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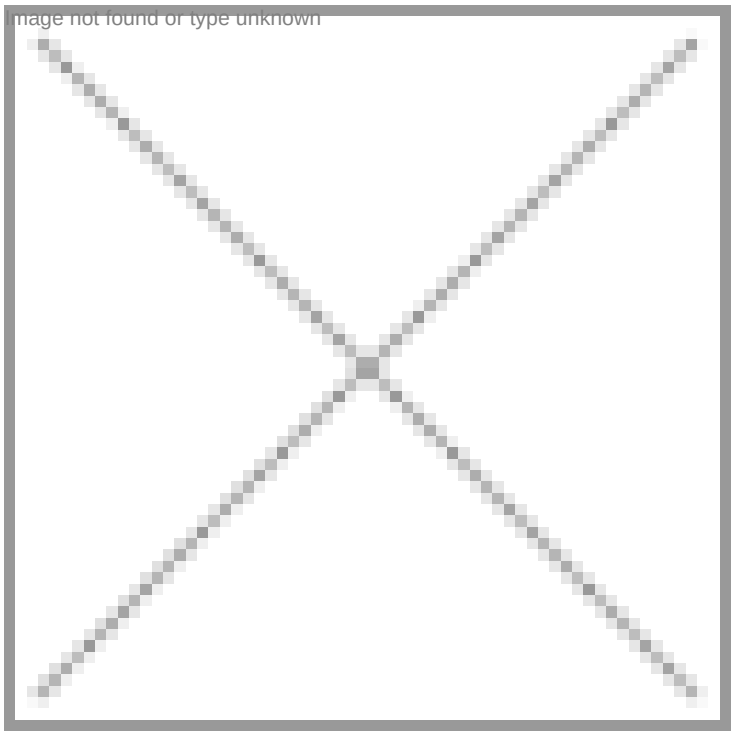
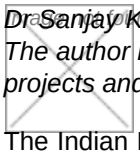
Avenues for Indian Players in Bio-Blockbuster Drugs

10 September 2008 | News



Avenues for Indian Players in Bio-Blockbuster Drugs

Today's Bio-blockbuster drugs are tomorrow's bio-similar drugs. Only our proactive strategy, vibrant dynamics and targeted speed could win the race of forthcoming opportunities.



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The Indian Biotechnology industry was slow to start but is now gaining momentum. The growth of biotech segment has been phenomenal in the current decade and has finally arrived on the global scene. Indian capabilities are not to be proven as we all know the success that India has experienced in the IT sector on the global settings as it offers the cost and creative advantages over other emerging markets. There is optimism, vibrant dynamics, young enthusiasm and confidence behind a futuristic biotech vision in India. Moreover, India has a globally recognized thriving and vibrant biotech community where whole world is looking at it for joining the hand.

Promise sector

India shows immense potential not only as a destination for new generation biotech products but is also being targeted as a potential hub for outsourcing of clinical trials, contract research and manufacturing. Now, this segment is being observed as

the latest booming sector in the Indian economy, as it is fast gaining ground to be at par with the information technology sector. India is today one of the five emerging biotech leaders in the Asia-Pacific region as reported by a survey of Ernst and Young (The Hindu; August 15, 2007). There has been a phenomenal increase in the number of start-up companies in this area in the current decade. An Ernst & Young survey, based on the number of biotech companies in the country, ranks India among the top three biotech hubs in the Asia-Pacific region, after Japan and South Korea (The Financial Express; June 08, 2007). The Indian Biotechnology sector today comprises over 340 companies generating revenues over $2.5 billion; where biopharma sector has been the major stake-holder and contributed for about 67 percent of the total biotech generated revenue (Biospectrum, Vol.: 6, Issue 7, Jul 2008). The biopharma is dominating in exports in the order of 70 percent in addition to its domestic domination of 64 percent of the total biotech sales (Biospectrum, Vol.: 6, Issue 7, Jul 2008). The biotech business is growing at a pace of 30-40 percent per annum and estimated to cross $5 billion by 2010 (ABLE-Biospectrum survey for 2006-07). The Indian biotech industry is expected to reach Rs 4,40,000 crore in 2020 (capitalmarket.com).

