

Shantha Biotechnics: Believing in a Dream

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It was May 27, 2010. Varaprasad Reddy Koduru (Varaprasad) was reflecting on an invitation from India's Ministry of Health. Varaprasad had started Shantha Biotechnics (Shantha Bio) 17 years back, and was revered as the harbinger of Indian high-end biotechnology industry. He was credited with getting Hyderabad the label of the Genome Valley or the biotech hub of India. He had inspired a new generation of biotech enthusiasts with revolutionary indigenous development of a Hepatitis-B vaccination – Shanvac-B. That vaccine had been distributed by the UNICEF to millions of children around the world for 1/40th of the price charged by the Western multinational corporations (MNCs). **“In the US, Hepatitis-B vaccine costs \$100 a dose. Shantha Biotech has brought it down to Rs.34 per dose. This is Gandhian Engineering in action and Dr. Reddy is indeed worth emulating,” says Dr. RA Mashelkar,** CSIR Bhatnagar Fellow & President, Global Research Alliance. Reacting to this magnificent accolade, he says, “I just wanted to do something for my country”. Varaprasad had received more than 150+ awards for the vaccine, which showed the possibility of making affordable preventive care vaccines, with limited investments, using an innovative recombinant technology. Though Shantha Bio's portfolio had expanded to include the development of generic biologicals, novel therapeutic antibodies, proteins and vaccines, Shanvac-B constituted nearly 90% of its revenues until last year. Because of Varaprasad's pioneering efforts, India was now being counted as the most promising emerging market for the biotech industry.

A tall, handsome man with a graciousness that belies the single-minded focus and conviction, Varaprasad's mission was to provide quality affordable healthcare to the world's impoverished population – a thought that

he had imbibed from his mother. He had faced serious challenges associated with single-handedly founding a new industry, deemed as high-tech and cutting edge even in the industrialized markets. Funding had been tough and venture capitalists were not willing to take the risk. The market had been under-developed, and required creating mass awareness amongst largely illiterate and poor people about preventive healthcare. Securing collaborations with the United Nations, non-profit organizations, government organizations, and private companies with marketing resources and networks required time. There were also questions about the bioethics of using illiterate subjects for vaccine trials, and about the public policy prudence of the emerging market governments investing their limited resources in further expansion of universal preventive immunization programs. Marketing opportunities in the industrialized markets had significant barriers to entry from tough regulations and costly distribution networks.

Just a year earlier, France's largest and world's 4th pharma major, Sanofi-Aventis, had acquired an 80% stake that another French family business Merieux Alliance held in Shantha Bio. The acquisition valued Shantha Bio at unexpectedly large amount, after a private bidding war with GlaxoSmithKline. Sanofi finally won the deal by reaffirming its commitment to Varaprasad's public health mission of providing affordable drugs. It planned to develop Shantha Bio into a global R&D hub, and to expand in India and in other emerging markets.

During 2008-10, with seven major and several minor acquisitions of Indian firms, the foreign pharma MNCs had increased their share of India's \$9.5 billion retail drug market to 25%. Many MNCs had set up outsourcing contracts in India. India's advantage included trained English-speaking physicians, diversity of diseases, large patient base, and development and manufacturing

costs that were 60% less than in the US. With US\$2.58 billion of revenues in fiscal 2008, India held a 2% share of the global biotech industry. Still, the growth of the nascent Indian biotechnology industry, with about 400 firms, was down to 20% annually, compared to 30% in the past due to lack of funds.

The media in India was worried that the sell-out of Indian biotechnology firms to foreign MNCs could prove disastrous for India. Drug prices in India were among the lowest in the world. The analysts worried that the MNCs will soon dominate the Indian biotech market, and raise the prices, making drugs out of reach of the hundreds of millions at the bottom of pyramid. Alarmed, on May 27, 2010, the Ministry of Health invited the heads of domestic biotech and pharma companies for an emergency meeting to discuss why there were an increasing number of Indian producers selling out to foreign interests.

Varaprasad wondered if he should he not be concerned about Sanofi asking for increased prices for its drugs. How could Sanofi's stake be leveraged to bring about the greatest benefits to Shantha Bio and to India? What should the government of India do to help Indian biotech firms maintain their independence?

Homespun Scientist: 1948

Varaprasad, born in 1948, hailed from an agriculture family in Papireddypalem Village, Nellore District, Andhra Pradesh. He was the only child and was brought up by his maternal uncle. He considers his mother - Shantha - his first guru. His father had just a primary school education, and his mother had gone only to a secondary school. He was the first to graduate in his extended family.

After completing his Bachelors in Science from Sri Venkateswara University in 1967, Varaprasad – an avid reader – wished to pursue literature. But Varaprasad's maternal uncle felt that the nation required engineers, and persuaded Varaprasad to join the engineering program in electronics and communication from Andhra University. A decade later, he studied at Biblengen University, West Germany for eight months in Automatic Quality Testing Systems.

