

Opportunities for Indian biosimilar players

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From India's perspective, we must first understand that the opportunity for Indian biosimilar players is in four key growth segments of products, services, technology and applications

When we say biosimilars, we tend to think about products and services segment, however, we seem to forget the applications and technology development segment. Some of the examples include:

Biosimilars product segment: Peptides, recombinant glycosylated proteins, recombinant non-glycosylated proteins and others.

Biosimilars service segment: Drug development, contract research, manufacturing services and clinical trials services.

Biosimilars applications segment: Oncology, infectious diseases, chronic and autoimmune diseases, and other diseases which are typical to Indian genome which incidentally contains Indo-European, Dravidian, Tibeto-Burmese, Austro-Asian and covers almost 65 percent of world's population that has 90-95 percent similar Indian genotypes.

Biosimilars technology segment: Recombinant DNA technology, monoclonal antibodies technologies, protein sequencing, bioassay, chromatography, nuclear magnetic resonance, and mass spectrometry.

In order to gain a fair share of the global biosimilars products, services, technology and applications market, Indian biosimilar players would need to invest heavily in creating alliances and discovery. Looking at the biopharma patent expiries, Epoetin, Human Insulin, Human Growth Hormone (HGH), Colony Stimulating Factors (CSFs), Interferon Alpha and Beta are the key products that would offer huge opportunity if Indian players are able to manage the time to market. While there is still unclear regulatory hurdles that Indian players would need to clear in the US and Europe, players who are able to pre-empt would be

successful in these major markets. Let us not forget that in the biosimilars services space, India does have the advantage over other Asian countries such as China, this is fast diminishing and eroding. Indian companies likely to succeed in the biosimilar market need to have an appropriate marketing structure as well as the financial resources to develop the products and to accept higher upfront risks in development, commercialization and capital investment.

Hurdles for Indian players

The process to develop a biosimilar -essentially generic version of biopharmaceuticals – is more complex than that of developing a generic copy of a chemical-based compound. The regulatory pathway is not completely finalized both in the US and EU which are the largest markets for biosimilars. Apart from the regulatory and clinical development hurdles that are costly and time consuming, Indian players need to upgrade their capabilities as their organizations mature. Some of these include joint venture and alliance management for collaborative research, contract research, contract manufacturing, developing technology transfer management, marketing arrangement for biosimilars globally, to name a few.

The biosimilar market will be characterized by price competition, even when there is only one or a very limited number of players for biosimilars. This will constrain the commercial opportunity. Even a small price difference reduces the incentive to switch. The consensus seems to be that a 20-25 percent discount is optimum to increase the switch back. Hence the ability of the Indian players to be cost-competitive producers of biosimilar products, services, applications and technology will enable them to lock in the customer and the final consumer.

The required capital investment and operating costs of manufacturing will be much higher for biosimilars than for generic drugs. Some of the key players in India have been able to raise capital on the global scale, however, with the recent downturn, the ability of Indian players to sustain and raise capital seems suspect given their leverage and capacity to raise funds.

Several potential biosimilars face competition from second-generation products with more convenient administration schedules. In many cases, the same biopharma or large pharma companies market the original and second-generation products and there may not be a marked difference in price. This would completely erode the incentive for Indian players to launch products that are price competitive, given their R&D and development investment loading.

Improved delivery devices can add significant value and enhance product differentiation. There are, however, a limited number of drug delivery companies, many of which are already working exclusively with the branded incumbents. This would restrict the options for Indian players trying out newer delivery systems as part of the differentiation and patenting.

Entry into EU and US

Entry barriers are relatively low and there tends to be severe price competition from several generic competitors reducing sales significantly after the first year of presence in the market. It is not clear if there will be enough biologic candidates for a company that is focused on launching biosimilars to sustain growth. There are not enough possible biosimilars for a company to rely on these alone to launch a new product every year. Biosimilar players will therefore need to adopt different business models and skill sets from those of conventional generics companies.

Other regions that Indian players can target include countries like Japan, Canada, Mexico and Latin America.

Global competition

Many countries are now realizing the need for biosimilar regulation to control and manage the growth of biosimilars in their country. Around 15 to 20 countries have put in some sort of guidelines in place. These countries are in the race and also potential competition to Indian players.

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