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Indian pharma eyes US gains as $63.7 bn patent cliff nears: Analysts

With a surge in US patent expiries and a $180 bn global LoE opportunity by 2035, Indian drugmakers are set to climb the value chain in generics and complex therapies

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This shift is expected to spur a rise in generic launches, particularly benefiting Indian players with emerging US operations and expertise in complex generics. The Indian pharmaceutical industry is poised to benefit from a major wave of patent expiries in the US, with small-molecule drugs worth $63.7 billion expected to go off-patent between 2025 and 2029—a 65 per cent increase over the previous five years. Combined with a broader Loss of Exclusivity (LoE) opportunity across the US and EU projected to reach $180 billion by 2035, this marks a significant opening for Indian drugmakers, according to a report by Antique Stock Broking Limited.

This shift is expected to spur a rise in generic launches, particularly benefiting Indian players with emerging US operations and expertise in complex generics. Firms such as Alembic Pharmaceuticals and Shilpa Medicare, which have smaller US footprints, and larger players like Cipla and Lupin, which have invested early in differentiated products such as injectables and respiratory therapies, are seen as well positioned to gain market share.

With global majors like Teva, Viatris and Sandoz having closed dozens of manufacturing sites since 2018, Indian companies are stepping in to fill the supply gap. However, the opportunity is unfolding amid growing strategic discipline. Filings of Abbreviated New Drug Applications (ANDAs) in the US declined 25 per cent year-on-year. FY25 filings are projected to close around 550—down from 740 in FY24 and 857 in FY22.

This signals a pivot from volume to portfolio quality, regulatory compliance and margin protection. Commenting on this shift, Nilaya Varma, Group CEO and Co-founder of Primus Partners, said, “India’s pharma exports have grown from $15 billion in 2013–14 to nearly $28 billion in a decade. With 750+ USFDA-approved plants and rising strength in complex generics and biosimilars, India is primed to lead the next wave of affordable, high-quality medicines. Tapping the $180 billion LoE opportunity will require continued focus on compliance and quality systems.”

Regulatory headwinds are also easing. The share of US FDA inspections resulting in Official Action Indicated (OAI) for Indian firms has fallen from 19 per cent in 2013 to 9 per cent in 2023.

Companies like Cipla are further de-risking their US supply chains by adopting multi-site manufacturing and digital quality systems. Cipla, which holds a robust US portfolio of 284 ANDA and NDA filings—175 of which are approved and 73 under review—is focusing on commercialisation-ready products, including PEPFAR-approved generics.

The company is betting on complex respiratory and injectable therapies to drive growth. Pharma major Lupin, which continues to benefit globally from its blockbuster autoimmune biologic Etanercept, plans to finalise its US commercialisation strategy closer to the drug’s 2029 patent expiry.

Meanwhile, Sun Pharma, despite offering a conservative FY26 outlook amid global macro uncertainties, is expanding its oncology pipeline. Its recently acquired UNLOXCYT (cosibelimab) is expected to significantly contribute to US revenues.

The company noted that Keytruda’s upcoming patent expiry was already factored into the acquisition. UNLOXCYT targets only one of Keytruda’s multiple indications, and Sun remains confident in its potential to become a meaningful contributor to its US specialty business. In parallel, Sun is also strengthening its immunotherapy portfolio through a global licensing agreement with Philogen.