In 1972, Varaprasad joined the Defense Electronics Research Lab (DLRL) as a Research Scientist in Electronic Counter Counter Measures. His specialization was in radar jammer controls. During his 5-year tenure there, Varaprasad has demonstrated his confidence in indigenous technology. He could achieve integration between radars of different makes. The process would have cost \$8.5 millions to the exchequer but Varaprasad did it at a fraction of the cost. In recognition of his talent he was awarded Tamra patra (Bronze Medal) but his innovation was published in some other's name. Frustrated, Varaprasad left the job.

Uncomfortable Bureaucrat: 1977

It took only a few weeks for Varaprasad to be appointed as a Deputy Manager in the technical department of the Andhra Pradesh Industrial Development Corporation (APIDC). His job was to assist small and medium scale enterprises in product development and quality assurance. Most entrepreneurs he met were not interested in product design, and were not even interested in quality. So, Varaprasad asked the CEO Ram K Vepa to transfer him to the Headquarters to look after the promotion of electronics industry.

Varaprasad then joined the part-time MBA program at Osmania University with a desire to learn more about balance sheets, and finished the program in 1980. With management skills on hand, he saw through the (mal) practice of maintaining different balance sheets by entrepreneurs. He became frustrated with the system and started looking out for an opportunity to get out of it and become entrepreneur himself.

It was at this time that Varaprasad came in contact with a professor at the Administrative Staff College of India at Hyderabad, and a visiting faculty at New York University. He had an MBA from MIT and a doctorate in international business from Columbia University. Varaprasad felt stimulated by him and noted "As a visionary, he could see what was going to happen 20 years down – in terms of technological changes and acceptability of the society. He wrote three books visualizing the future trends."

Enthusiastic Entrepreneur: 1985

The professor had founded a small scale enterprise producing industrial batteries. Over its history, the maximum revenues had been Rs.1.7 million, and that was in 1978-80. Since then, the equity had been wiped out. He had limited interest and time for business, and was looking for a managing partner. Varaprasad was a perfect implementer and adept at developing harmony with people without creating turbulence in the environment. They complemented each other.

Using financial support from his father and some loans, Varaprasad began developing the firm by implementing the ideas of the professor. They focused on quality and built excellent facilities. In 1986, the duo promoted Indo-Swedish venture, for the development and production of high tech batteries for Defense applications like submarines and MIG aircrafts. In the first year itself, the revenues touched Rs.50 million in 1985, and by 1990 had grown to Rs.500 million, and employee base to 780. In those six years, the company got several awards for its performance and exports.

Though the business was growing, the bonhomie between the partners was waning. One momentous day in 1991, the professor wrote up a memo to the Board, stating that Varaprasad wrote to him that admitting that he had wasted a lot of money and be pardoned for all his misdeeds; and as repentance he would surrender all his shares and property to the professor and walk out of company to do spiritual cleansing. Varaprasad was not even allowed to sell his stock, on the plea that it would destabilize the management of the company. The market value of Varaprasad's stock was about Rs.15 million. Each stock was valued at Rs.74, but the professor demanded its transfer in his name at par at Rs.10. Varaprasad offered to give his stock for as low as Rs.50, but he refused and filed a lawsuit. The legal fight lingered on for several years, when the court eventually decided in Varaprasad's favor.

The Insult and the Initiative: 1991

Varaprasad felt totally devastated. He would cry like a child into the night, as his mother and wife consoled him and strived to rebuild his self-confidence. Unable to come

to terms with this sense of betrayal, Varaprasad started to look for peace. Varaprasad described his condition in terms of the Sanskrit word "Mahabhinishkramanam" (to walk away barefoot without anything on hand). To recover and to start his life afresh, Varaprasad went to the US looking for opportunities. During his stay with his cousin at Cincinnati, on his suggestion, he accompanied his cousin to Geneva, where his cousin had been invited to present a paper at a conference conducted by the World Health Organization on Global Impact of Immunization.

At Geneva, attendees from western countries expressed a feeling that India and other developing nations did not have the commitment to provide vaccination to their children and accused that they came with a begging bowl to them for subsidized vaccinations. Varaprasad found it insulting and derogatory. He heard for the first time about the mandate of the World Health Organization to incorporate Hepatitis-B into the immunization schedule, and that India and other developing nations were not able to do so because of a serious foreign exchange shortage and high cost of vaccine.

Varaprasad called his family doctor in Hyderabad, who informed him that the Hepatitis-B vaccination was very expensive, and was only for rich and for those with connections. For immunization three doses were needed, and a family of four members needed Rs.10,000 for vaccination. Even if one member of the family was already affected with the disease, the cost of the treatment would be whopping, very few families in the nation could afford.

Varaprasad made up his mind to start the Hepatitis-B vaccination project, because one of the delegates at WHO program was repeatedly telling that "Indians were beggars begging for vaccines." He asked his cousin to find out about the technology, and found that only three companies in the world were making the vaccine first introduced to the world by SmithKline Beecham in 1987.

