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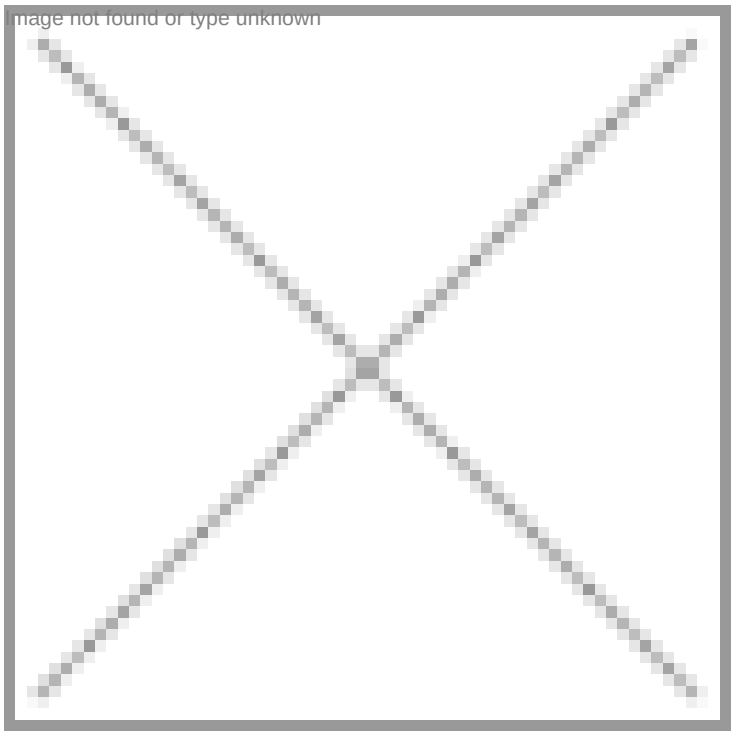

The door opens slightly for biosimilars in US

A simple US legislation, the Drug Price Competition and Patent Terms Restoration Act of 1984, popularly called the Hatch-Waxman Act, allowed the entry of generic pharmaceuticals and spawned the growth of the global generics pharma industry now estimated at Rs 9.99 lakh crore.

The world has been waiting for an encore on biosimilars or follow-on-biologics. Now there is a flood of legislative proposal that seek to permit the sale of copy cat or generic versions of many life-saving biotechnology drugs.

A flurry of legislative activity on this front to allow the entry of biosimilar drugs had started after Democratic leader Barack Obama assumed office as the President of the US in January 2009. He had publicly supported the entry of biosimilar drugs to enhance reach, increase affordability and reduce medicare costs.

A few bills to authorize the drug regulatory, the Food and Drugs Administration (FDA), were introduced in March. But the most significant proposal came from Senators, Charles E Schumer, a New York Democrat, and Orrin G Hatch, a Utah Republican, through a proposal called S. 726, have sought permission for biosimilars. Their legislative proposal will be a companion piece for the Hatch-Waxman Act and has suggested several far-reaching measures. The proposal is supported by other influential senators like Susan Collins, Sherrod Brown, Mel Martinez, Debbie Stabenow and David Vitter.

The Schumer-Hatch proposal seeks to reduce the exclusive marketing period given to patented biotech drugs from the current 14 years to just five years. The legislation, introduced on March 26, has caught global attention because of this drastic proposal on patent exclusivity period. The US legislature has now adjourned for summer vacation but the last minute proposal is a clear step to prepare the ground for the introduction of biosimilars when the legislature reassembles in a few months.

With both Democratic and Republican Senators proposing such a legislation and the President who has to finally approve it, favoring such a popular step, analysts are confident that biosimilars will be a reality in the US market place sometime in the

year 2010.

More significantly, the Schumer-Hatch proposal has overshadowed two other competing legislative proposals introduced in the US Congress in early March. On March 11, 2009, a bill, H. R 1427, titled, “Promoting Innovation and Access to Life-Saving Medicine Act,” was introduced in the US House of Representatives by Henry Waxman with support from Frank Pallon, Nathan Deal and Jo Ann Emerson. A week later, on March 11, another proposal, H.R. 1548, known as “Pathway to Biosimilars Act” was introduced in the same legislature by Anna Eshoo, Jay Inslee and Joe Barton.

The US biotechnology industry is strongly opposed to the proposal to allow the entry of biosimialr products. Nearly half-a-dozen blockbuster biotech drugs are expected to reach their patent expiry stage in 2011 and these have annual sales exceeding Rs 55,092 crore ($11 billion). Top biotech companies like Amgen and Genentech will be impacted severely by the entry of biosimilars.

“This legislation sets a path that jeopardizes our ability to help meet President Obama’s call for a cure to cancer ‘within our time’ and help realize the promise of stem cell research. This bill seeks to cut prices but instead cuts corners. This proposal leads us off the map as we seek an effective, fair and safe pathway to the biosimilars market,” said Jim Greenwood, the president of biotech industry lobby group, Biotechnology Industry Organization (BIO), based in Washington DC.

However, consumer activists and generic drug companies are ecstatic about the proposed entry of biosimilars. “Thecrushing cost of biologic drugs is leaving far too many Americans without access to life-saving treatments for devastating illness like multiple sclerosis and cancer,” said Nancy LeaMond, vice president of American Association of Retired Persons (AARP), in an interview to the New York Times.

