

## News Details

### Scientist-turned-entrepreneur

Dec 18, 2003

During the past few months, Dr Krishna M Ella, chairman and managing director, Bharat Biotech International Ltd (BBIL) has been having sleepless nights. Not because he is the center of any controversy, but because he has been busy with several initiatives. Towards the last week of September, Ella was busy readying Indikinase, a recombinant streptokinase (a first-line therapy for myocardial infarction) for launch in the market place.

Besides, he was preparing to hand over the first batch of Haemophilus Influenzae B (HIB) conjugate vaccine to Wyeth Lederle. Mid-October, he was busy managing the visit of South African President Thabo Mbeki, to BBIL's manufacturing facility in Genome Valley (Thurkapally). During November, he was busy with the team from Indo-US Vaccine Action Program (VAP) reviewing the progress of the rotavirus vaccine. The proposed vaccine will protect children against the scourge of rotaviral diarrhoea.

Interpretation of these events will give a better insight in the persona of Dr Ella. BBIL, which had a major contract for manufacturing HIB conjugate vaccine from Wyeth Lederle, dispatched the first batch of vaccine, constituting 0.5 million doses, to Dr VB Sovani, Director, Wyeth Lederle, during the Biotec India International 2003 show in Hyderabad. This is seen as a major achievement for Bharat Biotech as Wyeth has for the first time looked to manufacture HIB vaccines outside the US. Further Indikinase launch in October made BBIL among the first few in the world to manufacture recombinant streptokinase.

The visit of South African President Thabo Mbeki was leveraged not only to showcase BBIL's strength, but also as an occasion to spread its reach beyond the Indian shores. Ella and Tokyo Screwale, executive chairman, Mvelaphanda Holdings of South Africa, the world's second largest gold and diamond company, signed an agreement. This is to replicate BBIL's facility and take the technology developed by it to South Africa. A joint venture for the same would be floated. The third development was to review the progress of the development of the vaccine at about a hundredth of the cost of the average MNC.

All these show the aggressive entrepreneurship of Krishna M Ella. His mission empowered by the Indian President Dr APJ Abdul Kalam's, three-vaccine dream for the country--hepatitis B, malaria and HIV. "It is his dream that is fuelling our efforts and leading us closer to realizing the goal of bringing affordable, world-class healthcare to the needy in our country," slated Ella. "My current challenges include getting out of biogenerics mode and concentrating on new molecule development. The next thing is to become a global player. Bringing affordable vaccine to rural population of India and gearing up my company to face post-2005 scenario." He is synchronizing the product development and marketing very well.

Of course, nothing comes risk-free

It is neither mission impossible nor mission accomplished yet for Ella. He recounted, "After staying 15 years in the US, it was not easy for us (Dr Ella and his wife Suchitra) to relocate to India. It was a tough decision to make. But we both wanted to come back. The decision seemed risky. But then as a graduate student in Madison, Wisconsin, we were taught to take risks. I decided to become a bioentrepreneur. We brought together like-minded professionals from the US. Sold personal assets in the US to make this dream come true. There were so many challenges we had to face.

"For the first time, I proposed to produce the hepatitis B vaccine for one dollar in 1994. None of the financial institutions in India were prepared to believe this. But perseverance pays. Bharat produced the world's first

cesium free hepatitis B vaccine at an affordable price for the common man. Today, UNICEF buys Bharat's hepatitis B vaccine for 23 cents ( Rs 10) per dose. I think that the real challenge for a scientist is not only develop a product but also envisage its pricing." In the early 1990s, when the first hepatitis B vaccine was introduced in the country by SmithKline Beecham, it was priced at Rs 1400 per dose.

What is very embellishing about Ella is his capability as a scientist and as an entrepreneur. Born in Tiruthani, near Chennai, Ella has been a very good scientist. He acquired his doctorate from the University of Wisconsin-Madison in molecular biology in 1992 and spent more than a decade conducting independent research and teaching in renowned universities in the US. He is well versed in plant, human and animal systems. Before embarking on BBIL, in 1996, he served as a professor (research) with Medical University of South Carolina (1993-96). He started his career as a research fellow with Indian Council of Agricultural Research, then joined Sandoz (I) Ltd as technical representative, moved to Bayer as technical officer, went to University of Wisconsin as research assistant among other things, before joining the South Carolina Medical University.

Does being a bioentrepreneur come easy? No guesses on that. The matter of fact is that he is a first-generation entrepreneur and braved many a challenge. Ella explained. "The concept of bioentrepreneurship is still new in India. There is no easypath and we have to create one for ourselves. This is the industry's biggest challenge. Scientists in our country follow the road lined with obvious well-defined rules and symbols, While the need for academic excellence is understandable, the world out there is waiting for safe, affordable, healthcare solutions that can affect millions of lives. It is biotechnology that can come up with answers. I think we have found the right balance at Bharat. We have adopted a business model that ensures that scientific and business perspectives are given due place equally."