They then went to a pioneering genetic engineering company in California. There, after a tedious wait for 90 minutes, he was advised by an executive, "In India,

you do not need this expensive vaccination. India has enough people and death of a few hardly makes a difference.” When Varaprasad persisted, the executive said the Hepatitis-B vaccination technology became commercial only in 1988, and India will not be able to afford it. Even before Varaprasad could say anything, he added that the technology would cost \$100 million, and challenged that Indian scientists will not be able to even absorb its complex technology for at least two decades. With that the meeting ended. Varaprasad was very angry – he vowed that they would come out with a better vaccine within two years, leave aside two decades.

Varaprasad decided to go to New Jersey to meet another cousin and sought his help to prove that Indians were capable of producing high quality vaccines and offering them at affordable prices to the masses. The cousin called all his friends, and got 35-40 families into a meeting hall. After two days, when they realized Varaprasad was not giving up, they decided to do something to help. But they did not know the technology and said so. Varaprasad passionately and emotionally appealed that since some of them were scientists and knew the techniques; they could meet experts in different spheres, hire and train graduates, evolve the techniques, and finally put them together to develop the technology. The idea was highly risky – the time frame was unknown, fund requirement unknown, and even the outcome was unknown. Varaprasad said all he required was their support with the techniques. He knew the other ingredient – technology management – i.e. how to manage people and how to properly sequence them to get the product based on his previous R&D experience. He challenged them to give something back to their country. His friends agreed to pool together Rs.12 million to support his noble mission.

Search for Funding: 1992

In 1992, Varaprasad promoted Shantha Bio as a privately held company – named after his mother Shantha. The goal was to develop recombinant based vaccines and therapeutic proteins for human health care. The mission was to produce cost-effective drugs to reach the common man at an affordable price while meeting international quality standards. He asked his father to

sell off some of his property, wary that he might not agree. But to his surprise his father readily agreed and so the initial seed investment was raised and then he impressed Dr. Malla Reddy, Vice Chancellor of the Hyderabad-based Osmania University to allow him to use the University microlab for research under the industry-university interactive program. Years later Malla Reddy would say “I agreed only because of Varaprasad’s enthusiasm and sincere efforts.” Varaprasad recruited Dr. Gita, a senior scientist in the department, to work as the lead on the project at this microlab. Dr. Guntaka Rami Reddy, a brilliant microbiologist in the US, offered his lab to work on developing the technology. In two years, Dr. Gita perfected the technology at the US lab, but their lab facility usage at Osmania University was withdrawn though Varaprasad spent quite a money on to upgrade it. Dr. Guntaka referred Varaprasad to Hyderabad-based Center for Cellular and Molecular Biology (CCMB) to start animal tests. CCMB had been founded in 1977 as a constituent national laboratory of the Council of Scientific and Industrial Research (CSIR), the premier multidisciplinary Research & Development organization of the Government of India.

In the interim, no bank or venture capitalist was willing to fund the fledgling project. First, the venture capital industry was under-developed in India, and biotechnology was in nascent stage. Second, even though 45 million Indians were affected by Hepatitis-B, mortality data showed only 80,000 deaths and there was limited use of vaccines because of a lack of awareness. The investors thought that it was too small a number to make the venture viable. Third, the investors wondered how Varaprasad with his electronics background could succeed in a life-sciences project. Even in the West, Hepatitis-B vaccination project was a frontier technology, and required fifteen years to develop. The financiers were concerned about how many years Varaprasad would take, how could he develop, and how could he assure returns on the investment.

One Government of India financial institution, Industrial Development Bank of India (IDBI), did agree to provide the funding, but expected a return of 80%. Varaprasad asked for a rationale, and was told that out of every

100 projects supported, only 1 project would be the jackpot, and the remaining would fail. So, each project was expected to compensate for the other 99 projects. Varaprasad felt this rationale was not fair, and decided not to go for those funds.

Varaprasad continued to look for every possible source of funding. Finally, in 1994, he met Khalil Ahmed, the healthcare investment representative for H.E. Yusuf Alawi Abdullah, the foreign minister of the Sultanate of Oman. Abdullah and his associates offered to invest but demanded a matching equity share of 50%. Abdullah said they would not interfere or participate in the management, will not guide him in any manner; will not expect any guidance from him, but wanted to maintain their status and have an equal equity share. They showed full faith in Varaprasad's philosophy of offering the vaccination at an affordable cost. Abdullah also arranged long term loans from Oman International Bank at low rates of interest. Abdullah sensed that "Varaprasad was a man in a hurry. He would go ahead with nothing in hand."

Varaprasad obtained Rs.6.5 million of loans from his cousins and friends, and sold some of his property for Rs.2.3 million, for his own share of the equity, as he was unable to secure any external funds. After that, another Government of India institution – ICICI – agreed to offer a loan for technology development. When the R&D results were viable for commercialization of the product, the newly established Technology Development Board (TDB), under the Ministry of Science & Technology offered a loan of Rs.50 million.

