Enhancing healthcare through quality products

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Unichem Laboratories

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India:

An Emerging Knowledge Superpower

Courtesy of Ranbaxy

"India, as a manufacturing hub, offers safe, effective, quality medicines, at the very best prices. Now, we are on our way to become a R&D hub." For Dilip Shah, General Secretary of the Indian Pharmaceutical Alliance (IPA), India is currently on its way to undertake one of the greatest transformations ever experienced within the pharmaceutical industry, although the excitement has been over 30 years in the making. In 1970, India introduced "process" patents, which, unlike patents in America, allowed innovators to protect the way they made drugs, rather than the molecules themselves. This encouraged thousands of small drug copying companies to invent new processes.

The advantage of cost competitiveness

At present, the pharmaceutical industry has become one of the fastest growing industries in the country, with a value of $10 billion and a growth rate of 8 percent. When the country joined the WTO ten years ago, Indian pharmaceutical exports were less than 4,000 Crore Rupees. A decade later, its pharmaceutical exports are 14,000 Crore Rupees, and account for more than a third of the industry's turnover. This is mostly the result of the confidence built up in this strategic industry due to India's progressive adherence to its IP commitments. Now, the country is poised to achieve an annual compounded growth rate of 30 percent in order to double its pharmaceutical exports in three years. Some $60 billion worth of drugs are going off patent in the next few years.

This industry at present consists of around 300 firms in the large and medium sector, and nearly 1,000 units in the small-scale sector. The market share of Indian pharmaceutical companies has increased from around 20 percent in 1970 to over 70 percent today. The Indian pharmaceutical sector has witnessed a remarkable growth, from around $1 billion in 1990 to $11.2 billion in 2004/2005. The industry accounts today for 8 percent of the world's production by volume and over 2 percent in terms of value in 2004/2005. Furthermore, the country has demonstrated its potential in high technological capabilities and manufacturing standards by presenting the highest number of FDA-approved plants outside the United States.

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Indian companies' biggest competitive advantage is their cost-competitiveness. A generic medicine can indeed be locally developed, tested, manufactured, and marketed for 20 to 40 percent of what it costs in the West. This mixture of low costs and ingenuity has helped Indian firms to expand their sales and acquire companies far beyond their borders. For example, both Ranbaxy and Dr Reddy's, India's two largest drug firms, have daring patent strategies, challenging big drug makers on some of their core patents in key western markets.

Another great asset is that India has the second largest English speaking technical and scientific brainpower. This is why a lot of companies have started doing global clinical trials R&D, custom synthesis, bioinform atics, and statistics work in India, saving tremendous amounts in expenditures, because most of these things cost 50 percent less than in Europe or America. India offers, for example, a great opportunity to conduct clinical trials because a large number of patients are available and they are drug naïve--the system is pure from a research point of view. These trials can thus be completed for less than 30 or 40 percent of the cost in the United States.

Dilip Shah, general secretary, Indian Pharmaceutical Alliance

"India is moving to a knowledge-based economy that includes the contribution of IT and technical manpower, which makes the cost of production cheaper", says Dr. Ajay Dua, Secretary to the Government of India for the Department of Industrial Policy & Promotion.

International compliance

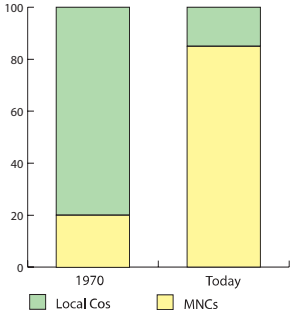
In 2005, India took another step into intellectual-property protection by recognizing full product patents on pharmaceuticals. As India is a signatory of the WTO and the Trade Related Aspects of Intellectual Property agreement (TRIPS), the country's patent law has been made TRIPS compliant by fulfilling various commitments required. Pharmaceutical patents were introduced on April 1, 2005, with the amendment of the 1970 Act. These patented drugs would be subject to mandatory price negotiation before being granted marketing approval.

The law caused an outcry by public-health activists, who worry about its effect on drug affordability—not just in India, but also in even poorer countries that rely on Indian drug makers for their medicine. Dr. Dua is aware of these risks but remains optimistic regarding the side effects of the new legislation: "This is something that in the long term will be beneficial to everyone," he says. "There will be time for people to readjust, but the industry as a whole will grow faster than it was for two reasons: New markets will open to India, because we are internationally compliant; and the country will benefit because several nations will be attracted by cost advantages in setting up physical facilities."

