequacy in court, however unstable that turned out to be in GlaxoSmithKline v. Teva. An Indian generic cannot attempt anything comparable, because nothing on the public record exists to carve against.

A generic manufacturer deciding whether to launch against this background is not choosing blindly. It is pricing a bet: the size of the market it expects to capture, the odds that any live

[22]Bayer Corp. & Anr. v. Union of India & Ors., L.P.A. No. 443 of 2009 (Del. H.C. Feb. 9, 2010).

secondary patent survives a validity challenge, the damages a court might award if it does, and the cost of litigating long enough to find out. Pharmaceutical economics has a name for a launch made under exactly this uncertainty, an at-risk launch, and both Roche v. Cipla and Merck v. Glenmark were, from the generic side, at-risk launches that resolved against the generic years after the product had already reached patients. Patent linkage moves part of that calculation earlier, before launch, by forcing some of the missing variables into the open. India's model leaves the whole calculation to be resolved after the fact, with the manufacturer carrying the interim risk regardless of which way the case lands.

This is the freedom-to-operate problem in ordinary commercial language. A freedom-to-operate assessment asks whether a company can make, use, or sell a product without infringing another party's rights, and it is standard diligence in any patent-dense industry before launch. Indian generics cannot run a reliable freedom-to-operate assessment against indication-specific protection, because the indication sits nowhere on the record CDSCO relies on, and the patent record that exists is scattered across individually filed applications rather than organised by molecule or use. Freedom to operate is exactly what independence without disclosure denies a generic manufacturer the means to establish.

THE AMERICAN BASELINE REVISITED: DATA EXCLUSIVITY AND THE MISSING LAYER

In the United States, an issued patent sits under an Orange Book listing tied to a specific approved use, under a further layer of regulatory data exclusivity, five years for a new chemical entity and three for a new use backed by fresh clinical data, under the section viii carve-out that lets a generic attempt a skinny label before launch[23]. Each layer gives a manufacturer information or time to plan around before commercial production. In India, an issued patent sits on top of a CDSCO approval process that asks about safety and efficacy and nothing about patent status[24], with no statutory data-exclusivity period of any kind between them. India's TRIPS Article 39.3 obligation on undisclosed test data has never been implemented through dedicated legislation. The Indian manufacturer plans around litigation risk that becomes visible only after the fact.

[23]21 U.S.C. § 355(c)(3)(E), § 355(j)(5)(F).
[24]New Drugs and Clinical Trials Rules, 2019, G.S.R. 227(E) (India).

None of this argues that India should import data exclusivity. A five-year exclusivity window bolted onto India's existing patent term would delay generic entry for reasons unrelated to patentability, and would sit badly against India's settled preference for access over added protection. The comparison serves a narrower point: what reduces uncertainty in the American system is not the patent alone, or even linkage alone, but linkage combined with public, indication-specific disclosure. India can take the disclosure piece without the linkage piece, and without the exclusivity piece either; nothing about a public record of protected indications requires a regulator to enforce that record by withholding approval.

THE VARIANTS OF MODEL TWO: THE EUROPEAN UNION AND CANADA

The European Patent Convention takes the opposite doctrinal path from India and still arrives at a disclosure-based answer to the same problem. Article 54(5) allows a substance already known for a first medical use to be patented again for a further use that is itself novel and inventive, the purpose-limited product claim India refuses outright under Section 3(i)[25]. The European system runs no use-code registry. It relies instead on Article 11 of Directive 2001/83/EC, which lets a generic omit from its own product information any indication still covered by patent protection on the reference product, so its label carries only what has gone off patent[26]. It is a skinny label built into ordinary regulatory practice, and it generates its own disputes: in Warner-Lambert Co. LLC v. Generics (UK) Ltd., the UK Supreme Court had to work out whether a generic's skinny label for pregabalin, alongside NHS prescribing guidance, was enough to avoid liability under Warner-Lambert's Swiss-type pain-indication patent[27].

Canada offers a sharper contrast, because it borrows the American premise, link patents to approval, while running its own procedure. Health Canada maintains a Patent Register under the Patented Medicines (Notice of Compliance) Regulations, and an innovator must list patents relevant to an approved drug within a set period after grant or approval, whichever comes later[28]. A generic must address every listed patent, either by waiting out its term or by serving a notice of allegation contesting it, and the innovator then has a limited window to seek a court stay. Canada's system splits the difference between American-style delay and full openness in a way neither the American nor the European model quite manages. India does not need Canada's stay mechanism, which would import precisely the delay India's rejection of linkage

[25]Convention on the Grant of European Patents art. 54(5), Oct. 5, 1973, 1065 U.N.T.S. 199.
[26]Directive 2001/83/EC of the European Parliament and of the Council, art. 11, 2001 O.J. (L 311) 67 (EC).
[27]Warner-Lambert Co. LLC v. Generics (UK) Ltd. (t/a Mylan), [2018] UKSC 56.
[28]Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 (Can.).

was designed to avoid. What India can take is narrower, a proof that a public register can force patent-status information into view through disclosure rather than through litigation risk alone.