Actualizing the Dream: 1997

Varaprasad now was able to invest in a state-of-the-art R&D facility, largest in India, devoted exclusively to biotechnology-base healthcare products. He formed collaborations for research with reputed academic institutes like CCMB (Hyderabad) IISc (Bangalore), JNU (New Delhi), Anna University (Chennai), Bhabha Atomic Research Centre (Mumbai) and NII (Delhi). His goal was to make Hepatitis-B available at 10% of the cost – Rs.70 per dose, as against Rs.780 charged by SKB. The figure was kept low as most of the Indians were

getting free vaccination from the government. Paying for vaccine was unknown phenomenon for Indian poor. Varaprasad did not use any rational approach of estimating the project cost or evaluating the process.

In 1997, Shantha Bio successfully developed India's first genetically engineered product "SHANVAC-B", vaccine against Hepatitis-B virus after five years of intense research. India joined the select club of four countries in the world to have the know-how to make a genetically engineered Hep-B vaccine. When Varaprasad approached the founder of a leading pharmaceutical company in India, to market his Hepatitis-B vaccination, he suggested that the drug be priced at the market price of Rs.780, as he was uncomfortable with low-cost product since it does not leave scope for margins and incentives to doctors. Varaprasad was committed to price at Rs.70, and decided to go on his own. Varaprasad felt that in order to truly make a difference and realize his dream of serving the greatest good to the underprivileged and poor of this country, profit maximization cannot be an objective at a time of severe Hepatitis-B vaccine shortage in India.

Varaprasad began directly marketing Hepatitis-B vaccination through his own field force. SmithKline Beecham, who held the monopoly in the Indian market, responded by crashing its own price, increasing the incentives to doctors and spreading the rumor that Shanvac-B vaccine was unsafe. Varaprasad took the matter up with the Drug control Authority to conduct a comparison test, which showed that Shanvac was at par and in some parameters better than the SmithKline Beecham product. The results were published in an internationally respected journal "Vaccine" and 200 doctors rallied to support Shanvac-B. Taking distribution expenses and doctors' margin into consideration, Shanvac-B was marketed at Rs.180. Varaprasad reached out to the Indian Medical Association to give lectures and organize camps and committed to offer Shanvac-B for Rs.100 (adult) Rs.50 (child) for mass public vaccination through the Government of India. He even gave away 10% of the production free for orphan children through the Ramakrishna Mission. NGOs and Rotary Clubs also joined in the campaign to help create mass awareness

and conducted mass vaccination camps on never-before scale using Shanvac-B. Pharma associations protested for bypassing market chain system but there was no looking back for Varaprasad. Thanks to these camps, where children were vaccinated at Rs.50 including cost of syringe and inoculation, the consumption has gone up many folds.

Varaprasad mainly harped on 'Swadeshi' (indigenous) theme and it paid rich dividends. Shanvac-B became one of the fastest growing brands in the Indian pharma industry, securing a 46% of market share in Hepatitis-B vaccinations by 2001. Until 1997, India was totally dependent on an expensive imported vaccine, and Shanvac-B offered an affordable home-grown solution. Within three years, Shantha Bio's success attracted four new Indian companies to launch their competing Hepatitis-B vaccine. SmithKline Beecham's share in India for r-DNA Hepatitis-B vaccine fell from 100% in 1997 to just 10% in 2000. As a first mover, Shantha Bio garnered sales of Rs.240 million in 18 months, and of Rs.320 million in fiscal 1999-2000. Over 1998-2000, Varaprasad received 47 awards. This included the first-ever National Technology award received from the Prime Minister in May 1999 for commercialization of home-grown technologies. In 2000, Ernst & Young bestowed 'Entrepreneur of the Year' Award on him for his contributions to the field of life sciences. Every product coming from Shantha stable won some or the other award.

Varaprasad was reinvesting 25% of revenues back into R&D – the highest of any company in the country. In India, R&D average was only 0.1 to 0.2%, and in the US, most major companies put only 4-5% into R&D. Still, Varaprasad needed more funds to tap new opportunities and be ahead of the competition.

In 2000, Varaprasad decided to list 30% of Shantha Bio with the NASDAQ stock exchange in the US – but had to abandon that plan due to unfavorable market conditions. In September 2000, Varaprasad divested 6.9% of the company's equity from his stake to a mutual fund owned by Morgan Stanley Dean Witter (3.9%) and to State Bank of India (3%), in a private equity placement worth Rs.500 million. The divestment valued the company at Rs.7.5 billion – 50 times its historical

earnings and 22 times its historic sales. The proceeds provided working capital cash, and also financed the Rs.600 million manufacturing facility. Varaprasad also retained ABN Amro Asia Corporate Finance to divest another 26% stake to a strategic investor. Though more than 20 companies showed their interest, a deal could not be finalized.