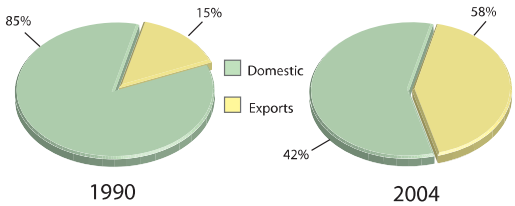
Companies from the West are indeed already in the process of setting up R&D centers in India. Multi-National Corporations (MNCs) were so far not well positioned in the country. Quite a few of them even left in the 1990s when patents were not respected in the country. Today, with the New Amendment in the Patent Law, as well as with the fully integration of India into TRIPS, some MNCs are coming back. The leading MNC companies in the country are GlaxoSmithKline, Novartis, Sanofi, and Pfizer.

There is an inducement to relocate the research work here; this will be followed by relocation of manufacturing. Once that happens, the capabilities of the local producers will become

Leading at Home, Aiming Globally

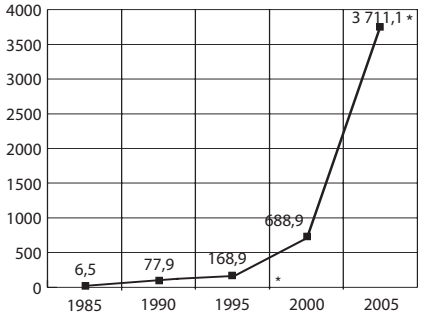


Share of Indian Market



Mn $	1990	2004
Domestic	1,000	4,556
Exports	178	3,333

Looking at Global Markets



Evolution of exports in Mn $

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Dr. Reddy facility

much larger than they were before, and will bring in more revenue for the country.

The success of the Indian pharmaceutical industry has undoubtedly been fuelled by the financial sector, just as Eximbank has been helping to promote Indian foreign trade for 25 years. It also functions as the principal financial institution in the country. "There has to be an APEX bank," says Sridhar, the former Executive Director of the Export-Import Bank of India. "Not only to finance, but also to play a developmental role in a particular sector like for instance pharmaceuticals."

Eximbank's first triumph during the economic reforms was in information technology. India has since become synonymous with IT. "To the pharmaceutical industry, we pioneered the concept of strategic export marketing in India because we said that marketing is different from selling," Sridhar recalls. "Whatever you produce you try to sell, but with marketing, you produce what the customer wants. As far as pharmaceutical companies are concerned, we provide them with the whole range of products that we have on offer."

Sridhar also shares the vision of India as an emerging knowledge superpower: "The pharmaceutical industry is a knowledge industry. The reason that the big players are doing well abroad is because they have the knowledge that is required. Our strength is that we provide first rate knowledge very cheaply."

The challenge of accessibility

For all its promise, some important challenges remain ahead in India. The main concerns of the Indian pharmaceutical industry are accessibility and affordability of drugs, despite that the country is one of the major producers in the world. Despite having one of the lowest prices in medicines, access remains a great problem—only 35 percent of the population has access to drugs.

India has the largest number of FDA approved manufacturing plants outside of the USA

Infrastructure is another sensitive issue. The number of hospitals with the infrastructure to undertake clinical trials is still limited, and patients need to be followed closely so they do not drift away. Some firms have also had problems with Indian contract research organizations that caused some of their drugs temporarily to be taken off the World Health Organization's approved list.

But with experience, quality is definitely improving, as confirmed by Dr. Dua: "Our infrastructure investments might have come later than they should, but we are investing heavily on that. In ten years time, you will see an amazing development of infrastructure of this country. Around $40 billion will be invested in roads, and another $40 billion will be invested in other engineering programs," he claims. Dilip Shah is equally enthusiastic about infrastructure in India: "The key to accessibility is not giving free medicines, but there is a need to create an infrastructure which will guarantee both access to medicines and provide medical support for the poor." ■

The Resilience of API Companies

"The strategy for any API player today should consist in two elements," says Mehul Parekh, Executive Director of Unimark. "Firstly, it is very important to maximize the number of molecules that we can create for the regulated markets. The second element is backward integration, manufacturing the product from the basic stage. Integration is of great importance because chemistry skills are more or less equal for most API players, so one way to differentiate oneself is by achieving backward integration."

This strategy is particularly relevant to most Indian API companies, which currently stand among the top five global manufacturers of active pharmaceutical ingredients. The production of APIs continues to swell with an increasing number of international companies making a beeline to India to meet their supply needs. Bulk drugs produced in India belong to all major therapeutic groups. India ranks 17th in terms of export value of bulk activities and dosage forms. By 2010, the sector is estimated to achieve $22.5 billion in formulation, with bulk drug production expected to touch 5.6 billion. The Indian API manufacturing

Matrix API manufacturing facility in Pashamylaram

industry is currently the third largest in the world and is expected to generate sales of $4.8 billion by 2010 (up from $2 billion in 2005), at an average yearly growth rate of 19.3 per cent. Today, most of them who intend to stay in the race are looking towards America.

