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World's Pharma Hub

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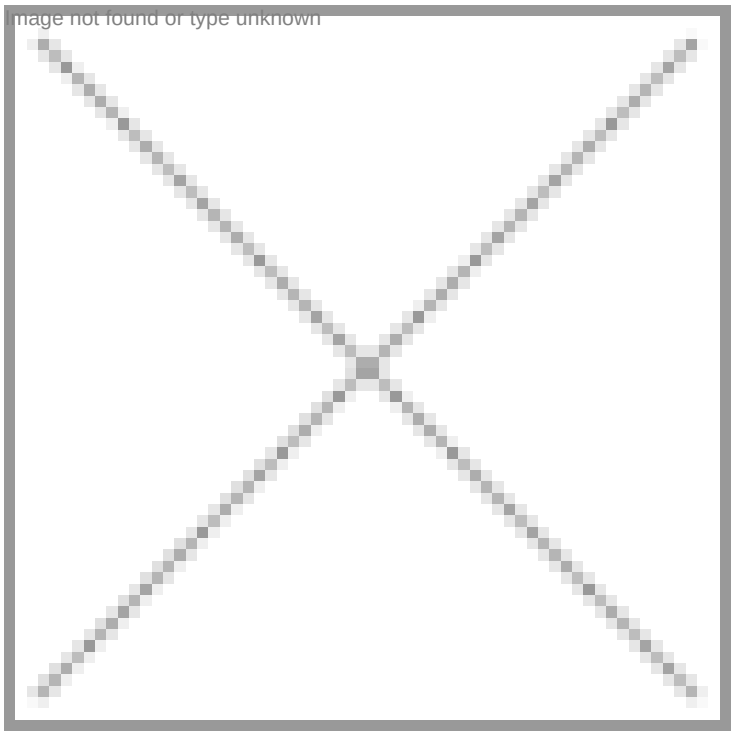

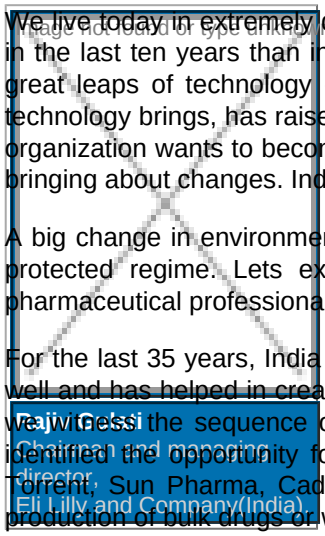

Rajiv Dalvi
Chairman and managing director
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We live today in extremely dynamic and exciting times. As far as India is concerned, perhaps there have been more changes in the last ten years than in the previous one hundred. Today we are witnessing exponential economic growth coupled with great leaps of technology - Internet, cellphones and cable TV touch our lives in every way and the awareness that the technology brings, has raised our expectations sky high. Today, every professional looks forward to a global career and every organization wants to become a global player. Pharmaceutical industry also has been at the forefront in experiencing, as well bringing about changes. India is emerging as one of the largest suppliers of pharmaceuticals to the world.

A big change in environment that will impact the pharmaceutical industry in India, is the transition to an intellectual property protected regime. Lets examine the changes that have happened and that will happen in the industry and for the pharmaceutical professionals, in more detail.

For the last 35 years, India experienced an environment where there were no product patents. At that time, this served India well and has helped in creating organizations such as Ranbaxy and Dr Reddy's Lab which are global players in true sense. If we witness the sequence of growth, it started by importing bulk drugs and formulating them in India. The companies that identified the opportunity for new products faster, gained more. Soon there were a large number of companies including Torrent, Sun Pharma, Cadila, and Cipla that mastered this art. At that time, the more evolved organizations moved into production of bulk drugs or what is today called â€œreverse engineering.â€?

Let us remember that those days the customs duty on bulk drugs exceeded 100 percent and it made eminent sense to make bulk drugs in India. This expertise in bulk drugs remained not only within the large and fully integrated pharmaceutical companies, but also lead to genesis of highly specialized companies with deep expertise in chemistry and synthesis of bulk drugs. These companies are spread throughout the country, but more so in Andhra Pradesh than anywhere else. This deep

expertise led to the next opportunity: exports. Within this timeframe, Indian companies also gained tremendous expertise in formulation development. Today, India has the largest number of FDA-approved bulk and formulation plants outside of the US. Today, India has emerged as the largest supplier of generics to the world.
But the year 2005 is the year of discontinuity. As the third and final amendment to the Patents Act comes close, there are concerns that are being raised within the industry and equally so in the society. Lets look at these concerns to examine their validity. One big concern appears to be the re-emergence of MNCs in India that may ring the death knell for the Indian pharmaceutical industry. Another concern is the rising prices of medicines and increasing cost of health care.

However, the reality is far from it. One can understand intuitively that from 2005 onwards, the number of new molecules which are under patent to be launched in any calendar year, will not exceed a single digit. Starting with 2-3 new molecules in 2005 and in 2006, it may stabilize to 7-8 new molecules every year after that. Not only that, the molecules eligible for patent, the application for which has been filed in 1995 onwards, will start going off patent from 2015 onwards. Thus, it is predicted that at any given point of time over the next 25 years, the number of molecules under patent will never exceed even10 percent of the total molecules being marketed. Also, the patented molecules will always have therapeutic equivalents available. The countries have that embraced patents in recent past, have had exactly the same experience. To reiterate, all the existing molecules being sold in the market will continue to be available at the existing prices. Thus, the question of health care cost rising does not arise at all.