To increase Shantha Bio's profile in the US for a future listing, Varaprasad was connected with the US-based East-West laboratories. East West Labs held an exclusive global license for TB94, a complete human monoclonal antibody for the treatment of small-cell lung cancer. The market value for the product was estimated at \$1 billion. Shantha Bio agreed to make a phased investment of \$9 million in a 51% joint venture named Shantha West. Ghassal Shekhar, an NRI investor took 40%, while another nine% was taken by two other investors.

In September 2000, Pfizer paid Rs.60 million for exclusive rights to co-market Shanvac-B under the brand name Hepashield in India and overseas. Pfizer had been courting Shantha Bio since 1997. Varaprasad was not keen because of his bitter experiences with some of the multinationals, but eventually gave in to Pfizer persistence and commitment to India after Pfizer also agreed to subcontract some of its R&D to Shantha Bio. Within six months of the agreement, Hepashield emerged as the No. 2 selling brand among over 700 brands launched by various pharma companies worldwide. In April 2001, Pfizer paid an additional amount to obtain the first refusal rights for exclusively marketing the future stream of Shantha Bio's products.

In 2002, Varaprasad received Rs.180 million in loans from Export Import Bank of India and Rs.90 million in loans from Technology Development Board for setting up a manufacturing facility for four-in-one combo vaccination -Shantetra – for hepatitis B and DPT (Diphtheria, Pertussis and Tetanus). Internal accruals financed the rest of the Rs.400 million investments. The facility, compliant with the international Good Manufacturing Practices, was slated to open in September 2004. Varaprasad expected to lead a shift of the Indian bio tech towards combo drugs, as they allowed for an easier immunization for the government and for the children, and supported

greater margins through R&D. A dose of DPT vaccine was priced at 10 cents (Rs.4.40), and a dose of Hepatitis B at 27 cents (Rs.11.88). Varaprasad intended to price Shantetra – the first indigenously developed combo vaccine in India – at \$1.75 (Rs.80) initially, and bring that to 87 cents (Rs.38.28) within two years. Only GlaxoSmithKline and Chiron offered this four-in-one combo, priced at Rs.225 per dose. Varaprasad intended to capture a 20% share of the 390 million combo doses required annually globally.

In April 2002, Shantha Bio launched the first indigenous Interferon Alpha (brand: Shanferon) for the treatment of cancer and viral hepatitis. Interferon was priced at Rs.300 / dose, against the import price of Rs.1800. The annual cost of Interferon for the patient fell from Rs.750,000 to Rs.150,000.

Keeping pace with the growing competition, Shanvac-B prices were reduced to Rs.25 by 2003. Profit margins fell gradually from 20-25% at the time of launch. However, turnover stagnated over 2000-2003, and was only Rs.340 million in 2003. Shantha Bio was denied a major opportunity to deliver Shanvac-B to UNICEF for worldwide distribution, under the Global Alliance for Vaccine and Immunization program of the Bill & Melinda Gates Foundation. Andhra Pradesh State government refused to recommend Shanvac-B for the program, launched in 2000, because of a controversy surrounding another local rival Hepatitis-B drug maker. The issue was resolved only in 2003, paving way for the World Health Organization to pre-qualify both Shanvac-B and Shanferon for a long-term UNICEF contract for low cost drugs. Shanvac-B happens to be the first vaccine to obtain WHO pre-qualification. The results immediately impacted the top line: in fiscal 2004, sales almost doubled to Rs.650 million, of which exports were Rs.550 million. In 2004, Morgan Stanley Dean Witter offloaded its 3.9% stake taking the revived growth as an exit opportunity to the US-based non-resident Indians, and Varaprasad was also forced to offload an additional 6.1% of his stake to them to generate resources. However, Varaprasad was able to tie up with the US-based Spectrum Pharmaceuticals who agreed to take care of all regulatory, marketing and distribution issues for marketing Shanvac-B and Shanferon in the US.

Shantha Bio at a Crossroads: 2005

In 2005, Varaprasad was conferred the third highest civilian honor – Padma Bhushan – by the Government of India. Three drugs were launched within a span of 12 months. First, in October 2004, Shankinase brand of life-saving drug for acute heart attacks, and to help dissolve blood clots was launched. Varaprasad targeted a 10% share in the first year of the Rs.400 million domestic market, pricing the drug at less than half the Rs.2400 cost of the imported drug. Shankinase launch was delayed by a year, because of bio-ethic controversy surrounding the death of 3 of the 96 patients on which had been tested. Second, in January 2005, “Shanpoietin” brand of pre-filled syringes – developed over a five year period with a R&D of Rs.200 million – were launched for treating anemia and renal failure. At the time, India was importing 70% of the Rs.750 million demand. Third, in October 2005, the 4-in-1 combo drug Shantetra was launched, delayed by a year because of resource issues. In the interim, the new factory opened in September 2004 was used for making the DPT vaccine. Critics questioned the benefits of government paying for a combo drug, when the DPT and Hepatitis-B vaccinations separately cost much lower. Therefore, Shantetra remained excluded from the national immunization program.

