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Discovery Led Innovation By 2010 In India

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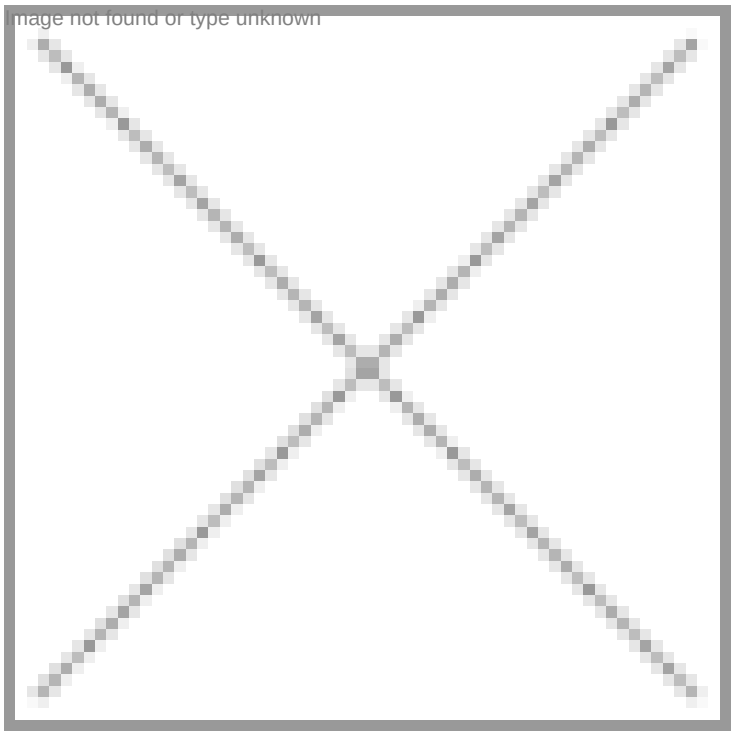

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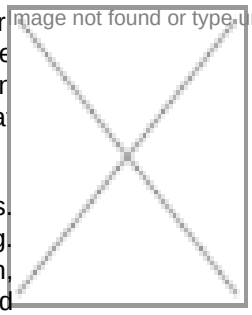

Discovery research is becoming increasingly challenging and prohibitively expensive the world over. Drug development timelines can extend up to 15 years and more and it takes billions of dollars to move a molecule to the market. This in turn leads to exorbitant drug prices that only the affluent world can afford. For countries like India, we need to evolve alternate paths of drug discovery and innovation that aim to deliver affordable drugs by leveraging our competitive advantages.

India's large population and widespread poverty have provided the impetus for affordable medicines. Our competitive edge is provided by our low cost base in research, development and manufacturing. Our large pool of scientists, engineers and medical professionals offer us a low cost base in research, clinical development and manufacturing. India's dense and diverse disease populations allow for speed of patient enrollment and superior statistical data thus positioning India as a rapidly emerging hub for clinical development with potentially shorter commercialization timelines. Academia-industry research partnerships are gaining popularity and this will further augment the low cost of innovation.

The advent of the new patent regime at the start of this year poses a new challenge to the Indian Pharmaceutical and Biotech sectors. Indian companies are now attempting to re-invent themselves as innovators by building patenting capabilities and pursuing discovery led research strategies. The Indian market offers faster entry opportunities to such efforts. However, the

affordability factor will be key to market penetration. Successful launches in the Indian market will be a great boost for the viability of new drugs and it is forecast that a number of new blockbuster drugs can expect to hit the Indian market by 2010.

Companies that have developed a global as well as a long-term perspective of investing in R&D will be in an advantageous position to cope with the changes that the new patent regime will ring in. So far the underlying method employed by most successful Indian companies has been to fund discovery led-research through a generic development strategy. Today, the generics space is crowded and calls for a differentiated strategy. Follow on biologics for the regulated markets is one such strategy, novel drug delivery systems is another. All these call for new and expensive clinical development capabilities, which is expected to see a new breed of innovator biotech companies emerge. On the other hand, Indian Biotech companies can also partake in the global CMO (Contract Manufacturing) opportunity by evolving proprietary and cost competitive bio-process capabilities.

The handicap of no financial backers in the early start up days, forced biotech companies to adopt services or generics products as a business strategy. Biocon for example, started with a strong R&D focus on enzymes, leveraging India's low cost advantage. Shantha Biotech opted for generic Hepatitis B vaccines. From this modest base, the sector has gradually built critical mass both in terms of infrastructure as well as markets. Now vaccine producers from India (Serum Institute, Bharat Biotech, Shantha Biotech, Panacea Biotech, Wockhardt, Bharat Immunologicals) command a global leadership position. And this has been well recognized by international organizations like WHO, The Gates Foundation and others. Biocon sees itself as a global Insulin producer and so on.

Innovation and discovery led research is also an enormous opportunity for international bio-partnering. There are currently more than 350 biotech drugs in late stage of development addressing a wide disease area. In India several collaborative partnerships have been initiated such as Biocon's JV with Cuba's CIMAB and its investment cum co-development programs with Nobex & Vaccinex to develop proprietary products. Panacea Biotech has a JV with Cuba's Heber Biotech. Shantha Biotechnics, Strand Genomics, Bharat Biotech and others are also pursuing such strategic partnerships to build strong research pipelines. International bio-partnering also bridges the need for forward and backward integration needs of Indian and overseas Biotech companies respectively.

India's role is increasingly expanding in the global marketplace, especially in research, clinical trials and bio-manufacturing. The greater incentive for original drug discovery will create opportunities for Indian companies to develop new competencies through collaborative research and global alliances.

If we were to set 2010 as the timeline for India to be a successful innovator, the Government needs to ensure that the regulatory environment is conducive for the development of the entire drug discovery process. India needs to proactively embrace the path of innovation whole-heartedly through an enforceable patent regime. We need to develop and strengthen the scientist skill base through regular training programs in order to equip them with world-class drug discovery skills. There is a pressing need to increase interaction between industry and academia and pay attention to the quality of the products we develop. Discovery Led Innovation by 2010 in India will also depend on the collaborative growth of companies through global partnerships and alliances.

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