International Journal of Law
www.lawjournals.org
ISSN: 2455-2194
Received: 03-03-2026, Accepted: 03-04-2026, Published: 18-04-2026
Volume 12, Issue 2, 2026, Page No. 132-133

From process patents to product protection: Recasting India's patent regime after the omission of Section 5

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Abstract
India's shift from granting only process patents to allowing product patents marked a huge moment in its legal landscape, especially when it comes to medicines and chemicals. The whole journey is about finding a balance between driving innovation and making sure the public can actually get the medicines they need. At the heart of this is Section 5 of the Patents Act, 1970—it kept out product patents for pharmaceuticals and chemicals for decades, letting India build a thriving generic drug industry and keep meds affordable. But India couldn't hold off change forever. With TRIPS (the WTO's intellectual property treaty), things had to move. The government set up a transition: introducing the mailbox system and offering Exclusive Marketing Rights (EMR) as halfway measures. The big change came in 2005, when Section 5 was scrapped and product patents returned for pharmacy and chemicals. Instead of opening the floodgates to monopolies, lawmakers added protections like Section 3(d) to stop companies from gaining endless extensions on patents through small, insignificant tweaks. The Novartis case in 2013 put the courts right in the mix, showing they were serious about upholding public interest. Even as India shifted its system, the core idea stuck: make room for innovation, but never at the cost of affordable medicines.

Keywords: Section 5, process patent, product patent, TRIPS, mailbox, EMR, Section 3(d), Novartis, Indian Patent Law

Introduction
Patent law in India has always tried to walk a tightrope—protect inventors' rights, but don't forget the public, especially when it comes to health. Unlike countries that just let the market do all the work, India wrote in strong checks and balances, because for a country of over a billion, public health can't be left to chance. The Patents Act of 1970 laid down the process patent regime, signalling a strong move to protect domestic interests.
Section 5 was really the backbone of this approach. By keeping product patents out of key sectors, it limited the risk of long monopolies and high prices. But with India entering the world stage under TRIPS, things had to change. Repealing Section 5 in 2005 didn't just swap one system for another; it forced lawmakers and courts to find ways to keep old goals alive in a new world.

Section 5 and the Foundations of the Process Patent Regime
Section 5 rewrote the rules in India. It basically said: "No product patents for pharmacy and chemicals. The only thing you can patent is the way you make them." This choice wasn't random; lawmakers wanted to keep dangerous monopolies out and make sure life-saving medicines didn't become unreachable for millions. What did this actually mean on the ground? It encouraged Indian companies to reverse engineer drugs and find cheaper ways to make them—resulting in a massive growth in generic drugs, helping India and many other developing countries. So, Section 5 didn't just shape the law; it built an industry, supported public health, and boosted India's self-reliance.

TRIPS Obligations and the Gradual Transition
Joining the WTO in 1995 meant India had to play by new rules. TRIPS demanded product patents across all fields, which ran right into everything Section 5 stood for. Luckily, India didn't have to change overnight. TRIPS gave developing countries some breathing room, and India used this time wisely. Lawmakers took a slow and steady approach—keeping domestic needs front and centre, while they set up the steps needed for future changes. Instead of junking the old regime at once, they introduced new policies in phases, showing a deep awareness of what these changes meant for the country.

Mailbox Facility and Exclusive Marketing Rights
The "mailbox facility" was a key element of the transition puzzle. This enabled enterprises to file product patent applications during the transition. India would not give full patents just yet, but innovators may still submit their applications. It safeguarded their spot in the queue and allowed India to continue with its old structure for a bit longer. The Exclusive Marketing Rights (EMR) program was based on this, granting inventors a brief monopoly under certain restrictions, but not the full force of a product patent. Both the mailbox and EMR movements demonstrated that India could respond to global forces (like as TRIPS) while keeping its own priorities—such as affordability and local industry—at the centre of the process.

Omission of Section 5 and Reintroduction of Product Patents
Everything changed in 2005 with the Patents (Amendment) Act. Section 5 was axed, and suddenly product patents were back for medicines and chemicals. This wasn't just legal housekeeping—it was a big, structural shift. But lawmakers didn't throw caution out the window. They knew that letting companies patent every small tweak could lead to expensive drugs and shut out competition. So, the return of product patents came loaded with new safeguards and restrictions. Removing Section 5 didn't erase its legacy; it just updated it for a new era.

Section 3(d) and the Continuity of Public Interest Protection
If Section 5 was about blocking product patents in the first place, Section 3(d) is about keeping them from multiplying

for the wrong reasons. Post-2005, Section 3(d) raised the bar for new patents on already-known substances. Now, a company had to prove their "new" version really worked better in a meaningful way, not just that it was a tiny tweak. This section zeroes in on ever greening, where firms keep making small changes to stretch out their patent control. So, India didn't just replace one system with another—it found a smarter way to make sure patents serve people, not just profits.

Judicial Reinforcement: The Novartis Decision:- Everything about Section 3(d) came into focus with the Novartis case in 2013. The Supreme Court had to decide whether a slightly tweaked drug formula deserved a fresh patent. They said no, because it didn't actually work better medically. That case stood out because it didn't just tidy up legal doctrine—it sent a loud message that access to medicines and real innovation both matter and must be balanced. The judges basically made clear: scrapping Section 5 didn't mean giving up on the public.

Critical Evaluation

Reforming Indian patent law hasn't been simple. On one hand, allowing product patents helps India play on the world stage and draws more money into research and development. On the other, it raises real fears—like rising drug prices or too much power in too few hands. India's answer has been to build a hybrid model: stick to TRIPS rules, but keep sharp tools like Section 3(d) to protect what matters most. Yes, there's friction—interpretations can get messy—but at its core, this is an attempt to square global rules with local realities.

Conclusion

Axing Section 5 marked a defining change for Indian patent law—from process to product protection. But the switch didn't abandon India's guiding principles. The country stayed firmly committed to public health and access to medicines. With protections like Section 3(d), and strong court decisions backing it up, the Indian patent regime has found a way to balance global integration with justice at home. It's a live model for other countries in the same boat—proving that you can take on global commitments without losing sight of what really matters on the ground.

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