Year 2003, a new chapter in Ella's life

For Ella, a classic case of successful scientist-turned entrepreneur, the year 2003 has been an eventful one. There were just two products from its stable till May in 2003—Revac-B, the recombinant vaccine for hepatitis-B in 1998, and Biogit, claimed to be India's first indigenous probiotic yeast. BBIL launched its typhoid vaccine, Tybar, in May 2003. Then in September end, he launched streptokinase. While the market for the typhoid vaccine in India is estimated at around Rs 60 crore, the market for streptokinase is estimated at around Rs 80 crore in the country. This heralds the beginning of the consolidation of his dream sojourn in biotech.

Though, the turnover during 2002-03 was about Rs. 20 crore, Ella sees 2003-04 as a year of turnaround. He expects to see the topline to grow to Rs 60-80 crore. He has also set his eyes now on the insulin market, estimated to be worth Rs 250 crore. If all his projects come through, which Ella is confident of, by 2010 BBIL could touch the Rs 1,000 crore mark.

## **FACT FILE OF**

### **Dr Krishna M Ella**

**Position:** Chairman and managing director, Bharat Biotech International Ltd

**Age:** 40+ years

**Academics:** Did his BS and MS from Nagpur and Bangalore with distinction and honours. Doctorate from the University of Wisconsin-Madison, in molecular biology (1992)

**Family:** He is married to Suchitra Ella, who is the founder director of Bharat Biotech. The couple has a son and a daughter.

**Entrepreneurship:** Started Bharat Biotech in 1996

**Other hats:** Member of the CII national committee on IPR (2003-04). Other professional honours include: member, FICCI Pharmaceutical and biotechnology committee; member (2002), working group of science & technology. Planning Commission (2001); member, Vaccine Board, Government of India (2000), member, Pharma Task Force (2000), AP government (2000), member, National Health Mission, headed by Dr APJ Abdul Kalam (2000), among other. Since fall 1993, he has mentored two graduate students and two postdoctoral fellows

### **Awards & Accolades:**

Dr. KC Chatterjee Memorial Award from the Indian Pharmaceutical Association (1999)

## **BBIL MILES**

- Established in 1996.
- Launching and Commercial production of Revac-B (World's first cesium chloride free Hepatitis B vaccine) in 1998. Marketing of Revac-B in 1999.
- Launched typhoid vaccine, Typbar, in May 2003.
- Launched Indikinase in October 2003.
- Contract manufacture a vaccine— HibTITER for Wyeth Lederle Ltd in September 2003

He has a penchant for attracting investments and people. He has already attracted investments to the tune of Rs 125 crore. Said Ella. "We have invested more than Rs 100 crore in developing world class manufacturing facility at Genome Valley in Hyderabad for manufacturing vaccines, biotherapeutics, and biopharmaceuticals. We raised the funds through internal accruals, State Bank of India and IDBI (Industrial Development Board of India), ICICI, and Technology Development Board of India. BBIL is the first Indian company to get two grants from the Bill & Melinda Gates Foundation's Program for appropriate technologies for health—for children's vaccine program and malaria vaccine initiative."

Further, Ella has been able to work smoothly with the Indian institutions. This has been a major resource for BBIL's R&D; work. Not just Indian institutes, but Ella has been able to forge ties with international institutes of repute like Center for Disease Control-Atlanta, USA, National Institute of Health-Washington DC, National Child Health Institute, National Institute of Allergy & Infectious; Diseases (US-Govt.), University of Wisconsin-Madison, Stanford University, and International Vaccine Institute, Seoul, to name a few.

These collaborations have paved the way for not only getting grants but also coming up with new products in relatively quick time and in a cost-effective mode. As a result of all this, BBIL has eight patents granted. The most significant one is a global patent for a biotech molecule, Lysostaphin, which targets staphylococcus infection.

That characterizes Ella's approach—think big. His formula has been better technology management and process innovation as the differentiation. The modus operandi he followed was a mix of collaborative research and funding from international and national bodies to minimize risks, coupled with huge volumes to roll out products.

He draws his inspiration from the likes of Dr RA Mashelkar, DG CSIR. Indian President, Dr APJ Abdul Kalam, Dr G Padmanabhan, former director of Indian Institute of Science. Bangalore, Dr Roger Glass, CDC Atlanta, and Prof. Harry Greenburg, Standford University. He admires Dr Anji Reddy for his passion for science.

Hence, it is not surprising that Ella has an easy nature, is approachable, and has all the warmth. He is not averse to meeting people and goes about sharing his ambition of realizing the goal of bringing affordable, world-class quality health care to the needy in our country with his team members. He is articulate too and his speeches are by the spur of the moment. All these qualities make him a very good technopreneur.

### **What is the current mission and vision of your company?**

We at Bharat envision a disease-free future.

