

## Biotechs weathering the storm

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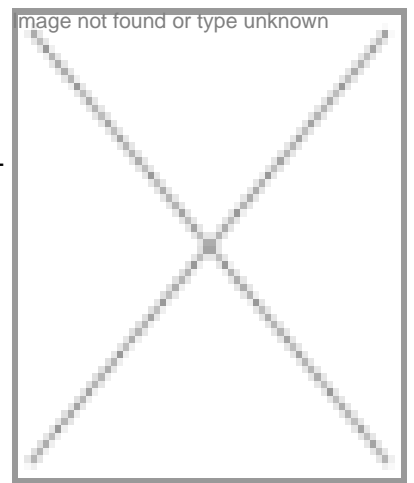
### Biotechs weathering the storm

Things are looking up for the few dozen global biotech companies, including some of India's leading players, who have invested heavily to make biosimilar drugs. The world's biggest pharmaceutical market, the US, is taking some tentative steps to keep the doors open for biosimilar drugs. A new legislation introduced on March 26 in the US senate, with support from both the Republican and Democratic party, seeks to make things easy for the entry of biosimilar versions of expensive, patented biotechnology-based drugs.

The legislation proposes to provide discretionary powers to the US regulatory, the Food and Drugs Administration (FDA), to approve biosimilar products. Europe had allowed selective entry of biosimilars a few years ago and policy makers, opinion leaders and healthcare activists have been campaigning relentlessly for the entry of biosimilar for some time now to increase affordability of many of the life-enhancing drugs made through the biotechnological route. During his campaign phase, US President Barack Obama had stressed the need to lower medical costs and his administration is likely to override objections of the Big Pharma against biosimilar drugs.

A significant number of Indian biotechnology companies have been preparing for the much-awaited support to biosimilars in the world's largest market and many business plans were based on such a scenario. All these companies can now wait for the golden opportunity. In fact, companies like Biocon, Serum Institute, Shantha Biotech, Bharat Biotech, Panacea Biotec and new entrants like Lupin, Glenmark could benefit immensely in the long run by the imminent opening of the doors for biosimilars in the US market.

Shantha has started work on a new manufacturing facility for biologicals. Serum too is ramping up the capacity. Biocon has



just completed an expansion project. Many pharma companies have dusted up their biotech plans. Dr Reddy's has introduced two biotech products and is working on at least eight more biosimilars. Wockhardt's biotech unit is up for grabs as the company tries to reduce its debt burden and at least two global majors are eying this unit.

While biosimilar scene is hotting up, Bangalore-based Manipal Group company, Stempeutics, has got the regulatory approval to start clinical trials of a stem cell based drug to treat cardiovascular conditions.

And the biotech crop scenario is also looking up with India moving up the ladder to become the world's fourth largest grower of biotech crops. This is happening even as the opponents of biotech crops are upping the ante to stall the entry of the country's first biotech food crop, a Bt brinjal variety.

The year 2008 had been a year of robust growth for biotech crops according to the latest report released by the International Service for the Acquisition of Agri-biotech Applications (ISAAA). From six countries growing biotech crops in 1996, today the number is 25 and more and more developing nations are adopting transgenic crops. In 2008, the global hectareage of biotech crops reached 125 million hectares, up from 114.3 million hectares in 2007, which is 10.7 million more hectares (the sixth largest increase in 13 years) .

The year also saw the planting of the second-billionth acre (800 millionth hectare) of a biotech crop – only three years after the first one-billionth acre of a biotech crop was planted in 2005 which took 10 years. In 2008, two-thirds of the 25-biotech countries planted biotech maize, 10 biotech soybean, 10 biotech cotton, and three countries planted biotech canola. Over 13.3 million farmers benefited from Bt crops.

According to the report, the future surely belongs to Bt crops with more than 40 countries expected to adopt biotech crops, with 15 or more new countries projected to plant biotech crops for the first time during 2009-15

The results of a consumer survey conducted by the Asian Food Information Center (AFIC) indicated that Indian consumers are ready to embrace biotech foods. This is good news for farmers who intend to grow Bt brinjal, Bt rice, and other transgenic food crops when the regulatory clearances are given.

Bt rice could be launched in India by 2011–12 according to the ISAAA report. Rice is the second most consumed cereal grain, after maize, for a large part of the world's population and Bt rice is almost ready for adoption (pest/disease resistant biotech rice) in China. With over 43 million hectares, India has the largest rice acreage in the world and is the second largest producer of rice with production at 96.43 million tonnes in 2007-08. Things are indeed looking up for the biotech sector.

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