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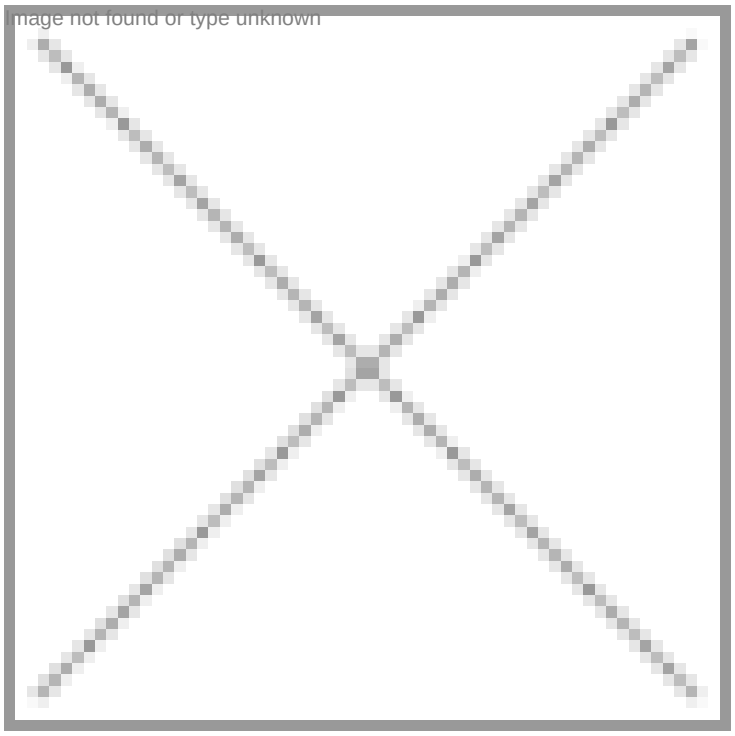
14 October 2008 | News




## "Indian patent laws do not encourage world-class research,"

*-Ranjit Shahani, Vice Chairman and MD, Novartis India Ltd*

*In a free wheeling conversation, Ranjit Shahani, Vice Chairman and MD, Novartis India Ltd, gives his side of the story on the Glivec issue while simultaneously throwing light on the blemishes in the patent laws of India, its detrimental effects on R&D thereby recommending a total facelift to the regulatory structure as a whole.*

In context to Glivec's patent being rejected, Novartis decided to challenge the provision of Section 3(d) itself. Why the risk to challenge the entire system?

Novartis on behalf of the pharmaceutical industry wanted clarity on how patentability will be implemented in India. Section 3(d) says that incremental innovation is not patentable. In my view its should be re-labeled not as incremental innovation but as patentable innovation because these are innovations which have a tremendous impact on healthcare outcomes. So while it might not be a breakthrough innovation but whatever steps are taken it can have a positive impact on healthcare and of course in the case of Glivec, the original salt imatinib mesylate by itself has no value but the beta crystalline salt which later becomes Glivec becomes a potent drug to cure chronic malign Leukemia. The 1993 patent was for synthesizing the molecule of imatinib and represented the first step in the process to develop Glivec. It is important to understand that this molecule was not suitable to be taken by patients in the form of pills. Therefore it was necessary to develop first the mesylate salt of imatinib and then the beta crystal form of imatinib mesylate to make it suitable for patients to take the medicine in pill form.

This beta crystal form of imatinib mesylate is the active ingredient of Glivec, which is the only medicine that has ever been marketed by Novartis worldwide as Glivec.

What then do you think were the flaws prevailing in the Indian patent system at that time?

In our view, the Indian patent law was not world-class compliant. In fact, the Mashelkar report also agreed to that very clearly. Glivec has been given a patent in 40 countries. It is a breakthrough research and a therapy which has changed the direction in which research is done in the area of cancer. Time magazine called it the magic bullet and FDA had held a press conference when it was launched which it rarely does.

Post the initiation of the TRIPs agreement in India, do you believe that the patent structure in its entirety is favorable to innovator companies?

The most important step that India took was move from a process patent to product patent after 35 long years. Now the question is to make it world â€“class, WTO and TRIPS agreement compliant. Clearly there are three areas which makes innovator companies feel that Indian laws are not world-class compliant and do not encourage world class research. That is clearly seen from the fact that the product patent came to India in 2005 and between 2005 and 2008, there were five MNC companies who invested in R&D in China like Novartis, AstraZeneca, GSK, Sanofi Aventis and Pfizer but not a single investment came to India. Innovation is the life blood for pharmaceutical companies. If there is no innovation there will be no new drugs and all the unmet medical needs will be pending. India has a great opportunity both in terms of scientific pool, demographic dividend, the cost structure, the patient pool.

Are there any steps being taken by the authorities to push the envelope for Data Protection laws?

None as of now. But we actually had a committee where it was unfortunately deliberated that we have a caliberated approach to data protection. India had a let-down period of 10 years from 1995-2005 and unfortunately the recommendation was that we have a calibrated approach up to 2015 which was the date given to the least developed countries (LDCS). India is a developing country and we cannot equate ourselves with LDCS. Today we have data protection for agro chemicals, in IT but for pharma there is no such law.

Miles of data is now available to a generic company, which uses it as its own and launches a product for commercial interest. But Article 39.3 of the TRIPS agreement clearly says that data generated by innovator company cannot be used by third parties for commercial interest. The data can be available for information, but not to use it and say that it is exclusive to the company.

All countries across Asia-Pacific have a minimum data protection of at least five years. Jordan has it for 15 years. India is not even going in that direction. Data protection across countries ranges between 5-10 years. India is pitching for five years.

Compare Novartis' performance in India and China.

China is a high growth market. The growth rate itself is somewhere between 30-40 percent. So Novartis' performance in China is growing at a significantly higher rate than India where the growth is between 10-12 per cent, almost one-third of what we do in China. India is in no way compared to China. The growth will happen but before that the framework has to be changed along with the healthcare infrastructure. China has 80 percent hospital sales exactly reverse of India (80 percent market sales and 20 percent hospital sales).

Coming to world class research, the debatable issue in the industry today is that of Indian companies not actively involved in world-class discovery research. Can you give a comparison between an MNC and that of an Indian company?

One way or the other if a company in India wants to get its products globally they need to have a creative alliance with a global company. It is feasible in the long run that global and Indian companies ally to share the risk and rewards, the capabilities, and assets. R&D is a high- risk high-reward game. India became a product patent regime in 2005 and domestic companies have been investing in R&D even before 1995. Now we are yet to see some outcomes. There will be breakthroughs but to commercialize it and to take it global, costs a lot of money. If you see the larger picture, today globally it takes $1.2 billion to get a NCE out. It was $800 million a few years back and $300 million some 10 years ago. The costs have gone up dramatically and that is because of high rates of failure that happen somewhere within the process. To get a NCE takes 12-15 years where you start with 100,000 leads and end up with one at the end of 15 years and that might not be a blockbuster drug because you have a competitor who comes out with a similar product later on.

Given this, unfortunately the top 10 domestic companies spend about 8-10 percent of their topline on research which in totality is less than $300 million. An MNC spends anywhere between $4-6 billion.

In conclusion, what are the changes, in your observation, which need to come about in the patent structure of the country?

Firstly there should be a fully TRIPS compliant IPR regime including its enforcement.

There should be encouragement for investments in R&D, progressive pricing policies including those for patented products, regulatory reforms, and rationalization of the multiple-tax system. Also there must be deterrent legislation against counterfeit drugs, reduction in import tariffs on life saving and other essential drugs, regulatory and administrative reforms, flexible labor laws and last but not the least, a world-class infrastructure.

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