

Where China and India fit in the global active pharmaceutical ingredients (API) supply chain

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A 2004 Generics Bulletin interview with Newport Strategies' Kate Kuhrt examined how Chinese and Indian active pharmaceutical ingredient suppliers are striving to become global players. Expansion strategies have included having their plants inspected by the US Food and Drug Administration, and by alliances with, and acquisitions of, US and European players in this market. This interview has been a popular download from the Newport Strategies web site, and a PDF copy is now available via the web version of this article. Twelve months on, Newport Strategies is now part of Thomson Scientific, and Kate provides an update on the API industry in this part of the world.

Although the API industry in China is continuing to develop rapidly, it still lags behind its Indian counterpart. Today, China continues to be mostly a supplier of older, off-patent molecules, while Indian API manufacturers often focus on newer, still-patented molecules. As a result of the introduction of product patents in India this January¹, we may however see increased interest in older molecules by Indian API manufacturers, though the full impact of this change is difficult to determine at this time.

Changes in Established manufacturers

Since our article appeared in *Generics Bulletin* last year, the number of Indian and Chinese API manufacturers who have reached Newport's "Established" category, reserved for companies that Newport believes have been able to supply API to regulated markets for some time, has increased. While India still has more Established companies than China, the latter saw a bigger increase. Today, Newport rates 19 Indian and 12 Chinese API manufacturers as Established, as compared to 18 in India and 8 in China about one year ago.

Court decisions

Several high-profile court-cases mentioned in the 2004 article that involved patent challenges by generics using API from India have now been decided:

- In the case of latanoprost, Pfizer's glaucoma treatment XALATAN®, the District Court of New Jersey found in July 2004 that Par's ANDA infringed the innovator's patents.

- In the olanzapine (Eli Lilly's anti-psychotic ZYPREXA®) case, a U.S. district judge decided in April 2005 that Ivax, Dr. Reddy's Laboratories and Teva failed to prove that Eli Lilly's patent should be struck down.

Continued growth in US alliances

A number of the fast-growing "second wave" of Indian generic companies and API manufacturers have continued to forge alliances with generics in the U.S., with an increasing number of the Indians focusing on supplying the finished dosage form as opposed to just the active ingredient. For example, Strides Arcolab has recently joined forces with both KV Pharmaceutical and Akorn.

We have also begun to see more acquisitions of U.S. companies by Indian companies. For example, in April 2005, Indian company Jubilant Organosys announced that it had signed a memorandum of understanding to acquire 75% stake in an undisclosed US generics company. And in May 2005, Chennai-based Malladi Drugs announced the acquisition of Novus Fine Chemicals, which is believed to be the first such cross-border acquisition by an Indian pharmaceutical company in the API segment.

There is also much activity in the reverse direction, with U.S. and Western European generics continuing to acquire or take ownership stakes in Indian manufacturers. Recently, Teva and Mylan have created a lot of industry buzz by eyeing a stake in Hyderabad-based Aurobindo Pharma.

Further reading

1. **Changing times for patenting in India**, KnowledgeLinkSM (Business & Industry edition) February 2005
<http://www.thomsonscientific.com/news/newsletter/2005-02/8263720/>
2. **Horizon Global**: Powerful product targeting, global business development and competitive intelligence system created specifically for generic pharmaceutical companies and strategic API manufacturers.
<http://scientific.thomson.com/products/horizonglobal/>