

Obama push for lower data exclusivity for biosimilars to boost hopes for India

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Singapore, Feb 02, 2010: One man's loss is another man's gain. So is the situation with a new twist to the never-ending debate on the data exclusivity period for biologic drugs. Faced with vehement criticism for a slackened approach to his much talked about healthcare reform bill, US President Barack Obama recently voiced to Congressional Democratic leaders, his opinion on a data exclusivity period shorter than 12 years. Sources from the industry claim that the data exclusivity period could zero down to as short as seven years. The focus being cheap healthcare costs. While on one hand, this can mean doomsday for innovator biotech companies, on the brighter side it will accelerate plans for Indian biosimilar companies.

Data exclusivity for a drug begins right from the time when the drug is approved. Until this data exclusivity period comes to an end, no generic company can bring out a biosimilar version of the innovator drug. Hence, for a 12-year exclusivity period, Indian biosimilar companies would have to wait for 12 years, before they can take their products to the US market. "The US market for bio pharmaceuticals is expected to touch \$60 billion in another 1-2 years. If a 7 year data exclusivity period comes about and the biosimilars market opens up in the US, it could mean huge business for Indian companies," said a well renowned expert from the Indian industry.

Presently there are 25 companies in Indian operating in the biosimilar space. This includes companies like Dr Reddy's Labs, Ranbaxy, Biocon, Shantha Biotech and Intas Biopharmaceuticals and Reliance Life Sciences. It has been estimated that around 40 biosimilar products are been sold in the Indian market. While these companies already have a strong foothold in unregulated markets like South East Asia, markets like the US was a predicament. This was because of an absence of a regulatory pathway for biosimilars (follow-on-biologics) in the US and innovator biotech industry fighting in for a longer data exclusivity period to block competition from generic companies.

Says Milind Antani, Head, Pharma, Life Science and Healthcare Practice at Nishith Desai Associates, "A 12-year period was a challenge for Indian biosimilar companies looking at the US markets. A shorter data exclusivity period would bring an end to the monopoly of innovator products in the market, entry of to US markets would be faster, steep up competition and reduce prices of biotech drugs in the US market." The US population at large is reeling under exorbitant healthcare costs with for example a drug like Avastin costing around \$100,000 per year. Entry of Indian companies and biosimilar companies at large could be an answer to their woes.

Said Dr. Dhananjay Patankar, COO, Intas Biopharmaceuticals, "The lower the data exclusivity period the better for us. For a biologic product even when its patent expires after 20 years, its data exclusivity period would go beyond that patent expiry date. The US and EU markets are difficult but at the same time huge markets compared to the rest of the world. A shorter data exclusivity would perhaps accelerate plans for India."

Obama's move has spurred huge protests from the big biotech bandwagon. BIO which represents more than 1,200 members from the biotech fraternity was vouching for a 12 year period and is now vehemently opposing the President's stance saying that this will reduce incentives for bio-research, innovation and access to "powerful biologic drugs". BIO CEO, Jim Greenwood in a note also mentioned that the biosimilar provision for the date exclusivity was approved not just by both the parties but by universities, patient groups and venture capitalists alike.

Chances are that Obama's proposal might not be approved until then Indian companies should have reasons to rejoice.