AN AUDIENCE WITH…

Kiran Mazumdar-Shaw

Chairman and Managing Director, Biocon Limited, Bangalore, India. Since Kiran Mazumdar-Shaw started Biocon in 1978 the company has evolved from an industrial enzymes company to a biopharmaceutical enterprise. During this transition, Biocon has established two subsidiaries: Syngene (1994), which provides development support services for discovery research, and Clinigene (2000), which offers services in clinical development. Mazumdar-Shaw serves on the Advisory Council of the Indian Government's Department of Biotechnology, where she has been instrumental in bringing together government, industry and academia to chart a clear and progressive growth path for biotechnology in India.

How has your company evolved since it was founded?

I started Biocon India in 1978 as a biotech company based on industrial enzymes. It was a joint venture with an Irish company, Biocon Biochemicals. In the late 1990s, this company was acquired by Unilever and then, when Unilever sold the business to ICI in 1998, I had the opportunity to buy the shares in Biocon India and become independent. At that time, I realized that I could not develop the enzymes business to the size and scale that I wanted. This realization was a turning point at which I decided to leverage the recombinant technologies that we had developed for the enzymes business and apply them to biopharmaceuticals. We had a successful initial public offering in 2004, and now we are a fully integrated biopharmaceutical company focused on oncology, diabetes and autoimmune diseases.

Traditionally, India has been viewed as a country with expertise in pharmaceutical manufacturing and contract research, but not in innovative R&D. What changes could catalyse India's emergence as a source of therapeutic innovation?

For India to start focusing on innovation, we need to start providing innovative solutions for India's own health-care needs. There is a huge disease burden in India — diabetes, cancer, HIV/AIDS, tuberculosis and autoimmune diseases — and unfortunately very few people have access to or can afford the modern medications that are available for these kinds of diseases. Companies are starting to realize this and are focusing on affordable innovation to effectively address these needs. Also, as the income levels grow in India, the market for health-care products is increasing so there are enormous opportunities.

The government is trying to catalyse innovation by funding programmes in the academic research institutes. They are also encouraging collaborative programmes through cross-border partnerships. Biocon has an example of this type of partnership with a research institute in Cuba with whom we have several innovative research programmes. We have also funded a start-up company IATRICa, which is a spin-off from Johns Hopkins University, to develop novel cancer vaccines.

Science in India is of a satisfactory quality to meet health-care needs, but we need to improve the application of that knowledge. To help address this I recently funded a full postdoctoral programme at the Koch Institute at the Massachusetts Institute of Technology (MIT). The sole objective of this programme is to allow Indian researchers to spend a couple of years at MIT engaged in cutting-edge research on the condition that they return to India to continue that research. This is the kind of thing that we need to do to catch up.

Another thing that is essential for building a robust, innovation-led business model in India is to improve the intellectual property (IP) infrastructure. All of us in the innovation space realize that unless we can protect our IP, it is going to be difficult to create a strong innovation culture. So, we are starting to build the IP infrastructure which includes human capital, as well as the hardware and software support that are needed to handle patent requirements. On the hardware and software side, things are progressing rapidly. We have good databases in place, as well as the information technology infrastructure to handle the documentation. We are now putting the human capital in place — the expertise that is required, both legal and administrative, to ensure that you have a strong patent ecosystem that can handle patent challenges, patent cases, patent findings and so on. Over the next 10 years, it has the potential to become a robust system.

What are the aims of the Biocon Bristol-Myers Research Centre in Bangalore that was opened in 2009?

The Biocon Bristol-Myers Research Center (BBRC) is housed at Syngene, a subsidiary of Biocon. For many years prior to the development of the BBRC, Syngene provided R&D services to Bristol-Myers Squibb (BMS). However, BMS's use of Syngene's R&D services was fragmented. BMS recognized the fact that if they really wanted to derive the best benefit out of the talent pool and the cost base that we have in India then they must do much more integrated research. So, in 2009 Syngene created a fully dedicated facility for BMS to pursue R&D from discovery through to preclinical development and into the clinic. Apart from BMS, Syngene offers research services based on two formats. One is service-based, whereby we have a fee for service model, and the other is a milestone-based co-development format, which relies on a shared risk and reward model.

What impact do you think the recent establishment of a US biosimilars pathway will have on India's drug and biotechnology companies?

This presents a large opportunity for Indian biotech and pharmaceutical companies. However, I think that the regulatory requirements of introducing biosimilars in the United States and Europe are going to be challenging. I therefore do not expect many Indian companies to develop such products during the early phases of the availability of these regulatory pathways. I think that those who do choose to develop biosimilars will be able to command good pricing and healthy profit margins. Over time, I am sure that the biosimilars market will become like the generics market, in which Indian companies will become very competent at developing and manufacturing them for the global markets.

Interview by Bethan Hughes