We at Bharat envision a disease-free future. It is our cherished vision to offer affordable, safe and effective healthcare solutions to combat mankind's most dreaded illnesses and to thus eradicate or at least control their occurrence in the years to come. The corporate vision of Bharat is to ensure a healthy tomorrow. At the heart of all our efforts is the undaunted and ceaseless aspiration to develop and provide next-generation remedies through extensive research in genetic engineering and rDNA technology and to focus on augmenting national self-reliance in the sphere of affordable health care. We also would like to become a global player in the biotechnology sector.

### **What are the key achievements so far?**

BBIL has notched up a lot of firsts to its credit. We have the largest biotech facility in Asia-Pacific with over 3 lakh sq ft of clean room facility conforming to cGMP/USFDA/UKMCA. The first biotech plant in Asia with P2 and P3 production containment facilities. We were the first to produce world's first cesium free hepatitis-B vaccine. We have a global patent for a new biotech molecule-Lysostaphin to fight staph infection. Bharat is India's first and world's second manufacturer of Indikinase (obtained US-patent on the technology). We are the largest primary manufacturer of typhoid vaccine. We are the first Indian biotech company to manufacture HibTITER vaccine for Wyeth Lederle, USA. The first Indian company to be assigned the responsibility of developing two new vaccines - rotavirus and malaria. First Indian company to get two grants from the Bill & Melinda Gates Foundation's Program for Appropriate Technologies for Health. Bharat has also obtained five research grants from DST.

### **What has been the total investment in the company?**

We have invested more than Rs 100 crore in developing a world-class manufacturing facility at Genome Valley in Hyderabad. We raised the funds through internal accruals,

SBI and Industrial Development Board of India (IDBI), ICICI and Technology Development Board (TDB) of Indian government.

### **What are the research activities going on at Bharat?**

We are in the forefront of technology development. Bharat has come a long way after launching its flagship product, Revac-B, on 22 October 1998. The company has developed vaccines for infectious diseases pertinent to developing countries such as Typhoid. We are now actively involved in developing vaccines for rotavirus and malaria. Vaccines for Rabies and Japanese Encephalitis from Bharat have entered clinical trials. We are also in the forefront of developing critical life-saving drugs and biopharmaceuticals.

### **How have the products developed by Indian companies progressed?**

Indian biotechnology sector is progressing at a steady pace. I would say, we are on par with Korea and Cuba. But Indian companies need to focus on exports. The present trends suggest that more and more pharma companies are diversifying into the biotech sector. It would be wise to have synergy between the pharma and biotech companies to avoid cannibalization of effective products. The pharma industry should not lose focus at the market place. With the development of the domestic market, both availability and pricing have become competitive. This has resulted in a tangible advantage to the consumer.

Exports is another arena, which needs a lot of focus. Consistency, quality and competitive pricing can result in volumes and result in capturing new markets.

### **Exports of bioproducts still have to pickup. What is the issue?**

The exports of Indian bioproducts are not picking up as expected due to two main factors. The first is the mindset in the global market regarding quality of our products, which needs to be addressed immediately. The second is the pricing. Increasing awareness about Indian bioproducts can go a long way in demystifying these issues.

### **How many manufacturing plants do you have now and how do you plan to gear them to address new products?**

The company has over 3 lakh sq ft clean room facility conforming to cGMP protocols for production of vaccines, biotherapeutics and biopharmaceutical products as stipulated by WHO, USFDA and UKMCA. BBIL's state-of-the-art biological facility is the largest in its genre in the Asia Pacific region. BBIL has two large manufacturing facilities: a dedicated facility for hepatitis-B, the second largest in the world, with a capacity of 100 million doses per annum and the largest multi-product manufacturing facility consisting of biotech incubator, contract manufacturing and filling facility. The

first of its kind in the world, this facility can be utilized for contract manufacturing/formulations.

### **Strategic alliances are important in any venture...**

We view strategic alliances as key drivers for overall development and for augmenting the pace of growth. At Bharat we have adopted a "collaborative research model". We work in consonance with the world's best known research institutions such as CDC Atlanta and Stanford University.

### **What is the message for the biotech industry and the policy makers and industry?**

Biotechnology is skill-oriented and capital intensive. Companies in this sector should come together and cooperate instead of mindlessly competing with each other. The regulatory framework also needs to be reviewed. A single window comprising of DCGI, GEAC and DBT would greatly speed up the process. This would also help monitor a product from the beginning to the end. An advisory committee could help in making judicious decision relating to biotech products.

Dr Mashelkar pioneered the IPR concept in this country. We need someone to champion the regulatory reforms. The message is to keep the good work going. Consistency in our efforts will help us tide over the challenges posed by the patent regime. The need of the hour is to create awareness. The government along with the industry must pool in their efforts to increase responsiveness in the public towards biotech products.

The efforts of the global biotechnology community are setting an example. Much of the efforts today are focused on treating detecting and preventing human disease. With new-found information such as mapping of several genomes, novel therapeutic and diagnostic breakthroughs are emerging.