The global demand for Shanvac-B through UNICEF remained strong, and with other new vaccines, Shantha Bio generated sales of Rs.1 billion in fiscal 2005. In fiscal 2005, the Indian bio tech market was worth \$1 billion, growing @ 30% annually – double the global rate. As of March 2005, Shantha Bio’s cumulative investment was Rs.1.50 billion – Rs.650 million in equity and premium, Rs.300 million in loans, and Rs.550 million in internal accruals. Of this, Rs.650 million was invested in the manufacturing facility and Rs.850 million in R&D. Its cumulative sales were Rs.1840 million. It had 650 employees, of which 125 in R&D. Shantha Bio had brought down the global prices of Hepatitis-B vaccine by 40 times and raised the global consumption by 500 times since Shanvac-B launch. Shantha Bio now supplied 40% of the UNICEF’s worldwide distribution of this vaccine, impacting the health and lives of millions of children.

From a business standpoint, Shantha Bio had only five drugs on market till date since its founding in 1993, with only one truly winning product Shanvac-B that accounted for 91% of its revenues (see Table 1). Further, Shantha Bio had a direct presence in only 14 nations, with no presence in Western Europe. Shantha Bio feared falling behind its local rivals, who had roped in big global firms as strategic partners and investors. Shantha Bio had a potential to launch 2-3 products every year, subject to funding and global marketing access - the number of companies globally producing vaccines had fallen from 26 in 1967 to 4 in 2005, so opportunities were immense. Due to limited marketing resources, Shantha Bio was able to utilize only 38.31% of its installed capacity of 200 million doses in fiscal 2005.

Table 1: Shantha Bio's Idle Capacity and Hepatitis-B dependence

	Total Capacity Utilization	% of Revenue Contributed by Hepatitis-B Vaccine
Fiscal 2002	21.77%	92.57%
Fiscal 2003	46.78%	91.46%
Fiscal 2004	23.64%	91.36%
Fiscal 2005	38.31%	91.81%

Shantha Bio – just like the other Indian biotech companies – was at a crossroads. While it had demonstrated competence, the political and financial commitment required from the government and the market had not been forthcoming. As of January 1, 2006, India adopted the product patent regime, in conformity with World Trade Organization's intellectual property rights agreement. The new regime ended the ability of the Indian firms to reverse-engineer patented drugs till their patent was in existence. Therefore, to stay alive, there was a growing pressure on the Indian generic drug makers to refocus towards the developed country diseases, using the contract research work for the Western MNCs. Varaprasad had been able to avoid this pressure in the past through partnerships with public and private organizations in India and abroad, and by securing project-specific financing from government agencies. But now his partner investors wanted to cash in on their investment.

French Strategic Investor on-board: 2006

In November 2006, the Oman-based investors and the US-based NRIs then sold off their joint 60% stake to a 113-year-old Lyon-based French family business - Merieux Alliance, for \$110 million. Varaprasad was pressured to sell an additional 20% of his stake in exchange for Merieux infusing cash into Shantha Bio. That left 17.1% still with Varaprasad, and 3% with the State Bank of India.

Merieux appointed one of its directors, Georges Hibon, as the chairman of Shantha Bio. Merieux – with \$1.8 billion of revenues – was known for using biology in therapeutic (curative) drugs, and straddled the entire chain from diagnostics to immunotherapy. It was facing stiff global competition, in the maturing global therapeutics market, and was searching for a low-cost research and manufacturing hub in Asia to cut those costs by 20-30%. Shantha Bio would become its global hub for the preventive vaccine business, as the global vaccine development industry was projected to more than double to \$24 billion by 2010. The surging demand for new generation vaccines, such as Anthrax and flu, would allow Merieux to expand vaccine business in the Western markets, and to further penetrate the emerging markets.

Benefit potential for Shantha Bio was immense. First, Varaprasad hoped to generate “Rs.1 billion by doing R&D for group companies of Merieux over the next three years.” Merieux invested Rs.1300 million in a new R&D center at Shantha Bio to strengthen research activities and accelerate the development of product portfolio. Second, to tap the contract manufacturing opportunity, Merieux committed to invest \$250 million in expanding the manufacturing capacity. Third, Merieux committed to enable access to the global markets. Varaprasad noted, “We will work as partners to increase our growth rate, reduce time to market, while maintaining high quality standards. We share a vision of the need for affordable healthcare for all.” Fourth, Varaprasad was keen to use the alliance as an opportunity for Shantha Bio to make a foray into the therapeutics market by developing clinical diagnostic equipment. The global diagnostics market was estimated at \$80 billion, and

the Indian market at \$250 million. Though, Merieux was non-committal initially, it agreed to invest \$250 million into a new diagnostic equipment facility at a biotech park set up by the State government at Medak district.