Unimark is the perfect example of an API manufacturer wishing to venture into distribution. Parekh is fully aware that the service sector is growing in India: "We have realized that there is a strong potential for this business because right now the trend is to outsource this activity. Particularly when it comes to MNCs, these companies are looking for efficient logistics partners that can handle their entire distribution. Instead of setting up their own distribution departments, they prefer to have someone else doing this job for them so that they can get straight away into business."

Penetration, reach, and inventory management are, for Parekh, the major challenges a company needs to overcome in order to become an efficient partner. "As long as you are able to penetrate the market, to reach the chemist shop, and to manage the inventory, you will add value to your partner. The main reason why Unimark is one of the most competitive companies in the market is because we manufacture all our major products from earth, fire, and water. This way the entire value addition chain is captured in the product and remains in the company. This allows you to become more competitive by sharing this value with your partner."

Unimark has invested 4.5 million dollars in R&D, which is quite rare for a company that is mostly focused on APIs. "We will be investing at least another $10 million in the next couple of years to achieve this. At that point we will have reached an adequate standard that will enable us to start talking about contract research with innovative partners," says Parekh.

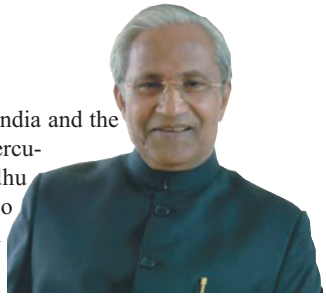
India's greatest success stories started with APIs.

Today, Indian generics and API companies represent about four percent of the world market. This means there is still 96 percent of the market available. "Considering that our closest competition comes from China and that no Chinese company is integrated—they specialize in either APIs or generics, but not both—I believe Indian companies will play a more important role and become more profitable in the future," concludes Parekh.

Lupin: number one for anti-tuberculosis

API is the core business of Lupin. In India, the company has a portfolio of more than 200 formulations in various segments. It is one of the world's largest manufacturers of drugs that combat tuberculosis, bacterial infection, and cardiovascular diseases.

"When I started the company in 1968, I realized that the disease



Dr. Gupta expects Lupin to become a billion dollar company by 2009

that killed the most people in India and the world was—and still is—tuberculosis," says Dr. Desh Bandhu Gupta, Chairman of Lupin. "So we decided to start working in that area and today we are the number one producers of Anti-TB drugs in the world. Furthermore, we are currently working on a new molecule against this disease."

Lupin was the first in India to manufacture Anti-TB APIs. "This earned for us the respect of our peers and we soon went on to become a front runner for the title of world leaders in Anti-TB drug manufacturing," recalls Dr. Gupta.

Lupin's range of formulation is marked by brand leadership across various several segments, for it believes that its branded business possesses significant potential to not just improve patient treatment but also address unmet medical needs.

At the beginning of 2006, Lupin signed a memorandum of understanding with ASPEN for the establishment of a joint venture. Huge product synergies are expected, for Lupin has traditional strengths in Anti-TB formulations and APIs, and ASPEN will bring a range of multi-drug resistant TB (MDR-TB) products to the venture. "We believe there is a large space for extending our cooperation with ASPEN. This first joint venture will serve us to generate the core of the relationship, to better understand each other. We are planning to go further as the potentiality for cooperation is immense," Dr. Gupta explains.

As a part of the global strategy to increase its participation in the high margin / high value advanced markets of US and EU, Lupin over the years created the right infrastructure by upgrading its facilities to globally accredited regulatory standards and invested in R&D to introduce a product pipeline specific to the market requirements. Lupin has entered into an alliance with Watson Pharmaceutical to market its Cefuroxime Axetil tablet in the United States. It has also entered into an agreement with Baxter Healthcare Corporation, by which Baxter will exclusively distribute Lupin's generic version of Ceftriaxone sterile vials for injection in the US post-patent approval.

It's no wonder that by the end of March 2009, Dr. Gupta expects to become a $1 billion dollar company. "I am confident we will achieve this goal," he claims. "In terms of research, we have four molecules under different stages of development. We also have three DDS platform patents. Regarding APIs and dosages, whatever we decide to manufacture we are either number one or number two in the world. We know the job."

Aurobindo Pharmaceutical, one of today's another Indian generic manufacturer, also started as an API manufacturer. In the mid 1990s, the company decided to focus on the regulated markets, which meant entering the generics business. It invested over $350 million, mainly in infrastructure and R&D, to achieve this target. During this period, the company built seven USFDA approved plants, four for APIs and three for formulations.

