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Biogenerics market gaining momentum

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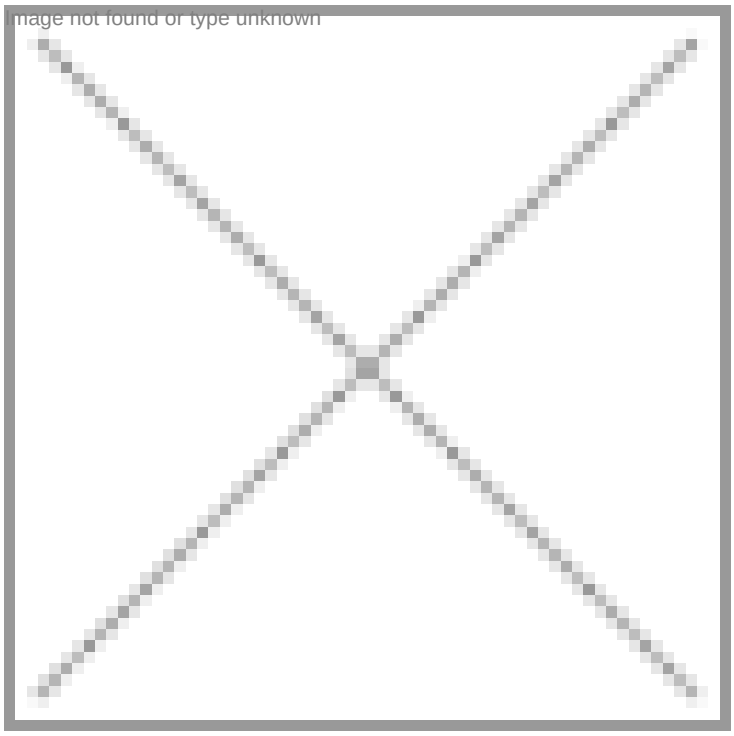

Biogenerics market gaining momentum

With India becoming TRIPS compliant, local companies are looking at drugs going off patent and also the biogenerics market so that they can produce and market the products at an affordable price.

During 2002-04, as many as 20 biotech drugs have lost their patents in the US. Of the many drugs, the US patents for 13 biotech products will expire during 2005. Similarly many other blockbuster drugs are expected to lose patent protection over the next few years, paving the way for competitors to legally manufacture biogeneric versions of the biotech products and market them. This represents tremendous potential for biogeneric manufacturers. Since there is no real need to invest in drug discovery and clinical development, biogeneric manufacturers can sell these products at lower prices than the patented original drugs.

This is expected to not only encourage consumers to purchase generic alternatives but also receive support from governments and healthcare providers seeking to reduce expenditure on therapeutics. This is why the Indian government faced resistance from non-government organizations, both local and international organizations, when it passed an ordinance for the product patent in December last year. However, the high manufacturing costs for biologics compared to conventional small molecule pharmaceuticals present a challenge to biogenerics manufacturers.

Companies in developing countries like India are looking at biogenerics as a large number of biologicals are slated to go off patent and the pipeline for potential generic launches is dwindling. Considering this, the market potential for biogenerics will grow significantly in the coming years. According to Frost & Sullivan estimates, the biogenerics markets in Europe and the

US alone has the potential to generate sales of $16.4 billion by 2011 at an average annual growth rate of 69.8 percent.

The branded biologic products generated an estimated $32 billion of sales for the biotechnology and pharmaceutical industries and represented the fastest growing group of drugs. While continued high demand, high prices, and applicability in previously untreatable conditions are behind the success of branded biologics, the absence of generic competition has meant that growth has gone unchallenged. By 2010, biologic products that accrue an estimated $11.2 billion worth of sales annually are expected to lose patent protection in developed pharmaceutical markets.

Rajesh Jain, joint managing director, Panacea Biotec said, "It is estimated that drugs worth $60 billion will go off patent by the year 2010. This does suggest a great opportunity for Indian pharmaceutical industry that can leverage the expertise and capabilities developed in the field of process chemistry. Many Indian pharmaceutical companies have already made serious efforts to bring out and market cheaper generic version of these drugs."

