



## **Did India need Product patent regime to Innovate?**

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India has entered the product patent regime starting 1st January 2005 under the TRIPS agreement. Consequently biotech products, drugs and chemicals can now be patented in India. One of the reasons being quoted for this transition is that it kick-starts innovation. In this context the Honorable Prime-minister of India in his Inaugural speech to Indian science congress<sup>1</sup>, in January 2005 has said “The industry will have to move from mere imitation to innovation now. It will have to get into new drug discovery research”.

It is a statement of deep impact, where the prime-minister acknowledges the fact that we imitate more than innovate. The product patent regime is being projected as the necessary catalyst to help innovation to survive competition. On the downside of it, the direct impact of not being able to reverse engineer new products will be felt in the drugs and agro-chemical sector. The patents regime means, that India can no longer manufacture drugs by reverse engineering.<sup>2</sup> India is at present the world's third-biggest producer and prime exporter of life saving generic drugs, which are much cheaper than their patented counterparts. Smaller companies that rely on generic sales to the domestic market may not survive under the new regulatory regime. India may not afford the escalated costs of new entrant drugs developed in western countries. For example the cost of new anticancer drug Glivec<sup>3</sup> is expected to raise 20 fold. The cost of anti-HIV drugs is also expected to raise manifold. On the contrary Shanvac, a recombinant DNA vaccine for Hepatitis B, indigenously developed by Shanta Biotech of India is being supplied to UNICEF for 50 cents per dose, whereas the same vaccine was being sold for US \$ 15 per dose. Hence for India to afford newer and better drugs, and provide affordable drugs to the suffering millions of the third world countries, either we should be allowed to reverse engineer or we should innovate. Is product patent regime the right route to innovation in India?

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<sup>1</sup> Prime ministers speech: <http://pmindia.nic.in/lpspeech.asp?id=63>

<sup>2</sup> This white paper by Robert Go, Deloitte and Ruth Given, director of Health Care with Deloitte Research. Presented at the Governors' Meeting for Health Care at The World Economic Forum's Annual Meeting in Davos, Switzerland, January 2005.

<sup>3</sup> BIOSPECTRUM Monday, February 14, 2005

## **Analysis:**

Among Indian industries, the average investment in R&D is only 0.7 per cent which is extremely low by world standards<sup>4</sup>. The lack of R&D investment is largely attributed to protectionism and a non-competitive market. Since a patent provides an economic incentive in terms of right to get some benefits out of the invention made, it is a good place to start. Again if industries are protected by lot of tariff barriers they generally are not very innovative as they don't need to. The government has cut import duties in the Pharma and biotech sector to reduce cost of drugs marketed from overseas. This is another measure to create a competitive environment. This will catalyze innovation by Indian companies in the long run as they have to innovate to survive.<sup>5</sup> As Indian Pharma and Agro based industries have been gearing up for this day we already have 30 patents obtained by Indian medical biotech companies in the US in the year 2003 alone. We have also seen certain breakthroughs in genetically modified plants in the form of BT cotton.

With the advent of patent regime, India is now being looked at as a genuine partner and a potential competitor by western countries. Lot of international companies have started collaborative R&D efforts with Indian Pharma companies. In spite of the fact that Indian Pharma industry grew under the shelter of Indian patents act 1970 which allowed for process patents, it has now attained a level of maturity and global presence that can do more than just reverse engineer. It has developed adequate R&D and manufacturing capabilities. In fact India has the largest number of FDA approved manufacturing facilities outside the USA. Pharma being an investment intensive sector, the patent regime has paved way for capital flow in the form of foreign investment.

India could benefit by revenues from contract manufacturing and knowledge process outsourcing by multinationals. It can enter into effective partnering and co-patenting of products. Indian company Ranbaxy, for example, recently signed an agreement with GlaxoSmithKline (GSK) to commercialize compounds they develop together although they were locked in a patent lawsuit a few years ago. This is a clear indication to the change of image of India from being a copycat, to meaning serious business. In the long run, we can retain more talent in Indian companies and help accelerate the process of innovating new products. India is cost effective in all aspects of drug discovery and development. Our patented products can be marketed at a lesser price as exemplified by Shanvac. When Indian companies become R&D intensive we can have hopes of cures to certain diseases specific to India and developing countries. These areas are generally neglected by foreign investors as the returns are not very high from marketing in developing countries. India can utilize the provisions of Article 7 of the TRIPS agreement to strike a balance between investors interests and prices of drugs in developing countries.

At the same time it is also important that the government plays a key role in regulating the grant of patents. Broad patents can snub any further innovation in that field. Adequate

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<sup>4</sup> THE GLIVEC CASE frontline magazine By Siddharth Narrain.

<sup>5</sup> BIOSPECTRUM Monday, February 14, 2005

efforts should be taken to prevent exploitation of our Intellectual property, like the CSIR's efforts to create traditional knowledge database. Parallel efforts to encourage innovation like grants from the "National Innovation Fund" etc should be streamlined. An integrated organizational approach from public funded organizations is also a good step towards more innovation. In fact recently CSIR has come with an indigenous anti-malarial drug that is being marketed by an Indian pharma company.

On the agricultural front, in 2002 half the seed sales to farmers were by public corporations and most innovations in farming were by government agencies. Private sectors delayed introduction of their products in India due to lack of patent laws. To get adequate fund flow the government has attempted public-private partnership machinery called Collaborative Agricultural Biotech Initiative (CABIO) encompassing Department of Biotechnology (DBT), the Indian Council for Agricultural Research (ICAR), the National Centre for Plant Genome Research (NCPGR) and Indo-US Science and Technology Forum. But such efforts are just a part of the move to innovation. Private funding can be expected only when patenting is possible. As Dr.Mashelkar, Director-General CSIR, in an interview puts it "The essential issue is that people feel their innovations are important enough to be protected".

### **Conclusion:**

In spite of having a good knowledge base and adequate government support in the form of tariff barriers India did not perform well with respect to innovation. Lack of competition, protectionism by government, lack of capital flow, inability to retain good talent, were all deterring India from taking the innovation path in the biotech sector. The patent regime reverses all the above trends. Thus patent regime seems to have indeed steered the innovation temper to the right path. With prudent handling of the patent policies we can see to it that granting monopoly is also socially justified. The government can hold adequate powers to protect the countries interests, given any situation arising out of patenting issues. Thus patenting will prove to be an overfull tool for innovation in India when handled wisely.