Patent Expiry to Unlock ~ USD 3-5 billion Opportunity for India

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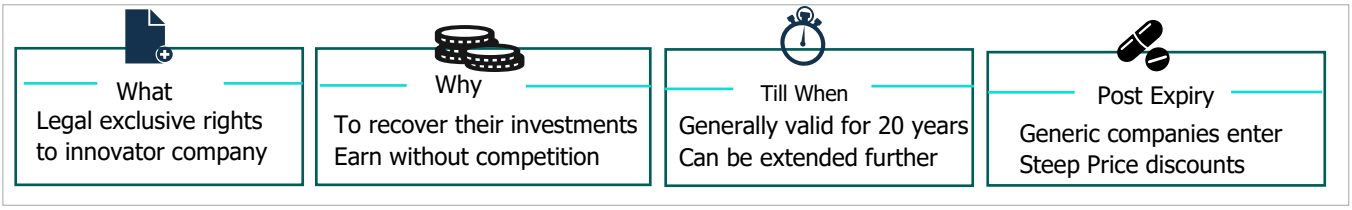
Synopsis

- Patents of drugs with CY25 sales of ~USD 142 billion are set to expire during 2026–2030, opening a large opportunity for generic and biosimilar entry during this period. Given India's favourable patent framework and proven cost-efficient generic manufacturing capabilities, Indian pharmaceutical companies are well-placed to capitalise on this opportunity. This is expected to translate into an opportunity of around USD 3-5 bn.
- Few key trends in the upcoming patent cliff are the increasing dominance of small molecules, and execution timelines becoming more critical than cost competitiveness.
- Innovator companies use various patent protection strategies like filing secondary patents, extending the timelines, strategic partnerships, pricing, brand migration, settlement with other generic players, etc., further delaying generic entry.

What, why and when of Patents

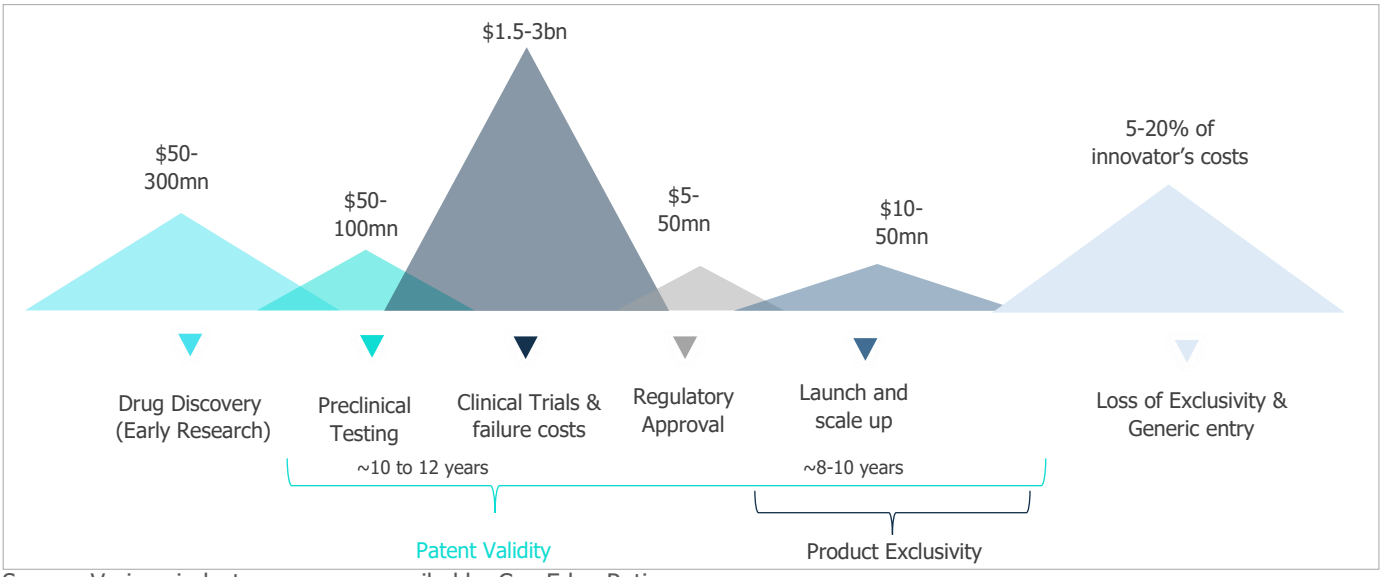


Patents in the pharmaceutical industry are legal rights granted to a company (the innovator) that develops a new drug (a patented drug). Pharmaceutical patents are territorial in nature, owing to which a drug may be patented in some countries but not in others, depending on the company's filing strategy.

The rationale behind this system is to enable innovators to recover their investments and earn returns without competition. Patents are typically valid up to 20 years from the date of filing, with certain exceptions. Once the patent expires—commonly referred to as the "loss of exclusivity" (LOE)—other companies can manufacture and sell equivalent versions known as generic drugs.

