Indian companies have an opportunity to capitalise on the patent cliff and gain a greater share of the growing generics market.

During 2014-2016, about $92 billion worth of patented drugs are expected to go off-patent in the USA as compared to $65 billion during 2010-12.

Indian companies' share in the US generics market has grown rapidly on the back of aggressive Abbreviated New Drug Application (ANDA) filings, successful pursuit of Para-IV and capitalisation on patent expiries of blockbuster drugs.

Under US laws, ANDA filed with a Para-IV certification states that the generic company which is the first-to-file a Para IV, gets "exclusive rights" to sell the generic version of a branded drug for 180 days, with only the patent holder as the other player in the market.

Ranbaxy, Dr Reddy's and Lupin have been the most prolific filers for Para-IVs. Indian players with a robust product portfolio, filings and necessary manufacturing infrastructure are well placed to capitalise on this forthcoming opportunity, CARE Ratings said.

Indian companies have built a strong pipeline of products to be sold in the US. During 2013, Indian companies secured 39 per cent of total 400 ANDA approvals from the United States Food and Drug Administration (USFDA) as against 37 per cent of total 476 ANDA approvals during 2012.

As per experts, the industry size is expected to increase from $24.87 billion in 2013 to $47.88 billion by 2018 at a CAGR of 14 per cent, the report added.

(PTI)