Added Dr Dhananjay Patankar, chief technical officer, Intas Biopharmaceuticals Limited, India, “The bill addresses lot of things which are good for biosimilar manufacturers and provides three options to them that include biosimilar without interchangeable, which is similar to the European approach; biosimilar with total interchangeable (termed as biogeneric), this is one step ahead of European Medicines Agency (EMEA) as it has left the interchangeability to the member states, the bill thus clearly introduces the idea of interchangeability; and lastly, dissimilarity in safety, purity and potency. The provisions of the bill could allow variants of existing biologics to be approved through an abbreviated process. This is the first time “biogeneric” as a term has been officially used. For a long time the term itself was considered invalid.”

A regulatory pathway for biosimilars in the US and Europe could completely change the dynamics of the biotech industry.

According to a report by PricewaterhouseCoopers (PWC) titled, ‘Opportunities and barriers in the biosimilar market: Evolution or revolution for generics companies?’, biopharmaceutical drugs or biologics have outperformed the pharmaceutical market largely due to two factors: they address areas of clinical need that are unmanageable with conventional therapeutics including many cancers and genetic diseases, and biosimilars are able to command a premium price. At some point the patents protecting the successful biologic will expire and the potential of a sizable market will attract generic companies. Some of the leading biosimilar products or targets include erythropoietin, granulocyte-colony stimulating factor (G-CSF), interferon alpha, interferon beta, human growth hormone, and recombinant human insulin.

The provision for exclusivity period of first biogeneric (with interchangeability) will help the biosimilar companies to develop high quality drugs and it also recognizes the fact that analytical and clinical studies can be designed to prove complete equivalence.

While predicting the outcome of the final bill Dr Patankar stated, “Similar to EMEA, product-specific guideline with respect to the non-clinical and clinical requirements should be specified. Also a clear guideline with respect to requirements for the biosimilar and biosimilar with complete interchangeability has to be specified for each product. Similar to EMEA all the comparabilities of quality, safety and efficacy are required with reference product. However it is not specified that the reference product has to be from the US, the industry needs one reference medicinal product for the US and the European Union.”

“Data exclusivity is an important element of the bill, the key would be to get clear guidelines for the introduction of biosimilars in the US, with definite time lines. If the final bill is passed in its current form, it will dramatically alter the face of the biotech industry and existing biotech giants will have to face competition for the first time in their market. The introduction of biosimilars would bring down the cost of medicines for critical diseases in the US and make them available to a wider population,” said KV Subramaniam, president and CEO, Reliance Life Sciences, India.

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Favorable for India companies

Indian Biotech Inc. has lauded the bill with the contention that this can open up new avenues and markets for Indian companies that have already ventured into biosimilars. Dr MK Sahib, director, Genomics and Biotechnology, Wockhardt, India, said, “The biosimilar bill definitely brings good news for those Indian companies that have already ventured into the

space and have filed Abbreviated New Drug Applications (ANDAs) in the US, the bill will give them an upper hand over those who are not focusing on biosimilars space."

"The US is the largest market for biopharmaceutical products, accounting for about 50 percent of global sales. The biosimilar bill will allow Indian companies operating in the biosimilars space to gain access to the largest market in the world for their products. This is a positive sign for domestic biopharmaceutical companies," commented Subramaniam. Reliance Life Sciences has launched three biosimilars-ReliPoietin [Erythropoietin (EPO)], ReliGrast [Granulocyte colony stimulating factor (GCSF)], and ReliFeron (Interferon Alpha 2b) in the domestic market in 2008. Reliance Life Sciences is currently working on a range of biosimilars, which are at different stages of development viz. clinical trials, pre-clinical studies, process development and molecular biology.

"We are concurrently conducting clinical trials for two biosimilars - EPO and GCSF - in Europe. Further, Reliance Life Sciences has built significant manufacturing capacity for biopharmaceuticals and all these facilities are compliant with USFDA and EMEA standards. Also, Reliance Clinical Research Services (RCRS), the contract research organization (CRO) arm of Reliance Life Sciences, is capable of conducting clinical studies for these products in multi-country setting and as per ICH-GCP protocols," added KV Subramaniam. Moreover, despite Obama vouching in for cheap healthcare, several experts opine that the age of generics is over. "The biotech companies in the US have mastered themselves in small molecules, which have provided a good opportunity for them all this while. Biosimilars on the other hand is limited to a small number of players in the market, so the competition is comparatively low, this will be a great boost for biosimilar players in the market," added Dr Sahib. Generics did have a revolutionary impact but experts opine that biosimilars will have much more impact if a regulatory pathway is chalked out.

It will definitely not be a cakewalk for Asian companies despite the attractive prospects that the biosimilar markets offer. A PWC report points at two important challenge areas. Firstly sales of most biopharmaceuticals are higher in the US than the rest of the world. However, there is unlikely to be a regulatory pathway for most biosimilars in the US until after 2010. The commercial decision on the new products will be taken on the basis of the sales a biosimilar can generate in Europe. The biosimilar market will be characterized by price competition, even when there is only one or a very limited number of players for a given product, this will constrain the size of the commercial opportunity. Manufacturers of branded products are likely to use sophisticated defensive tactics, including the development of complex biopharmaceuticals, to make their presence felt in the market. Indian companies including those companies that have ventured into biosimilar space should have to find a solution to overcome these obstacles before setting out to exploit the US market.

Narayanan Suresh and Nayantara Som with inputs from Jahanara Parveen and Shalini Gupta

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