Timeline and Costs Involved in the Drug Discovery Process

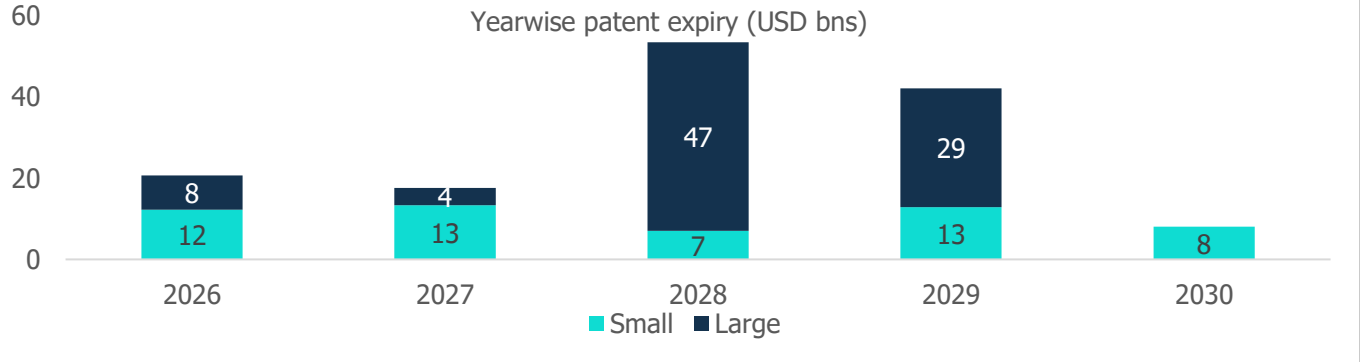
The entire journey of a drug from discovery to market typically takes 10–12 years. In terms of costs, estimates vary widely at around USD 1–2.5 billion per approved drug and including failed candidates and the cost of capital, the true all-in cost can even be higher, closer to USD 2-5 billion. In the absence of detailed R&D and other investments, the cost of a generic or biosimilar is often 60-90% lower than that of the patented ones.



Source: Various industry sources, compiled by CareEdge Ratings

Key Trends in the Upcoming Patent Cliff

Drugs generating nearly USD 142 billion in annual sales in CY25 are expected to lose exclusivity by 2030. After accounting for significant price erosion, this is expected to create a market opportunity exceeding USD 30-40 billion over five years, of which, Indian companies are expected to capture nearly USD 3-5 billion.



Source: Based on CY25 sales as disclosed by around 15 to 20 leading US and European Pharma companies' annual reports for ~50 patented drugs in the US and compiled by CareEdge Ratings

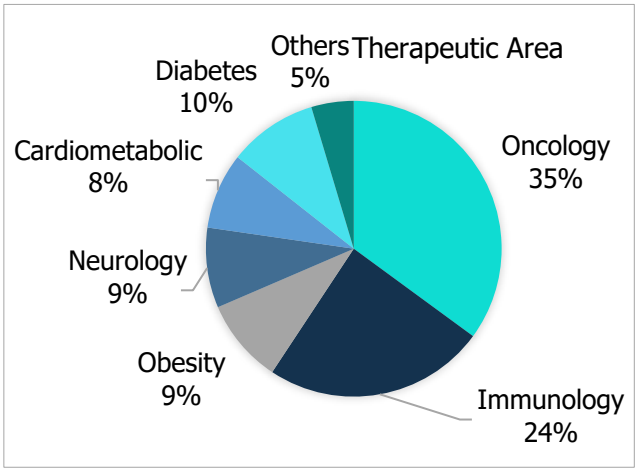
a) Small vs Large Molecule

More than 60% of drugs losing exclusivity are large-molecule biologics. This marks a structural shift from earlier patent cycles that were dominated by small-molecule drugs.

Small molecules are simple drugs made by chemical synthesis with a clearly defined structure, enabling the easy creation of generic versions and are also one of the primary reason for generics' cost advantage and quick launch post-patent expiry. In contrast, large molecules (biologics) are complex proteins produced in living cells, making biosimilars (generic versions of biologics) difficult to produce and scale. Biosimilars are highly similar to biologics but are not identical. Due to this complexity, biosimilars require significantly higher investment, longer development timelines, extensive testing and regulatory scrutiny. As a result, even after patents expire, biosimilar entry is often delayed by several years.

The additional complexities raise barriers to entry and limit the number of credible competitors, creating an attractive opportunity for players with established scale and scientific capabilities. In this context, Indian pharmaceutical companies with proven expertise in biosimilars and cost-efficient manufacturing are well positioned to selectively participate and capture value from this high-stakes transition.

b) Time-to-Market will Outweigh Cost Advantages



Source: Based on CY25 sales as disclosed by around 15 to 20 of leading US and European Pharma company's annual report for ~50 patented drugs in US and compiled by CareEdge Ratings

