Beyond the Patent Cliff

It is not just Big Pharma that has to prepare for life after the “patent cliff”, patent expiries on a slew of blockbuster drugs. Leading Indian generics companies do too. According to one estimate, the value of drugs going off patent between 2010 and 2012 will fall 92% from the value in the preceding five-year period (2011-15). For Indian companies, this means a smaller opportunity in their main business of off-patent drug exports. They will need other drivers to grow. Gauri Kamath breaks down four key growth drivers that could kick in around the same time for them.

**GENERIC BIOLOGICS**

**The Opportunity**

ILEINs, recombinant insulin analogs, have the potential to significantly reduce the cost of insulin. Three companies, Eli Lilly, Sanofi-Aventis and Takeda, have approval for insulin analogs. The major drivers for this market are the increasing number of people with diabetes, and the need to provide affordable insulin to help them control their disease. Similarly, other Israeli generics companies are producing insulin analogs. Vee Mediatrac is working on developing an insulin pen for injection. The company expects to launch the product in 2013.

**Challenges**

ILEINs are in a highly regulated environment. Every time a new product launches, regulatory authorities are not just concerned with the efficacy and safety of the product, but also the company that is making the product. In a government-controlled environment, this requirement is even more stringent. Vee Mediatrac is currently working on obtaining regulatory approval in India. The company has already obtained regulatory approval in the US and Europe.

**NEW DRUGS**

**The Opportunity**

The approval of new drugs is one of the most important events in the life of a pharmaceutical company. It means a new revenue stream for the company. The first drug for a new entity will have multiple patent claims that will extend the exclusivity period.