What this change really provides, is an opportunity for the Indian pharmaceutical companies to globalize in a true sense. This will be the next leap forward after the tremendous strength that the Indian sector has created over the last 34 years in terms of chemistry, formulation development, sales/marketing and exports. The good companies that have utilized these 34 years effectively, are now ready to venture into discovery research, development and global marketing of the patented molecules. This is obviously a very high risk proposition, but at the same time highly rewarding too. Crossing this bridge is the most challenging transition ever been attempted by the Indian pharmaceutical industry. Any attempt to compete against the established multinationals on an equal footing will throw up the challenges of innovation, infrastructure and investments.

At the same time this new era brings new opportunities as well. This transition is already leading to many symbiotic relationships in research, development, manufacturing, clinical trials as well as biotechnology. Within the last six months, various teams from the top 10 pharmaceutical multinationals have visited India to explore the possibility of tie-up in manufacturing, formulation development as well as various stages of research. This is spawning entirely new business opportunities for existing integrated Indian pharmaceutical companies as well as the specialized organizations.

Over the last three years, dozens of CROs (contract research organizations) have started operating in India, most of them profitably. These include divisions of existing companies, new entrepreneurs as well as Indian arms of multinational CROs. With more than 400,000 English-speaking physicians and millions of untreated patients, this is not at all a surprise. India possesses similar strengths in terms of chemistry and formulation development as well. Today, 16 percent of scientists working in the pharmaceutical industry in the US, are of Indian origin. Outsourcing of various activities in the value chain from discovery to launch, is clearly the next big opportunity for India. However, this trickle can become an avalanche only on the strength of a strong IPR regime.

If this infrastructure suggests partnerships, then there are even more compelling reasons for both Indian companies and MNCs to work together. Indian companies involved in discovery research face the hurdles of long gestation period, uncertainty of results, huge investments in global development and marketing. Multinationals on the other hand witness shorter period of exclusivity since competing molecules within the same chemical class are usually launched within two years of the original molecule now, against a period of 4-5 years that the first in class molecule used to enjoy. At the same time, development time and costs are increasing, and so are the marketing costs.
This dilemma clearly points towards partnership between Indian companies and the MNCs as the most viable way forward. Today, no Indian company can develop a molecule on a global basis, since that requires hundreds of millions of dollars. At the same time, MNCs needs infrastructure, and by partnering with Indian companies they can save lot of money.

In addition, to take advantage of the global market for the generics, research outsourcing and discovery research, Indian companies need to establish the brand â€œIndiaâ€?. I am confident that just like India is known today for software and the â€œMade In India Softwareâ€?, is sought-after in all the developed countries, similarly it will be, for various products and services in pharmaceutical industry.
The partnership needs of both Indian companies and MNCs will lead to cross-licensing of molecules. An Indian company wanting to develop a molecule on global basis will need an MNC. On the other hand, an MNC relatively stranger to India, will need a distribution, sales and marketing support from Indian companies to cover the entire geography of India. At the same time, partnership with MNCs can help Indian companies gain international credibility and also move up the learning curve much faster. The other business alliances with MNCs such as outsourcing, can provide the 'cash-flow' toinvest in

globalization.

As far as, discovery research is concerned, the way forward in the near future will definitely mean working on new molecules within the existing class only. This art was perfected by the Japanese, and is a declared strategy of Dr Reddy's Laboratory in India. The next and the final opportunity, of course, is the development of new class of molecules, but that will take time.

The other changes that are sweeping the country will continue to make India an attractive pharmaceutical market, for both Indian as well multinational companies. Relatively low inflation and fast growing GDP have lead to significant increase in disposable income. Changing lifestyle has brought in more lifestyle-related diseases and at the same time increasing income has brought about increasing awareness. Today, antibiotics which used to be the single largest therapeutic segment in Indian pharmaceutical industry, is actually declining. Today anti-diabetics, cardiovascular and anti-cancer are the fastest growing segments. The desire for better health care and ability to spend more money is leading to a literal explosion of corporate hospitals in India. Apollo today has 14 large multi specialty hospitals in India, and many satellite ones. Max, Wockhardt and Fortis are all in a mad race to acquire, build and franchise, large and small hospitals all across. This is leading to increasing demand for quality pharmaceuticals and specialized medicines.

To reiterate, India is not only becoming a more attractive market, it is also becoming an attractive destination for outsourcing and partnerships. Almost all the MNCs are looking towards India, and India is on the threshold of assimilating in global economy as an equal. In the words of Dr David Webber, director of Economic Policy, International Federation of Pharmaceutical Manufacturers & Association (IFPMA), Geneva:
â€œBecause of globalization, the world is drinking Colombian coffee, using Japanese cameras, driving American cars, wearing clothes made in Asia and using Finnish mobile phones .....
Let us hope we will in future be saying:
..... And being treated and cured by novel medicines discovered in India....â€?