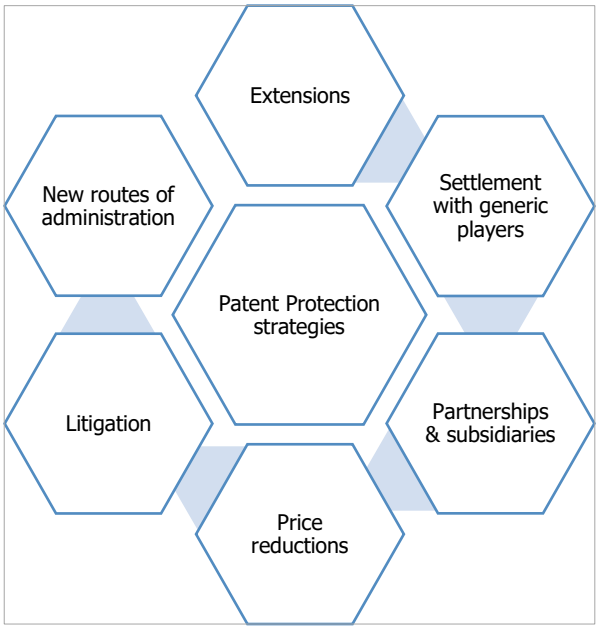
As the next phase of the patent cliff unfolds, a significant proportion of drugs losing exclusivity are in chronic therapy areas, where patients require continuous treatment over extended periods. In such categories, speed to market becomes critical, as the first product to launch is likely to establish prescribing habits and patient initiation early in the treatment lifecycle. Once patients are stabilised on a therapy, switching mid-treatment can raise concerns around efficacy, tolerance, or side effects, making both physicians and patients reluctant to change. As a result, early entrants benefit from a highly sticky and loyal customer base, reinforcing the strategic advantage of being first to market.

Drugs going off patent and certain Indian generic Companies with capability to tap opportunity

Drug	Active ingredient	Company Name
Keytruda	Pembrolizumab	Lupin Limited, Intas Pharmaceuticals Ltd., Enzene Biosciences Ltd., Sun Pharmaceutical Industries Limited, MSD Pharmaceutical Private Limited, Fortrea Development India Private Limited, PAREXEL International Clinical Research Private Limited
Ibrance	Palbociclib	Sun Pharmaceutical Industries Limited, MSN Laboratories Private Limited, Natco Pharma Limited
Darzalex	Daratumumab	Zydus Life Sciences Limited, Intas Pharmaceuticals Ltd., Dr Reddy's Laboratories Ltd.

Source: Minutes of SEC meetings for the past one year, CDSCO

Patent Protection Strategies Adopted by Innovators



Innovator companies often adopt a range of lifecycle management strategies to sustain the commercial value of a successful drug beyond its initial patent period. A key approach is the creation of a "patent wall" (or patent thicket), where multiple secondary patents are filed around the original drug—covering aspects such as developing improved formulations that enhance efficacy, reduce side effects, or simplify dosing, as well as explore new routes of administration and identify additional therapeutic uses to secure further patent protection—making it difficult for competitors to enter the market even after the primary patent expires. Strategic partnerships with generic manufacturers prior to patent expiry can help maintain brand value while generating interim royalty income, while competitive pricing strategies are used to retain market share. Firms may also establish their own generic subsidiaries ahead of rival entrants, shift patients toward newer patented products through brand migration, and create combination therapies that offer added clinical or convenience benefits, thereby reinforcing their market position and extending product longevity. However, the Indian patent framework significantly limits extensions and enables earlier generic entry. For example, the main patent for a drug called Humira expired in 2016. Still, biosimilar entry was delayed until 2023 due to various patent protection strategies adopted by the innovator company and other factors.

CareEdge Ratings' View

"The global pharmaceutical industry is approaching a significant inflection point as a large number of blockbuster drugs with sales of more than USD 142 billion near patent expiry during FY26-FY30. Factoring in deep price erosion following loss of exclusivity, this is expected to translate into a market opportunity of more than USD 3-5 billion for Indian companies. India stands uniquely positioned at this crossroads. Its proven strength in generics, growing capabilities in biosimilars, and ability to scale rapidly provide a strong structural advantage as the next phase of the patent cliff unfolds. However, success will increasingly depend on speed of execution, regulatory sophistication, and strategic selection of molecules, particularly in chronic therapy areas where first-mover advantage creates long-term value. The upcoming patent cliff is also fuelling increased M&A activity across the pharmaceutical sector," says Samyuktha R, Assistant Director at CareEdge Ratings.

"Unlike previous patent cliffs that were largely driven by small-molecule drugs, this cycle is increasingly focused on large-molecule biologics, which are inherently more complex to develop, manufacture, and replicate. Additionally, a significant share of these drugs are chronic therapies, where early market entry becomes critical as prescribing practices and patient stickiness are established up front—making speed-to-market more important than pure cost advantage. At the same time, innovator companies are expected to deploy a range of patent-protection and lifecycle-management strategies to delay competition, requiring generic and biosimilar players to carefully navigate legal, regulatory, and technical challenges. In this context, India's robust legal framework—which limits practices such as evergreening and provides safeguards against excessive patent barriers—combined with strong manufacturing and regulatory capabilities, offers structural support to Indian generic and biosimilar companies in capturing this opportunity," stated Pritesh Rathi, Associate Director at CareEdge Ratings.

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