

# THE UPCOMING PATENT CLIFF: IMPLICATIONS FOR INDIAN PHARMACEUTICALS

Leading global pharmaceutical firms are facing material challenges as a significant number of patents for branded drugs will be expiring over the next five years. The impending expiration of a range of lucrative pharmaceutical patents, also known as the “patent cliff”, is expected to have a significant impact on the pharmaceutical industry landscape.

## THE PATENT CLIFF

The total value<sup>1</sup> of patents expiring between 2010 and 2015 is expected to reach US \$100 Billion, which represents a significant increase from \$73 Billion in patent expirations during the previous five years. Indian pharmaceutical companies have the opportunity to capitalize on the patent cliff and gain a greater share of the growing generics market. Competition in this space is expected to increase as global pharmaceutical companies, in anticipation of the upcoming patent expirations, are focusing their resources and attention on the generics market. In a highly competitive marketplace, what will it take for Indian pharmaceutical companies to be successful?

## THE EVOLUTION OF THE INDIAN PHARMACEUTICAL INDUSTRY

Due to legal and regulatory changes in the Indian pharmaceutical industry, Indian drug companies have evolved into successful, globally competitive companies. Prior to 2005, Indian pharmaceutical companies were permitted to sell generic versions of patented drugs in India provided the manufacturing processes used were different from those used for patented drugs. This ‘process reengineering’ requirement resulted in the Indian drug companies developing expertise in process innovation.

In 2005, with the advent of the World Trade Organization (WTO) patent regime, regulations changed. Indian pharmaceutical companies were barred from copying patented drugs via process reengineering. However, this same WTO agreement allowed Indian companies to sell generic versions of off-patent drugs in developed countries. Quality and regulatory demands from the developed world were more stringent than in India. The best Indian pharmaceutical companies were able to adapt and have since established themselves as leaders in the global generics business. Today, four out of the top twenty generic drug companies in the world are Indian companies.

## INDIA’S COMPETITIVE EDGE

Historically, key factors that contributed to the global competitiveness of Indian firms in the generics business included:

- **The first mover advantage:** Indian companies have continued to invest significant resources in the development of a robust pipeline of generic drugs. Over the last three years, Indian companies have been responsible for one third of new drug applications submitted to the United States Food and Drug Administration (US FDA) for the launch of generic formulations, also known as the Abbreviated New Drug Application (ANDA) filings.
- **Low cost manufacturing base:** The costs of establishing a US FDA approved plant in India is up to 50% lower than in developed countries. As a result, India currently has the highest number of US FDA approved plants outside of the US. In addition, production costs in India are on average 40% to 70% lower than in developed countries due to local equipment sourcing, tax incentives and a focus on process innovation.
- **Deep and cost-efficient talent pool:** Labor costs in India are 60-70% lower than in developed countries due to the availability of a large pool of highly qualified personnel specializing in chemistry. India produces approximately 100,000 chemists and chemical engineers every year.

<sup>1</sup> As measured by annual sales



While these factors have contributed to the recent success of Indian firms, these advantages may not represent sustainable competitive advantages as global innovator firms focus their attention on the generics market. Many global pharmaceutical companies are now partnering with developing countries-based manufacturers in order to improve their cost competitiveness, resulting in low cost manufacturing being a common factor (no longer a differentiating factor) in pharmaceutical companies globally. In the future, to become a successful global leader, a company will need the following attributes:

- **Focus on complex and niche segments:** Long-term growth can be generated by focusing on specialized therapeutic areas and/or more complex molecules. In addition, generic firms with an advanced drug development pipeline may become defensive acquisition targets, as innovator pharmaceutical companies look to protect their patented drugs.
- **Strong competitive positioning:** New drug delivery systems can be used to compete with drugs whose formulation patents have not expired. These segments tend to be less competitive, but development of such applications requires significant capabilities in both research and marketing. Another leading indicator of strong competitive positioning and future profitability for a company can be its ANDA Para-IV pipeline, especially for companies who enjoy initial marketing exclusivity (a Para-IV filing involves challenging existing patents).
- **Backward integration:** Generic pharmaceutical firms that are backwards integrated, such as with captive Active Pharmaceutical Ingredient (API) manufacturing capabilities, are likely to have higher margins. Backward integration can enable generic players to maintain quality standards and improve cost competitiveness.

#### BENEFICIARIES OF THE PATENT CLIFF

Pharmaceutical manufacturers are not the only potential beneficiaries of the upcoming patent cliff. Other enterprises in the Indian pharmaceutical eco-system may also benefit. For example:

- **Contract research and manufacturing services (CRAMS),** which provide outsourced drug research and manufacturing activities, are poised to generate strong business from global pharmaceutical firms. Due to cost pressures resulting from declining R&D productivity, rising drug development costs and fewer new drug discoveries, the global firms are outsourcing more non-core activities to CRAMS in developing countries.
- While API manufacturing is currently the most dominant form of outsourcing service in India, demand for **Clinical Research Outsourcing (CROs)** has grown by more than 60% CAGR between 2007 and 2010, with a market size of \$1.5 Billion. This rapid growth could be attributed to the diverse genetic pool, strong technical expertise and increasing compliance with international standards.

Zephyr Peacock India (ZP) is well positioned to leverage India's competitive advantage in the global pharmaceutical industry. ZP recently invested in a provider of drug development solutions in India, and continues evaluating new investment opportunities in the Indian pharmaceutical sector.



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