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India on biologics trail

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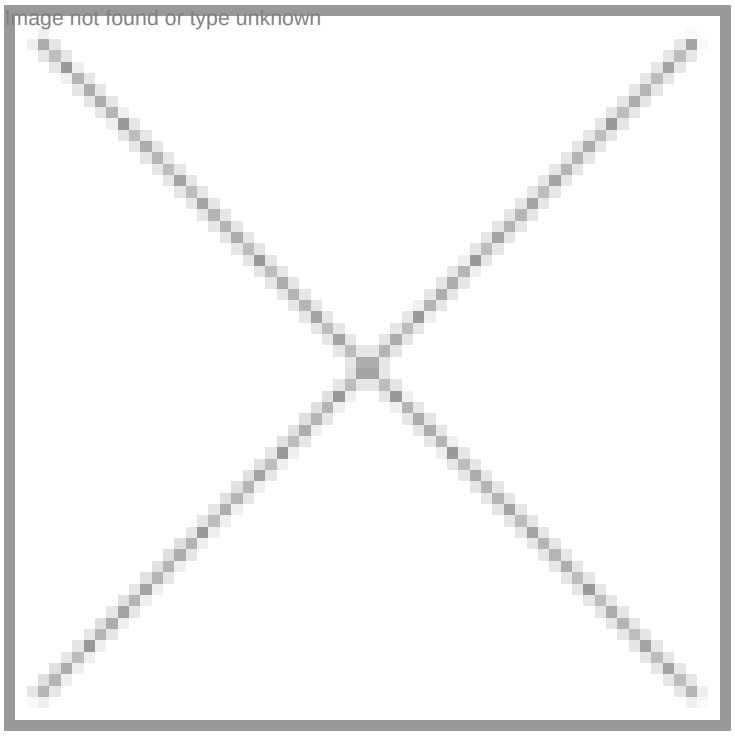

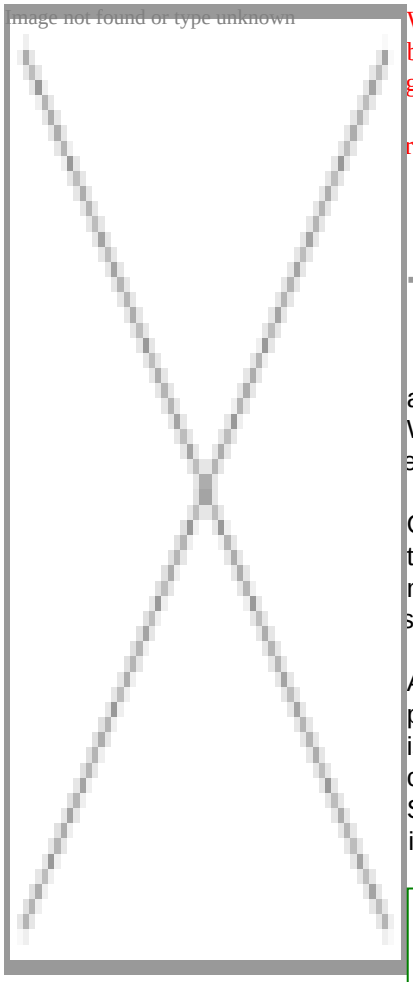

With its low costs and skilled manpower, India makes an ideal destination for manufacturing biologics. Biotech companies are ramping up their facilities and quality standards to meet the patent government regulations to match up.

ry's preparations and the hurdles on the way

The Indian biotechnology industry, which clocked total annual revenues of 20,000 crore ($4 billion) for FY 2010-11 (BioSpectrum-ABLE top 20 survey 2011) is slated as one of the fastest growing knowledge-based sectors in the country and is predicted to have a significant impact on the overall global landscape. The year 2012 has brought a world of opportunities for Indian biotech companies, with big-wig biotech firms in the West facing a spree of patent expiration of their blockbuster products. Gradual expiry of et opportunities for developers through to 2016.

Opportunities for India are mainly in areas such as biosimilars, vaccines and recombinant therapeutic products. Indian companies are leaving no stone unturned to expand their manufacturing capabilities. Adherence to current good manufacturing practices (cGMP) st.