Set against these variants, India's choice looks less like an oversight and more like an unfinished version of a genuine third model. The other systems disagree about how much to link patents to approval. None of them, including the ones that reject linkage most firmly, leaves the connection entirely dark.

SUGGESTED REFORMS

None of the four reforms below asks India to adopt the American, European, or Canadian model wholly. Each asks India to keep its own model, patent independence, approval and patent status legally apart, and add the one layer every comparator, in its own way, already has: some public account of what remains protected.

A public register, run jointly by CDSCO and the Patent Office, may answer the lack the publicly available information. The problem is that a generic receives full-label approval with no public indication of which parts of that label a live secondary patent still covers, because the New Drugs and Clinical Trials Rules ask nothing about patent status and the Patents Act imposes no disclosure duty running the other way. The fix is a searchable register listing, for each approved drug, the indications currently approved and those still covered by an unexpired secondary patent, cross-checked against the Patent Office's own grant database. Approval itself stays exactly as it is, so this is disclosure without linkage, closer to Canada's register than to the stay mechanism behind it. The obvious objection is that this reintroduces linkage under a gentler name. It does not: the register carries no power to block, delay, or condition an approval. It functions only as information a generic can weigh before launch and a court can weigh later, much as Teva's reliance on GSK's own representations became the central question on remand in GlaxoSmithKline v. Teva.

Patent Office guidelines specific to indication-adjacent formulation claims may respond to the institutional inconsistency. Examiners apply Sections 3(d) and 3(e) case by case, with outcomes turning on whatever comparative data an applicant files and how a controller weighs it, which is why a rifaximin polymorph clears the bar with absorption data while a sorafenib salt fails without it. A revised guideline could require comparative efficacy or synergy data tied to the specific indication named in the specification, not a generic bioavailability measure detached from any use, closing the drafting loophole without banning formulation claims

outright. The objection is that this discourages genuine formulation innovation, paediatric dosing, sustained-release systems, that deserves protection on its own terms. The reply is that the guideline targets the evidentiary link between data and indication, not the claim type. A formulation that genuinely improves outcomes for a named use will already have the data this standard asks for.

Routine, non-binding information sharing between CDSCO and the Patent Office may answer the institutional silence. Neither agency currently tells the other what it knows, so an approval file and a patent file for the same molecule sit in databases that never meet. An administrative direction, not new legislation, could require CDSCO to forward each new drug application to the Patent Office for a non-binding flag, and require the Patent Office to forward grant data to CDSCO for the public register above. Critics will call this linkage. The distinguishing feature is that DCGI's approval decision does not wait on anything the Patent Office reports. The flag informs the public record, exactly as Bayer held the two statutes are entitled to remain, functionally apart.

A disclosure duty at the point an innovator files a new drug application completes the register with information only the innovator holds, but the duty needs a narrower scope than a first pass might suggest. Requiring an innovator to list every patent application touching a molecule would invite the over-listing the American Orange Book has been criticised for, where broad listing maximises the certifications, a generic must clear. The duty proposed here covers only patents already granted, unexpired, and claiming a specific indication, formulation, or combination tied to the drug under application, not pending applications and not claims an innovator merely intends to file. A granted, unexpired, indication-specific patent is a fact the register can state without inviting speculation; a pending application is not. False or incomplete declarations should attract the same misrepresentation consequences the Patents Act already applies elsewhere, and the Patent Office's own cross-check gives the register an independent source rather than resting on the innovator's word alone.

CONCLUSION

India built its pharmaceutical patent regime to prevent monopoly extension through the strength of its patentability standards, not through a linkage system borrowed from Washington or a transparency mechanism borrowed from Brussels or Ottawa. That choice was sound in 2005, and the case for keeping it is still strong. But the problem now is narrower and more

troubling. Claim drafting has adapted around Section 3(d), 3(e), and 3(i) well enough that indication-adjacent protection survives in practice even where it cannot survive in name, while the two regulators who decide whether a generic can safely launch keep no shared record of where the patent protection sits. India does not need an Orange Book, a data-exclusivity term, or a skinny label of its own to fix this. It needs a register that tells a manufacturer what the patent system has already decided, before litigation tells it instead. India's challenge is no longer preventing evergreening through patent law. It is preventing uncertainty through regulatory design.