US law threatens Indian biotech

Indian biotechnology companies hoping to sell cheap drugs in the US have encountered a serious obstacle following a change in US legislation. The US Energy and Commerce Committee recently approved a legislative amendment to the Public Health Service Act that gives innovator biotech companies 12 years of data exclusivity protection from "biosimilars".

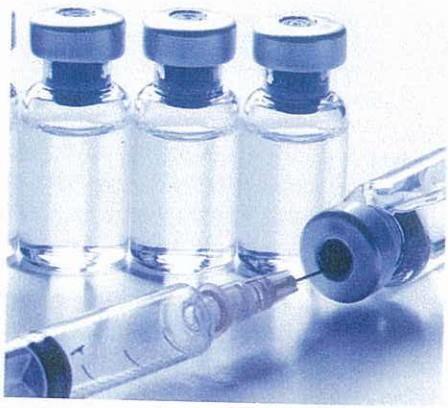
The US already offers a five-year data exclusivity period for traditional generic pharmaceutical drugs through the Hatch-Waxman Act, 1984. This act, however, does not apply to biological products that are derived from proteins manufactured in living cells and are difficult to accurately reproduce due to their molecular complexity.

Biosimilar drugs are copied versions of biotech drugs. The approved 12-year exclusivity protection begins from the moment the product reaches the market, protecting the companies that originally discovered the drugs and making it difficult for Indian companies to copy them.

In an interview with the *Economic Times*, Shrikumar Suryanarayan, director general of India's Association of Biotechnology-led Enterprises, said: "Biotech products, which are likely to lose patent protection soon, will not be impacted, but this is still not good news for Indian companies." Indian innovator companies will clearly benefit from this amendment, but the country's biotech companies, especially those focusing on biosimilars and bio-improvics (incremental innovation on existing products), will be expected to adopt new strategies, such as targeting off-patent products.

"Many biotech companies are active in manufacturing and marketing biogenerics in the US market," Dr Milind Antani, a partner at Nishith Desai Associates, told *India Business Law Journal*. "Indian companies are looking at the US biogenerics market and this amendment is likely to put breaks on their strategies. Indian companies would have to strategize to enter US market by looking at off-patent drugs that have crossed the exclusivity period."

Experts suggest that companies will now have to assess their product selection and carry out thorough IP investigations before investing in a product. Since data on the original drug will not be accessible, these companies may also have to spend more money on conducting their own clinical trials for submission to the US Food and Drug Administration.



"Many companies who are active in the biogenerics space may be inclined to develop new drugs," said Antani. "The thriving biopharma market which constitutes a major part of the biotech industry is likely to see an increased share of innovator drugs."