A large chunk of the Indian firms are also looking at contract manufacturing of biologic products for western companies. The contract manufacturing organization (CMO) market is a growing market in India and is expected to grow at an average of 20 percent in the coming years. Primary players in the CMO space include Piramal Healthcare, Jubilant Life Sciences, Strides Arcolab, Shasun, Dishman Pharma and Divi's Laboratories who have ities for the job.

Patent expiry and the market

Between 2012 and 2019, the market will see a patent expiry of a whopping 300,000 crore ($60 billion) worth of biotech drugs with Amgen being the most hard hit of all. Enbrel, its blockbuster drug for anemia, Epogen, which had a sale of about 12,500 crore ($2.5 billion) in 2008, will lose its patent in 2013. Another blockbuster drug Neupogen will lose its patent in 2013, while arthritis drug Enbreal will lose its patent in 2012. Epogen, Neupogen and Enbrel together account for half of Amgen's total revenue.

Back in 1997, Hyderabad-based Shantha Biotechnics introduced the first indigenously produced hepatitis-B vaccine, Shanvac-B. Since then, there has been no looking back. They have bolstered their manufacturing capabilities for recombinant DNA products and have maintained a healthy pipeline of products in the space, and once commercialized, they are also looking at exporting these products, mainly to the emerging markets of the world. At present, there are 20 recombinant therapeutic products approved for marketing in the Indian market.

â€œThe biopharmaceutical industry in India is expected to see strong growth in 2012, driven by growing markets, several new biosimilar product launches, exports of biosimilars and product-based partnerships,â€? says Mr KV Subramaniam, president, Reliance Life Sciences. Today there are around 25 Indian biosimilars players in the space with around 50 products in the market in the country. Some are also being sold in the unregulated markets.

Indian biotech organizations are also bullish on the vaccines market and are making significant contributions to both the domestic and international markets. This has led many of the homegrown companies to set up state-of-the-art manufacturing facilities and a chunk of the volume produced there are exported to global regions and non-institutional organizations, such as the World Health Organization, GAVI and PATH. The vaccine market had an estimated sales of 2,180 crore for the previous fiscal and they account for 50-to-60 percent of the total biopharma market.

Biologics manufacturers and their products

Company	Segment	Major products manufactured in India
Serum Institute of India	Vaccines	Bacterial vaccines, viral vaccines, recombinant and combination vaccines, Meningococcal A conjugate vaccine
Wockhardt	Biosimilars	Glaritus (24-hr insulin analog), Wosulin (recombinant insulin), Wepox (erythropoietin) and Biovac-B (hepatitis B vaccine)
Zydus Cadila	Biosimilars /Vaccines	Products still in pipeline which include G-CSF, PEG-GCSF, MABs, EPO / vaccines for infectious diseases. Main vaccine in recent past being VaxiFlu