Within five months, in May 2007, the new high-speed vaccine fill and finish facility was commissioned. The facility had 3 filling lines - a High speed vial filling line, Uniject filling line and Glass pre-fill syringe line. The facility would formulate and blend Shanvac-B and Shantetra, and other to-be-launched vaccines. The facility expanded the vaccine filling capacity from 100,000 vials per day to 350,000 vials per day. Pre-qualification was secured from WHO for Shentetra, opening new opportunities for its exports through UNICEF. Shantha Bio had increased its direct marketing presence to 35 nations, and was now looking to expand that to 50 nations.

In 2007, Shantha Bio formed an alliance with the global nonprofit health organization, PATH, to develop an affordable vaccine for rotavirus - which causes infant diarrhea. Bill & Melinda Gates Foundation offered the funding. Clinical trials began in 2008, and launch was slated for 2012. Increased R&D funding also allowed clinical trials for the Shantha West anti-bodies for treating lung cancer to begin in 2008.

In fiscal 2006, Shantha Bio enjoyed a turnover of Rs.1.48 billion, and grew to Rs.2.05 billion in fiscal 2007, and then to Rs.4 billion in fiscal 2008, with 700 employees, and 95% revenues from exports. The Indian biotech industry revenues were \$1.5 billion, \$2.1 billion, and \$2.5 billion respectively, of which 56% were exports. The industry was still young, and was referred to as “baby elephant” with considerable space to grow. Though the top three firms – Serum Institute, Biocon, and Panacea Biotech – held a 27% share of the industry revenues, the rest of the industry was highly fragmented. A significant transformation of the industry was expected, as the international pharma MNCs were beginning to shift their strategies.

Historically, the international pharma MNCs focused their marketing strategies on the industrialized markets, and charged very high prices. However, with global financial meltdown in 2008 and 2009, the industrialized

economies were slowing down. There was a growing pressure to cut healthcare costs, by reducing the drug prices. Additional pressures existed to offer discounted drugs for the public health systems in the emerging markets, as the attitudes globally had shifted to recognizing the value of healthcare in these markets also. To top it all, the pipeline of innovative drugs was drying up, and within next decade, 90% of the pharma revenues were expected to be from off-patent drugs. In contrast, the healthcare markets in the emerging markets were growing by double-digit, and the rural markets were seeing even faster growth. The emerging market biosimilar (generic) drug makers had excellent R&D teams and state-of-art manufacturing facilities that could be platform for growth in both industrialized as well as emerging markets, and had marketing networks extending into the fast growing rural markets. Therefore, the race to acquire emerging market generic drug makers had intensified among the international pharma MNCs. The race was heating up particularly in India, where the low prices of drugs made it nearly impossible for the MNCs to penetrate Indian urban and rural market with their high cost international technologies and assets.

A Replacement Strategic Investor in 2009

By early 2009, Merieux Alliance concluded that under its own corporate umbrella, Shantha Bio was valued at Rs.10-12 billion. That value was estimated to be much higher for a pharma MNC looking to integrate its own preventive medicine assets. As Merieux Alliance searched for prospective investors, GlaxoSmithKline Pharmaceuticals, the most affected by the development of Indian biotech industry, emerged as frontrunner. Varaprasad was alarmed enough to inform Merieux “that whoever comes, if the name of the company or its philosophy is changed, I’d exit.”

In an interview, Varaprasad gave deeper insights into his philosophy that he expected any potential partner to share. Varaprasad had set up Shantha Bio to offer affordable healthcare to each and every Indian. Varaprasad credited his career path and realizations to his mother’s aspirations, who wanted him to do something good for the people. He always took care of the needs of the poor when fixing the profit margins

on his products. He observed “I acted up on the great provocation, not on the great vision. I did several strategic mistakes in my life. But since I cared for the society, society, in turn, took care of me. I expect good intentioned people to carry on this torch of Societal Entrepreneurism.”

In July 2009, France’s biggest and world’s fourth largest pharma firm, Sanofi-Aventis, agreed to buy out the 80% stake, valuing Shantha Biotech at an enormous Rs.38 billion/ \$780 million. Sanofi already had 2870 employees in its existing operations in India, and had recently acquired three vaccine firms in Mexico (Laboratorios Kendrick), Brazil (Medley), and California (Bio Par Sciences). Shantha Biotech offered it an opportunity to aggressively expand its vaccine business in the emerging markets. Most importantly, Sanofi endorsed Varaprasad’s public health mission and Shantha Bio’s ongoing development as a platform to address the need for high quality affordable vaccines in international markets. They asked him to continue as Managing Director.