According to Beyond Borders 2005 - a global biotech report of Ernst& Young - Procrit (Recombinant erythropoietin) had recorded sales of $3,589 million in 2004. Similarly other leading biotech drugs like Rituxan (Chimeric monoclonal antibody; anti-CD20),

Remicade (Chimeric monoclonal antibody; anti-TNF-alpha), Epogen (Recombinant erythropoietin), Enbrel (Recombinant fusion protein; soluble TNF receptor linked to IgG1), Aranesp (Novel erythropoiesis-stimulating protein (2nd generation EPO)), Epogin/NeoRecormon (Recombinant erythropoietin), Neulasta (PEGylated version of Neupogen) Avonex (Recombinant interferon beta-1a) and Pegasys/ Copegus (Recombinant interferon alfa-2a modified with PEG (monotherapy; also in combination with Copegus [ribavirin])) have recorded sales of $2,963 million, $2,891 million, $2,600 million, $2,580 million, $2,500 million, $1,826 million, $1,700 million, $1,417 million and $1,370 million respectively. This gives an idea about the market potential for these biotech products world over.

Ernst & Young in its global biotech report also pointed out that Asia-Pacific nations such as India and China are emerging as major players in the development of a global market for biogenerics. Both countries are positioned to take advantage of moves by governments in the US and Europe to create a regulatory framework for approving generic versions of successful protein drugs.

Opportunities

Off the 50 odd biotech drugs 13 are available in India and seven biotech drugs are indigenously developed and produced by the Indian companies. "All the biotech products produced by Indian companies are generic in nature. India has a huge market potential for biogenerics. There are many products going off patent this year and in next couple of years. Insulin itself has a $5 billion global market annually. So the market potential for biotech drugs going off patent is huge. "Setting aside the present biogeneric market, I would say it would be in the range of Rs 500- 1000 crore by 2007-08 including the exports from India," said Dr Hemanth Nandigala, executive director, Virchow Biotech Pvt Ltd.

On the opportunity for biogenerics, Jayashri Kulkarni, director - Healthcare Practice, Frost & Sullivan, India said, "While the opportunity cannot be compared to that in the international markets since it is limited by pricing constraints in the Indian context, the very indication given by the number of applications for import/clinical evaluation/ manufacture and market applications in the sector are evidence enough of the opportunity in biogenerics in India."

Utkarsh Palnitkar, industry leader - health sciences too pointed out that the potential for biogenerics is definitely significant. However, the costs of conducting trials in the respective countries where these products are to be introduced should also be factored.

Commenting on the market potential for these products, Jayashri Kulkarni said, "Typically the market potential in India for biogenerics has been in the range of 0.1 percent (EPO) to 0.2 percent of (Insulin) of the global market value based on the type and class of molecule. Pricing dynamics and the promotional message of make and market have played a crucial role in the market composition historically and will continue to dominate the market dynamics for the soon-to-expire molecules as well."

" While the molecules currently marketed in India see majors like Wockhardt, Dr Reddy's and Shantha Biotechnics and now Biocon and Panacea Biotech which also have capabilities in developing the next group of products going off patent, quite a few companies are also preparing themselves to enter the market with the make and market strategy - these include Zenotech, Cadila, Ranbaxy, Intas and Serum Institute of India," she added.

Alok Gupta, country head, life sciences and biotechnology, YES Bank Ltd said, "Some of the biotech products from Amgen,

Serono, Johnson & Johnson, Genentech, Novo Nordisk, Eli Lilly, Pharmacia, Chiron, Biogen are in the list of patent expiry. Indian companies are working on these biotech products as they have a good market potential."

"There have been various reports that one or the other company is working on somatropin (basically human growth hormone) but nothing confirmed yet. As such it is a bacterial derived product and not that difficult to make for any company already making similar products. Interferon beta has a large market internationally but its only approved indication is multiple sclerosis, and does not have a large market in India. Alteplase is tPA (tissue plasminohgen activator) and again, I have not heard of any companies in India pursuing this product. This is a mammalian cell culture derived product. Currently streptokinase seems to be the only Indian manufactured product in this category (same indication as tPA)," said Dhananjay Patankar, head biotechnology, Intas Pharmaceuticals.

India is emerging as a key player as far as biogenerics are concerned. The domestic market sales from the biogenerics (only the recombinant biotech products) were estimated at about Rs 500 crore as many Indian companies are into both manufacturing and marketing of these products. Companies such as Bharat Biotech, Dr Reddy's Labs, Panacea Biotec, Shantha Biotechnics, Wockhardt, Biocon, Intas Pharmaceuticals, Shreya Life Sciences have showed that they are capable of producing biogenerics in India. These companies have already introduced as many as seven biotech drugs (Hepatitis B vaccine, Streptokinase, Insulin, G-CSF, Erythropoietin, Human Growth Hormone and Interferon alpha 2b) under many brands. With the introduction of these biogenerics, there is a drastic drop in the prices.

Issues to look at

Although there is a huge opportunity and market potential for the biotech drugs, there are some issues that might delay the companies to enter the biogeneric market.