CPL Biologicals	Vaccines, Biosimilars and Diagnostics	Streptokinase, Anti-Rabies Serum, VISIAL, Halonix (Sodium Hyaluronate)
Reliance Life Sciences	Biosimilars	ReliFeron (recombinant Interferon a), ReliPoietin (recombinant Erythropoietin), ReliGrast (recombinant GCSF), MIRel (recombinant Reteplase - tissue plasminogen activator), FostiRel (FSH), ReliBeta (recombinant Interferon beta-1a), ChorioRel (recombinant chorionic gonadotrophin hormone r-hCG)
USV	Biosimilar	This year, USV is planning to launch first indigenously developed Somatropin for injection and Teriparatide injection in the India market
Lupin	Biosimilar	Undisclosed â€“ to launch a biological product this year
Biocon	Biosimilar, recombinant proteins	Insugen and Basalog (Human Insulin), Erypro (Erythropoietin), Streptokinase, Nimotuzumab (humanized anti-EGFR monoclonal antibody), Statix (anti-cholesterol)
Transgene Biotek	Biosimilar, recombinant proteins	TrabiDHA(DHA), Tacrolimus, Orlistat
Virchow Biotech	Recombinant biopharmaceuticals	Hyorth (osteoarthritis), Hyopt (ophthalmology), wound care products
Shantha Biotechnics	Vaccines	ShanChol (cholera vaccine), Shanvac-B (Hep B), (vaccines for rotavirus, HPV, hexavalent vaccine in pipeline), Shantetra (DPT, Hep B vaccine), Shanferon (interferon a 2b)
Bharat Biotech	Vaccines	Comvac5 (Fully liquid pentavalent vaccine- DTWP+Hep B+Hib), Revac-B (Cesium chloride-free recombinant Hep-B vaccine), Typbar (typhoid vaccine), Indirab (anti-rabies vaccine), Bio-HCG (human chorionic gonadotrophin), Biopolio (Poliomyelitis vaccine), Regen-D (recombinant human epidermal growth factor gel)
Panacea Biotec	Vaccines	Recombinant Hep B vaccine, Ecovac4 (Quadruple vaccine-DPT+HepB), Easyfour (Tetravalent vaccine - DPT + Human Influenza Type b oligosaccharide), OPV (Trivalent, Monovalent- Type I & Type III, Bivalent)
Indian Immunologicals	Vaccines	Abhayrab (purified vero cell rabies vaccine), Abhay-Vac (MMR vaccine), Elovac-B (Hep B vaccine), Raksha and Raksharab (FNMD vaccine), Bruvax (Brucella arbotus vaccine)
Bharat Serums and Vaccines	Recombinant proteins	Rhoclone (anti-Rho-D immunoglobulin injection), Tetglob (tetanus hyper immune globulin (human) Foligraf (recombinant FSH), Bactovan (Amoxicillin + Clavulinic acid injection)
Zenotech Labs	Recombinant proteins	Macrogen (huGM-CSF), Nugraf (G-CSF)
Shreya Life Sciences	Recombinant biopharmaceuticals	Htrop (human chorionic gonadotropin), Ftrop (urofillitropin), Oral- Recosulin (insulin), Glycifit â€“ Metformin (oral antidiabetics)

Advantage India

Industry experts are unanimous in their opinion that this is the right time for companies to set up manufacturing bases in India. â€œOverall, India is still a great place to be located in at this juncture. The availability of manufacturing talent combined with the entrepreneurial zeal that pervades this economy make India the place to be in right now,â€? says Mr Chinny Rao, executive director, Transgene Biotek.

Rise in demand, increase in the purchasing power of the masses and a growing population, have contributed to the boom in biologics manufacturing in the country. â€œThe advantage in India is that the market is growing in volume as well as in revenue due to increasing awareness about the safety of therapeutic recombinant biotech products among doctors, and reduced cost of the therapy is increasing affordability of these high-end medicines,â€? says Dr Esmail Samiwala, senior vice president, biologics, USV.

This coupled with skilled talent and cheaper costs make India the hot bed for biologics manufacturing. Dr Cyrus Karkaria, president, biotechnology, Lupin, highlights this. â€œMost importantly, India has a large chunk of English-speaking skilled and well-educated workforce,â€? he says. Although the quality of manufactured products is the same, India has an upper hand against its Asian counterparts in terms of both pricing and skilled talent.

â€œFor example, in countries such as Singapore, the pricing structure offered for manufacturing is the same as that in the West. Moreover, they have an educated workforce, but not a critical mass. There are biotech companies setting up facilities in those markets too, but those facilities are mainly for local markets,â€? says Dr Karkaria.

Indian biotech companies are also gradually realizing the need for adherence to quality standards in order to compete in the global landscape. â€œIndian firms have a deep understanding and experience of cGMP for chemistry-based pharmaceutical product manufacturing. Indian firms should have an advantage in quickly understanding the need and in building these practices into their biologics operations,â€? says Mr Bart Janssens, partner and director, The Boston Consulting Group.

Mr Chinny Rao of Transgene Biotek, while speaking about the issues concerning quality control processes, says, â€œThe fact that the number of FDA-certified facilities in India are on the rise indicates that standards are also rising.â€?

The good news is that unlike in the recent past, Indian biotech companies are now positive about the regulatory structure for biologics. â€œThe current regulatory system for approval of biotech products allows a faster and more defined access to the market,â€? says Dr Hemanth Nandigala, director, Virchow Biotech.

Nayantara Som in Mumbai