



Evergreening or Genuine Innovation? The Patentability of New Drug Formulations in India

News & Updates • October 27, 2026

When a pharmaceutical company develops a new formulation of an existing drug, is it creating a genuine innovation or extending its monopoly over a medicine whose patent protection is approaching expiry?

The answer is not always straightforward. A new salt, crystalline form, dosage formulation or delivery mechanism may offer meaningful therapeutic benefits. It may also represent a modification that does not justify a fresh period of exclusivity. Indian patent law addresses this tension through [Section 3\(d\) of the Patents Act, 1970](#), which places a specific test on new forms of known pharmaceutical substances.

The distinction matters not only to pharmaceutical innovators but also to generic manufacturers and patients who depend on affordable medicines.

What Does Section 3(d) Actually Require?

Section 3(d) excludes the mere discovery of a new form of a known substance unless it results in an enhancement of the known efficacy of that substance. Its explanation specifically identifies derivatives such as salts, esters, polymorphs, metabolites and other forms of known substances.

The provision does not prohibit all incremental pharmaceutical innovation. It requires the claimed new form to satisfy the statutory efficacy threshold, alongside the other applicable patentability requirements, including novelty and inventive step.

For pharmaceutical products, the Supreme Court has interpreted efficacy under Section 3(d) primarily as therapeutic efficacy. Improvements in stability, solubility or other physical properties do not automatically establish enhanced therapeutic efficacy. Their significance must be assessed against the claimed invention and the evidence supporting it.

Novartis: The Case That Defined the Debate

In [Novartis AG v. Union of India \(2013\)](#), the Supreme Court considered a patent application concerning the beta-crystalline form of imatinib mesylate, used to treat certain cancers and marketed as Glivec.



Novartis argued that the crystalline form possessed improved properties, including better flow characteristics and increased bioavailability. The Court examined whether the evidence established enhanced therapeutic efficacy compared with the known substance.

It concluded that the claimed form did not satisfy Section 3(d). The judgment made clear that improvements in physical properties or bioavailability cannot, without adequate evidence of enhanced therapeutic efficacy, establish the required threshold.

The decision remains central to pharmaceutical patentability in India. It does not mean that a new formulation can never be patented. Rather, it requires the applicant to establish the legally relevant improvement instead of relying solely on the fact that the formulation is different.

When a New Drug Form Faces Another Patent Challenge

The dispute in [*Natco Pharma Ltd. v. Novartis AG*](#), decided by the Delhi High Court on 24 April 2024, concerned eltrombopag olamine, a salt form of eltrombopag.

The litigation involved challenges to the validity of the asserted patent, including questions relating to prior claiming, novelty and Section 3(d). The Court examined the relationship between the earlier patent covering eltrombopag and the later patent covering its olamine salt.

The case illustrates why a different chemical form does not automatically establish a patentable invention. The claims must be assessed against the prior art and the statutory requirements, including whether the claimed form meets the applicable efficacy standard.

The judgment also demonstrates that patent validity and infringement are separate questions. A manufacturer's product must be compared with the claims of the patent, while the patent itself may be challenged on statutory grounds.

Semaglutide: The Contemporary Evergreening Debate

In [*Novo Nordisk A/S v. Dr. Reddy's Laboratories Ltd. & Anr.*](#), decided by the Delhi High Court on 2 December 2025, the dispute concerned a patent for acylated GLP-1 analogues, including issues relating to semaglutide.

Dr. Reddy's challenged the patent's validity on grounds including anticipation and obviousness, arguing that the claimed invention was vulnerable in light of earlier disclosures. The Court examined the relationship between the asserted patent and prior art, including whether the claimed modifications involved an inventive advance.

The Court declined to grant Novo Nordisk the interim injunction it sought, finding a credible challenge



to the patent's validity at that stage. This was an interim decision, not a final determination that the patent was invalid or that every semaglutide-related patent was unprotectable.

The dispute shows how courts may scrutinise later pharmaceutical patents where the relationship between an earlier disclosure and a claimed modification raises questions about inventive step and evergreening.

Where Does Genuine Innovation Begin?

Section 3(d) is not a blanket rule against follow-on pharmaceutical patents. A genuinely improved formulation may offer a meaningful therapeutic advantage. But a new label, chemical form or physical property alone does not establish entitlement to another patent.

The legal question is whether the claimed invention satisfies the statutory requirements and, where Section 3(d) applies, whether the evidence establishes the required enhancement in efficacy.

For pharmaceutical companies, this makes comparative evidence and careful claim drafting essential. For generic manufacturers, it provides a basis to scrutinise patents that may not meet the statutory threshold. For patients, it forms part of India's broader effort to balance incentives for pharmaceutical research with access to medicines.

The dividing line is not between new formulations and old drugs. It is between a patentable therapeutic advance and a modification that fails the law's requirements for protection.



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