While the development of an abbreviated regulatory pathway is crucial to the approval of new biogenerics, growing concerns about the lack of a definition for bioequivalence and increasing pressure from major biotechnology companies anxious to defend their ailing blockbuster patents are preventing the growth of biogenerics market. This is currently the single largest hurdle facing the biogenerics market.

And innovators are employing delaying tactics aimed at preventing the biogenerics players from taking shorter routes to approval. Development of second-generation products that are significantly better than the originals, meaning that original products are unlikely to take significant market share.

Dr Hemanth Nandigala of Virchow Biotech said, "The only hurdle coming in the way of biogenerics is the regulatory system as there is no clear regulatory framework in USA, a huge market for biogeneric products. However, last year the FDA called for general opinion and feedback from the stakeholders to biogenerics. It is still compiling the same. On the other hand, Europe instituted a clear-cut pathway for the biogenerics products. Once the things are in place, then the opportunity for biogeneric manufacturers will be huge."

Sharing similar views, Rajesh Jain of Panacea Biotec said, "The regulatory issues are not yet very clear especially for 'biogeneric drugs'. However, there are likely to be challenges in regulatory issues for biogeneric drugs."

To overcome these hurdles, the biogenerics companies should look at strategies such as establishing strategic partnerships, expanding the operations through acquisitions, supplying into developing markets initially, followed by Europe and eventually the US and finally developing second-generation of products.

Number of drugs with patents expiring in 2000-04 (Grouped by treatment category)

In addition to adopting these strategies, the biogenerics companies need to be well financed, possess sufficient technical capability, and be operating to Western GMP standards, be sufficiently focused, usually on only one or two products, since they will need to understand the market segment they are entering and have sufficient finances to operate in the chosen market. These companies need to look at developing such products where they need to be certain that: there is no intellectual property barrier.

Against all these odds there is some relief for the biogeneric companies as Europe has started accepting applications for abbreviated market approval of new biogenerics. Earlier, biogenerics companies were thriving in less regulated countries such as India, China and other developing countries like Africa.

An European Medicines Evaluation Agency (EMEA) has recently issued guidelines for generic versions of some biopharmaceutical products. These guidelines will permit Indian companies to apply for approval to market generic versions of biotech products in Europe. But the US is yet to develop a shorter regulatory path to market biogenerics.

Companies like Wockhardt, Dr Reddy's Labs and Biocon are looking at entering the regulated market in Europe, which has regulatory system in place for the biogenerics. Wockhardt has received 17 registrations for its biopharmaceuticals and 36 registrations are being pursued in various overseas markets such as Russia, South America, North Africa, Central Asia, South East Asia. It has also formed majority joint ventures in Mexico and South Africa and has set up a subsidiary in Brazil.

Rajesh Jain said, "Panacea Biotec at the moment is working on several bio-pharmaceutical products and several new therapeutic molecules with its own IPR backing the development. One example is Hair Growth Utilizing Actin Binding Peptide."

Treatment category	2000	2001	2002	2003
1. Cancer and cancer related treatments	5	6	4	2
2. Anti-infective treatments	2	6	2	3
3. Central nervous system treatments	6	2	2	5
4. Cardiovascular/cerebro-vascular treatments	13	13	6	17
5. Respiratory treatments	5	3	4	5
6. Endocrine, nutritional, metabolic and immunity treatments	3	2	2	3
7. Topical treatments	5	1	3	7
8. Hormonal treatments	1	4	1	5
9. Musculo-skeletal and connective tissue treatments	1	0	1	0
10. AIDS and AIDS related treatments	2	2	0	1
11. Analgesic treatments	1	5	5	1
12. Digestive system treatments	5	1	5	0
13. Blood disorder treatments	0	0	0	0

However, global biotechnology companies are likely to go to great lengths to reinforce their patents, reformulate existing products and improve delivery systems in an effort to maintain the customer base for their branded products. But once regulations are clearly established, one can see a flood of biogeneric alternatives to hit the market soon after the expiry of each blockbuster patent.

Dr P K Ghosh said that in the infrastructure development, one strategic action the government could look at is to continuously publish the protection period of useful biotech products that are protected under IPR so as to draw the attention of entrepreneurs/researcher on a continuous basis.

Dr KK Tripathi, advisor, Department of Biotechnology said, "Indian companies working on the products going off patent under the various provisions of the IPR, will enter the world market in a big way. They will be able to export the product if the FDA approves it. This will definitely open a big avenue for the Indian companies."

Narayan Kulkarni with
Rolly Dureha in New Delhi