Interview with Tapan RAY, , Organisation of Pharmaceutical Producers of India (OPPI)

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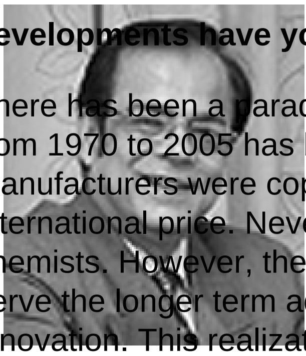
Organisation of Pharmaceutical Producers of India (OPPI)



dates back to 2006, right after the Patent Law was passed. What developments have you seen happening in the industry since then?

There has been a paradigm shift with the Product Patent Regime coming in place in 2005. The era from 1970 to 2005 has been a very successful era of reverse engineering, when Indian manufacturers were copying and marketing innovative products in India at a fraction of their international price. Nevertheless, this also required talent, for which India had brilliant process chemists. However, the country eventually realized that reverse engineering model would not truly serve the longer term advancement of the economy in creating a conducive ecosystem to foster innovation. This realization process started in 1990 and was reinforced after signing the WTO Agreement in 1995. After the ten-year transition period, the patent law came into force in January 2005.

Since around 2005 Indian companies, which had mainly been relying on cost efficient processes, started investing in the drug discovery research. There are now at least 10 Indian companies engaged in basic research, while around 32 New Chemical Entities (NCEs) are at various stages of development.

This significant step that the country has taken so far, could not have been possible without a conscious decision to move away from the paradigm of replication to the new paradigm of innovation. More importantly, this shift has not happened at the cost of fast growing generic pharmaceutical industry in the country. Branded generics continue to grow rapidly in the new paradigm.

Today, branded generics constitute over 99% of the domestic pharmaceutical market. Of course, according to McKinsey (2007), the share of patented medicines is expected to increase to 10% by 2015. Even in that scenario 90% of the market will still constitute with branded generics in value terms.

At the same time, companies are still only spending some 4% of their revenues on R&D, while internationally these numbers amount up to 12%. Many of the people in the industry seem to still see the future of India for the next 10 years to remain in manufacturing. Is innovation really the story of India right now?

As I mentioned earlier, around 32 NCEs are at various stages of development from pre-clinical to Phase III. Thus, what Indian companies have achieved since 2005, is, indeed remarkable. If you now look at the investments made by the Indian pharmaceutical companies in R&D, as a percentage of turnover, you will notice an ascending trend. Though the R&D ecosystem in India cannot be compared with the developed world just yet, India is catching up.

In some previous interviews we have conducted, concerns were raised over the Indian industry, saying that the local companies are selling off to international players. What is your take on this?

In India, we all express a lot of sentiments and are generally emotional in nature. These are not bad qualities by any standard. However, such expressions should ideally be supported by hard facts. Otherwise these expressions cannot be justified.

Consolidation process within the industry is a worldwide phenomenon and is also taking place in India. One of the apprehensions of such consolidation process in India is that drug prices would go up, as a consequence. In my view, all such apprehensions should be judged by what has already happened in our country by now, in this area.

One example we can cite is the Ranbaxy-Daiichi-Sankyo deal, an acquisition which has not at all led to an increase in Ranbaxyâ??s product prices. Similarly, the acquisition of India-based Shantha Biotech by the French pharmaceutical major, Sanofi-Aventis did not lead to any increase in product prices either. It is difficult to make out how could possibly the drug prices go up when we have an effective national price regulator called National Pharmaceutical Pricing Authority (NPPA) in India? Currently, 100% of the pharmaceutical market in the country is regulated by NPPA in one way or the other.

India is currently having a drug policy which came into force way back in 1995. As per this drug policy, any company which increases its product price which are outside price control, by more than 10% in a year, will be called for an explanation by the NPPA. Without a satisfactory explanation, the concerned product â?? not the product category â?? will be brought under price control, that too for good. In addition, intensive cut-throat competition has made pharmaceutical product prices in India the cheapest in the world, even lower than in the neighbouring countries such as Bangladesh, Pakistan and Sri Lanka. Moreover, if the potential to increase prices exists, why would any company wait for an acquisition in a highly fragmented pharmaceutical market in India?

Many of the concerns are, therefore, difficult to justify due to lack of factual data. In fact, on the contrary, the presence of multinational pharmaceutical companies in India is good for the country. These companies with their international expertise and resources would help India to build capacity in terms of training and creating a world-class talent pool. Indian companies, therefore, should consider to take more and more initiatives to partner and collaborate with these MNCs to create a win-win situation for India.

Another key advantage is in the area of market penetration. Market penetration through value-added innovative marketing has happened and has been happening all over the world; India should not let go this opportunity.

In that case, how do you feel about some of the proposed protectionist measures such as a 49% cap on Foreign Direct Investment (FDI)?

This may, once again, be related to the strong local sentiments. India needs financial reforms and wants to attract more and more FDI. The country wants to liberalize the process of FDI and, to the best of my knowledge, any step to move backward in this area should not be contemplated.

It is also worth mentioning that the acquisitions that have taken place were not of any hostile nature. Both Indian companies and MNCs have their own sets of skills, competencies and best practices. Both cost revenue and value synergy through such consolidation process could be made beneficial for the country.

Without commenting on any specific cases, I believe India has taken significant steps to encourage and protect innovation by putting in place the product patent Act in 2005. However, there are some additional steps that the Government should take to further strengthen the process, such as fast-track courts that can quickly decide on the cases of patent infringements. Another example is that when any company will apply for marketing approval for a product, the regulator will upload the same on its website. This is an easy way for other players to detect patent infringement and start taking counter-measures at an early stage. These are examples of steps that can be taken to create a proper ecosystem without amending the law.

You mentioned the paradigm shift towards innovation earlier, to some extent a similar path as China. How innovative has India become in this respect and is it sufficient in terms of clinical trials and other related aspects of the sector?

With regards to attracting FDI in areas such as R&D and clinical trials, India at present is far behind China. The reason for this, as said earlier, is that the country should try to analyse why the innovator companies are not preferring India to China in these areas. Simultaneously, there is a need to assess the expectations of the innovative companies from India in various areas of IPR. One such factor that is bothering the global innovative companies is the absence of regulatory data protection in India. The Government should seriously ponder over this need and take active steps towards this direction as was proposed by Satwant Reddy Committee in 2007.â?•

In your view, what is the industry going to look like in the coming years?

I do not expect a radical shift in the way the Pharmaceutical Industry will be operating in the next few years. Changes will take place gradually and, perhaps, less radically. The increase of the share of patented medicines to 10% of the market share by 2015 as was forecasted by McKinsey in 2007, in my opinion, is rather ambitious. We will certainly see more and more patented products in the market, but it will be slow and gradual unless corrective measures are taken to tighten the loose knots in the Patent Amendment Act 2005, as stated earlier. As more and more Indian companies will start embracing an innovation-driven business model, the strengths and the international experience of the MNCs in this area should be leveraged to catapult the Indian pharmaceutical industry to a much higher growth trajectory.

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