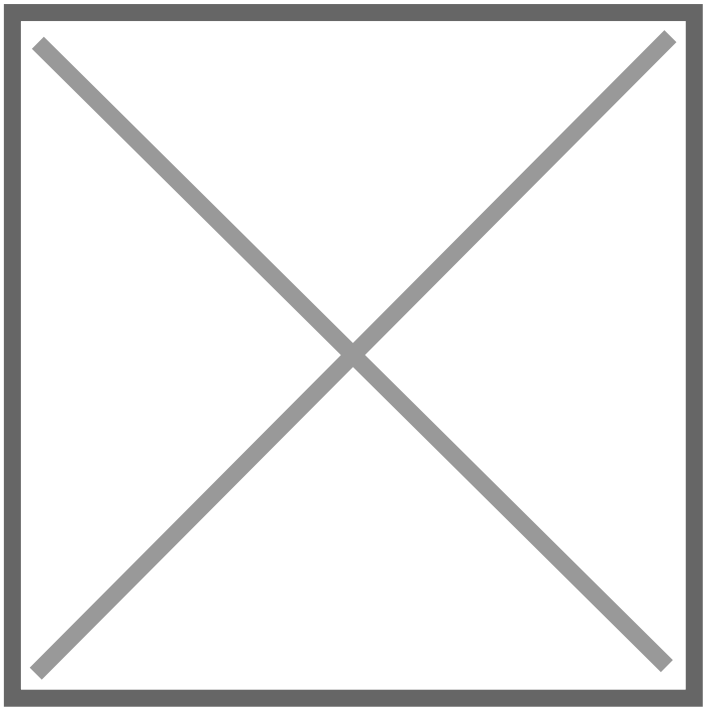
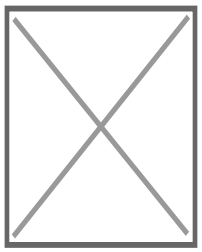
BioSpect
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

Right partnerships to aid growth

11 October 2011 | News





Mr Sudhir Vaid
Chairman & MD, Concord Biotech

The author has around 35 years of experience in the development of biopharmaceutical products, production management, marketing, US FDA approvals and strategic planning. His last job assignment was as director-fermentation with Ranbaxy Laboratories, where he initiated and successfully completed biotechnology green field projects.

The biotechnology industry is one of the fastest growing sectors with total global sales for the pharmaceutical and biotech sector at around $400 billion. Therefore, this market represents a significant target for the generic companies. Due to the patent expiry of several biotech products, a great opportunity is emerging for the pharmaceutical companies in India. However, these opportunities are also associated with a lot of marketing challenges. If these challenges are understood well by the companies in India, they can definitely have an edge over the Chinese companies. The major formulation companies in India understand these challenges very well as far as the marketing of the finished products is concerned, but it is not well taken by the bulk biopharmaceuticals companies in India who are getting very tough competition from the Chinese companies.

Patent issues: The major marketing challenge for the biotech industry is to understand intellectual property (IP) relating to its drug candidates on a variety of levels during the early stages. How strong is patent protection? Will the company have freedom to operate in the regulated or the semi-regulated markets? How will a buyer or partner view the IP rights? How well will the patents hold up against the challenges from generic companies? What plans are in place to develop and commercialize drugs in the US, Europe, Asia and the emerging markets?

It is very important to understand the IP-related issues and spend wisely and analyze the global patents to avoid an IP nightmare. Concord Biotech has understood this issue and works to develop its own non-infringing processes to enter the major markets on the day-one launch with its abbreviated new drug application partners to get the maximum advantage of the generic market.

Life-cycle of drugs: In a world where new products are constantly entering the market, making other products obsolete, one of the marketing challenges faced by the biotech industry is the selection of the products, understanding its lifecycle and proactively working on adding new molecules to its portfolio in order to reduce any financial risk to the organization.

One of the main reasons for the success of Concord is faster identification and commercialization of the product, to get the benefit of the market as an early entrant. This way, Concord enters the market when the product is in its early lifecycle phase.

It is very well-known fact that the market for all matured antibiotics or secondary metabolites made through the fermentation route are now controlled by China and they have become a big challenge for the companies in India. For such products, Concord's team first evaluates their commercial viability and then utilizes its R&D team's expertise and knowledge base to deliver high quality products at competitive prices.

Regulatory issues: The other major hurdles are the different regulatory approvals that delay the entry of a product in the markets. The approvals from the different regulatory authorities come within 24-to-36 months, which makes it very difficult for the companies to enter markets, such as the US, Europe, Japan and Mexico.
It requires proper planning to enter these markets and to get the advantage from them. Concord has already got all the approvals from different regulatory authorities, such as the US FDA, EUGMP, the regulatory authority of Japan and among others, and has dedicated facilities for all its products, which makes it different from other companies in the same segment.

Global uncertainity: One of the other challenges faced by the biotech industry in India is that due to the global economic uncertainty, companies have become slightly more risk averse in selecting new products for their portfolio. This has led to delay in decision on selection of products for their portfolio.
Long gestation period: On certain occasions, the therapeutic segment, to which the company is catering to, can also become a challenge in the short term and critical to the growth of the organization. Usually, for products that fall under the life saving drugs' category, the generic penetration is much slower as patients don't like to change the brand and requires convincing the doctors and their patients.

Considering the fact that the biotechnology segment is highly capital-intensive, such a prolonged gestation period can affect profitability of the company in the short term. In the long run, this creates a barrier in entry. Companies need to build such a portfolio in which risk from one therapeutic class or product can be mitigated by another, hence not affecting the short-term business profitability.

Right partnership: In the biopharmaceutical industry, particularly in the generics sector, the new trend is towards having novel business models, such as hybrid models, between generic and innovator companies, and between generic companies partnering and third-party sales teams, to increase growth. The benefits from these partnerships are wide-ranging for the generics companies, from better access to R&D capabilities to innovator drugs access and wider penetration in new markets. The challenge is to collaborate with the right kind of partner and Concord is constantly working on identifying such partners and working with them to enter different markets for its existing and new products.

Price pressure: Globally, one of the challenges faced by the innovator companies is the pricing pressure on drugs from a larger number of generic players. This erodes profitability and the challenge is to retain market share once the product patent is over. One of the ways to overcome this challenge is the strategy of authorized generics, which are copycat versions of a company's branded drugs, sold through licensing agreements between the innovator company and generic drug manufacturers. Concord with its expertise in biopharmaceuticals is looking at such opportunities.

These are some of the challenges faced by the generic biopharmaceutical companies, and Concord Biotech is proactively working to overcome these challenges in order to create a solid base for the company and to make its business sustainable.