Varaprasad noted with pride, “It is very unusual that such a high valuation has come to an Indian company. Before my eyes Shantha has grown beyond my comprehension. This deal means that now Shantha can grow bigger. Being a manufacturer of affordable drugs and vaccines, the company operates on thin margins, hampering its ability to invest in R&D. Now we can do all that and more without compromising on our philosophy of providing affordable drugs to society.” In addition to using Shantha Bio brand in other emerging markets, Sanofi-Aventis wanted to develop Shantha Bio into a global hub for R&D. Varaprasad added, “For new molecules, we need lots of money. Even if our research costs are about 20% of what they would be in the U.S., no bank in India will give money for R&D.”

By early 2010, several more MNCs had acquired Indian bio tech firms, raising the MNC share of India’s bio tech market to 25%. Both media as well as Ministry of Health were alarmed about the possibility of the MNCs raising the drug prices in India, after eliminating local competitors. Varaprasad felt that the lack of funds and lack of supportive government policy made it essential for him to seek foreign investment. He also

believed that Sanofi-Aventis complemented his mission through its global vision. Varaprasad considered his major weakness to be his inability to convince the successive governments the need to support indigenous endeavors and to promote R&D. He did have a strong urge to do something for the people, and knew that it will transform into concrete action. Unlike the Western pharma companies that maintained 100% margins to cover the high costs of drug discovery, he had kept the margins to no more than 10%. Varaprasad longed for India to walk back into glorious past, when India was renowned for its innovative technologies, by creating several generations of technologies. His aim was India should not get technologies from the West, and instead should create own technologies, and offer those technologies to the West. Varaprasad believed that India had a vast pool of talented people who can develop the latest technology available in the world. He wanted Shantha Research Foundation to grow. He wanted to provide contract research and contract manufacturing services, and develop collaborative arrangements for the co-development of new drugs or molecules.

At his heart, Varaprasad was a family man. His office desk had photographs of his mother, his wife Vasantha, two daughters Sangeeta and Sravanthi, and four grandchildren. One thing Varaprasad never misses an opportunity to enjoy his first love – music. He has great sense of humor too. And he published magazine and currently runs “Haasam Publications” and “Haasam Clubs” to promote music and humor. Varaprasad’s managerial skills lay in identifying the right kind of person with good attitude, with a passion to do something for the society. He was not looking for the graduates of Indian Institute of Managements – the elite business schools of India. He did not look around for great scientists; instead he sought great human beings, with noble thinking. He created a congenial atmosphere for the people to perform with their mind as well as heart, and a passion to do something new. The employees would not say that they were working for Varaprasad or for Shantha Bio – instead they would say they are working for themselves, as members of Shantha Bio family. Varaprasad never acted like a boss to his employees – he felt “My presence is insignificant

there; whether or not I am there, they will do their work.” He believed management was more of an art, than science. Management had to be adapted to the context depending upon the intention (bhava), the expression (raga), situation (sandharbham) and its importance, the poet’s heart (kavi hridayam) behind it and his/her *chamatkara* (communication skill).

He is a firm believer in the “Gayatri Mantra” – a Hindu spiritual chanting, which, he says, gives him inspiration and moral strength. He followed the principle that “Let noble thoughts pass through, and everything will fall in your way.” The secret of shantha, Varaprasad felt, was in a noble intention which helped his enterprise more than

his managerial skills or capabilities. Name, fame, and money followed as by-products. But talk about success and he retorts “I have not been successful. I will not feel like I have succeeded until the Government of India launches a mass immunization program for children using low-cost vaccines. That has always been my goal.”

A true reflection of the man who emerged, because of his straightforwardness, transparency, humility and amiability, as a role model and an inspiration for the budding bio-techs, who he advises, “Believe in your vision; do not lose sight of society and never give up on your dream fearing hurdles.”

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Dr Vipin Gupta (*gupta05@gmail.com*) is a Professor of International Management at California State University - San Bernardino, USA. He has a doctoral degree from the Wharton School of Business, Pennsylvania, a post doctoral fellowship from Tokyo University and a Post Graduate Diploma in Business Management from the Indian Institute of Management, Ahmedabad. Under his stewardship, Dhruva conducted Global Leadership and Organizational Behavior Effectiveness (GLOBE) – a Wharton School’s path breaking research.

Dhruva Consulting Group (DCG) is an eclectic mix of Industry and Academia which undertakes consulting projects far and wide. Global Leadership and Organizational Behavior Effectiveness (GLOBE) is a multi-phase, multi-method research project in which investigators spanning over 72 countries in the world are examining the inter-relationship between societal culture, organizational culture and organizational leadership. This project is envisaged by Robert J House of Wharton School along with Dr. Vipin Gupta. DCG has been retained as the sole Principal co-investigator for the state of Andhra Pradesh, India. DCG has managed the daunting task of profiling the case studies of about top 50 CEOs of Andhra Pradesh. DHRUVA retains the right over these case studies including that of Shantha Biotechnics. DHRUVA eventually will publish these GLOBE case studies under the title - “Models of Organizational Excellence in AP”.

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Dreaming the seemingly impossible

We must not be afraid of dreaming the seemingly impossible if we want the seemingly impossible to become a reality.

– **Vaclav Havel**

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