



INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

Protect Innovation. Enable Competition.

Balanced IP rewards
genuine innovation
and supports timely
market entry.

Core Proposition

A balanced IP environment rewards genuine innovation while enabling timely competition once legitimate protection ends.

Practices that create additional delay can postpone the benefits of generic and biosimilar competition for patients and health systems.

Why it Matters

IP protection exists to reward genuine innovation for a defined period. A balanced system allows competition to begin promptly and predictably once that protection ends. Health systems gain the benefits of competition, while the incentive to develop future medicines remains intact.

The balance can be pushed off centre by practices that extend market exclusivity or delay entry beyond what legitimate protection was intended to provide. Naming and addressing those practices makes the case for timely competition without weakening support for genuine innovation.

US\$1 Billion

in additional costs to Germany's healthcare system caused by unjustified secondary patents on just four medicines.

Generic patent challenges helped prevent a further US\$770 million in costs.

What Timely Competition Requires

IP Systems and Courts

Ensure protection is granted and upheld for genuine innovation only, so exclusivity is not extended without corresponding patient benefit.

Regulators and Industry

Publish clear, predictable expiry and entry timelines, so competition can be planned for and begins as scheduled.

Policymakers

Remove regulatory, legal and procedural barriers that delay competition beyond the end of legitimate exclusivity.

Shared Outcome

Timely, predictable competition.

Generic and biosimilar competition begins as scheduled when legitimate protection ends, allowing patients and health systems to benefit without unnecessary delay.

WHY BALANCED IP MATTERS

When Patent Litigation Delays Generic Entry

The Trajenta (linagliptin) case in India illustrates how patent litigation can delay generic competition beyond the intended period of exclusivity.

Parallel infringement proceedings resulted in preliminary injunctions that prevented generic manufacturers from entering the market from February 2022 to March 2023 – approximately 13 months.

The Delhi High Court subsequently rejected the injunctions and characterised the multiple patent claims as an attempt at evergreening and re-monopolisation. The case shows how strategic patent litigation can postpone generic entry and shift the balance between innovation incentives and competition.

Conclusion

Legal and procedural delay can keep generic competition out of the market even after the intended period of protection has run its course. Clear rules and timely resolution help ensure that legitimate innovation is rewarded without postponing competition unnecessarily.

13 months

Generic competition delayed in India



Scan this QR code to access all 4 fact sheets on the IGBA website.

igbamedicines.org



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Sources

International Generic and Biosimilar Medicines Association. IP and Competition Report. January 2025.

'Patent Reform Could Save Lives', Julia Pike, Sandoz. Legal Affairs Conference of Medicines for Europe, June 2026

IGBA and its members remain committed to partnering with governments, international organisations, civil society, and industry stakeholders to improve patients' access to quality-assured, safe and cost-effective medicines.