Biotech drugs today account for 10-15 percent of the world pharma industry, and the sector is outperforming the market as a whole
(Express Pharma:16-31 July 2008; Market Research.com, Injectable Generic Drugs: Prospects & Opportunities to 2010, Revised Edition).

The exponential growth in the therapeutic monoclonal antibodies segment has been seen for last 4-5 years. Today, anti-cancer monoclonal antibodies segment has a highest contribution in the blockbuster drugs (R&D Pipeline News, Top 20 Biologics 2007: March 2008). The opportunities for biosimilar molecules are predicted to increase tremendously in the next decade as several blockbuster drugs are expected to go off-patent. The global markets for Indian player appear to be well positioned to leverage their cost-effective operational capabilities and compete on a global platform. With the forthcoming opportunities, Indian biopharma industry has potential to touch the mark of 20 billion in the next decade.

Multi-billion blockbuster drugs (Biosimilar drugs of next decade) and their sales value in 2007*

Drugs	Indications	Sales Value in 2007 (Millions US $)
Etanercept	Rheumatoid arthritis; psoriasis	5,453
Rituximab	non-Hodgkin's lymphoma	5,392
Trastuzumab	Metastatic breast cancer	4,743
Infliximab	Rheumatoid arthritis, etc.	4,465
Bevacizumab	Metastatic colorectal cancer	4,014
Darbepoetin	Renal and cancer anemia	4,004
Adalimumab	Rheumatoid arthritis; psoriasis	3,064
Neulasta	Neutropenia	3,000

Epoetin beta	Renal and cancer anemia	2,047
Insulin analogs	Diabetes mellitus	8,256
* R&D Pipeline News, Top 20 Biologics 2007, March 2008.		

Acceleration needed

Indian companies need to accelerate the selection and development of new generation biosimlar drugs, so that India could win the race of presenting the drugs to the world after their patent expiry. Indian firms are required to be geared up to upgrade the manufacturing facility and systems compliance to the standards of international regulatory agencies, such as the US Food and Drug Administration (FDA), European Medicines Agency (EMEA), Therapeutic Goods Administration (TGA) and the World Health Organization (WHO), to facilitate access to international markets not only for biosimilars but also novel protein products currently in their pipelines. Some Indian firms have proactively sensed the needs and demands of the next decade and initiated working towards the development and scale-up to manufacture such drugs for regulated markets.

India already has skills and infrastructure for recombinant proteins production and now evolving into the production of monoclonal antibody based drugs. Strength from India's perspective are in strong bio-manufacturing skills with low-cost base generating high capital efficiency, established settings to assess the indigenously made biosimilar drugs comparable to the originator's products through physicochemical characterization, in-vivo and in-vitro potency evaluation, pharmacokinetic and pharmacodynamic studies, immunogenicity, allergenicity, hypersensitivity and clinical studies.

Key challenges

Though, India has intrinsic strengths in biotechnology, but several challenges still remain to be addressed to make India aspire to join the ranks of the truly powerful players in the world. Following are the challenges which need to be addressed.

Setting up a single window regulatory clearance framework to speedup the process to commercialize the products. Though, the single window regulatory clearance is in the process but sooner we have a well-equipped statutory national regulatory body, the quicker products would see the markets.

Pharmacopoeia contented with the current biotech drugs and future biosimilar drugs to be developed;

Though, the government policies have been largely supportive, there is need for more innovative, creative, substantive, priority funding and the funding from venture capitalists, banks and other financial institutions that somehow seem too coy of financing biotech firms and its initiatives.

Conclusively, I would say that jump to grab the visible opportunities, before hand, of getting blockbuster drugs off-patent and let India win the race on the global set.

The views expressed herein are the personal views of the authors and do not necessarily represent the views of the company they represent or any of its member firms.