"Our large modern plants have allowed us to become very strong in the APIs segment," insists K.Nityananda Reddy, Managing Director, of Aurobindo Pharma Ltd "These plants have also boosted our strength in the generics business as we manufacture the APIs that are used in most formulations that we file. We manufacture our own APIs for most of the ANDAs and dossiers that we file in Europe." The company has today a product portfolio of over 180 APIs and 250 formulations. Furthermore, this API strength has helped them to position Aurobindo among the world's top four manufacturers of semi-synthetic Penicillin, Cephalosporin and Anti-Retroviral.

Last year, 80 percent of the company's revenues came from APIs' sales, and 20 percent came from generics. However, according to Reddy , this balance should change, as Aurobindo has lately been very aggressive at filing its products in the United States, Canada, and Europe. "We have also been using these dossiers to file our products in other important markets such as Brazil, Mexico, and South Africa. Subsequently, we expect that in the next three to four years the balance will shift to 35 percent APIs and 65 percent formulations."

LUPIN

Innovation & Inspiration

Our Values :

Superior Performance, Entrepreneurship, Customer Orientation, Working Together, Respect for People, Integrity

LUPIN

LUPIN

Towards the vision of being an **Innovation** led **Transnational Pharmaceutical** Company

Lupin, one of the world's largest manufacturer of drugs to combat tuberculosis, bacterial infections and cardiovascular ailments was founded in 1968 by Chairman Dr. Desh Bandhu Gupta in Mumbai, India, Lupin has a portfolio of 80 products reaching more than 50 countries. Ranked among the top six pharmaceutical companies in India, Lupin is an integrated player with a noteworthy presence in both API and Formulations with a significant presence in US, Europe, CIS countries, Japan, Latin America and China. Through the process of creative transformation Lupin has moved up the value chain from being present in developing markets to advanced markets. Lupin has innovatively moved from process research to cutting edge ANDA, NDDS and NCE focus. Lupin's portfolio of drugs are manufactured in global scale USFDA and UKMCA approved plants which includes Cephalosporins, Anti-TB drugs, ACE inhibitors, Statins, NSAIDS, COX2 inhibitors and herbal-based phytomedicines. Already, a phenomenon in India, Lupin is now poised for recognition as a global provider of remedies.

As a result of these successes, Forbes magazine recently listed Aurobindo on its top 100 best-rising Asian companies. A fair decision, according to Mr. N. Venkat, Senior Vice President :"Aurobindo is a very strong company that is committed to investing in the necessary infrastructure for accomplishing our medium and long-term goals. In the last four years no other Indian player has invested more than $350 million, as Aurobindo did. These four new USFDA approved plants have given a boost to our manufacturing and R&D capabilities, which together with our efficiency at dealing with filings make Aurobindo a very interesting company."

N. Prasad (Left) and Rajiv Malik (Right)

The success of 'Peopleware'

Based in Hyderabad since its creation in 2000, Matrix Laboratories Limited is a public company engaged in the manufacture of APIs and Solid Oral Dosage Forms. Within five years under the present management led by Executive Chairman N. Prasad, Matrix has transformed into one of the fastest growing pharmaceutical companies in India, with a focus on advanced markets, such as the United States and Europe. "While we created global scale manufacturing infrastructure (hardware) and well represented marketing base (software), we attribute our success to Peopleware," explains Prasad. "Being a knowledge-driven company, we strongly believe in human capital. Our progressive HR policy is driven by the philosophy of 3 R: Recognize, Respect and Reward the knowledge."

Matrix has four manufacturing sites for APIs and intermediates in India. Of these, three are located near Hyderabad and one near Visakhapatnam; all are approved by FDA. The combined FDA-approved capacity is one of the largest in India.
Before Reddy acquired Betapharm, Matrix made history last year in the Indian pharmaceutical industry by acquiring Doc Pharma in Belgium. The company continues to look for synergetic alliances and acquisitions, after various alliances with ASPEN, Mchem, and Concord. To its CEO, Rajiv Malik, Matrix's success relies on "exploiting our potential, and partnering with different players at different sides. We never put all our eggs in the same basket. We cooperate with different partners at both ends."

R&D is naturally playing a vital role in the development of this leading pharmaceutical company, which is trying to further sharpen its skills around research. "We have already put decent assets to provide sufficient capacity for the forthcoming patent expiries," says Malik. "We stand out in this area. In today's competitive world, you need some sort of specialization to stand out and survive. Innovation will be the underlying fabric in our business."
Even though formulations account for a significant portion of Unichem's revenues, the company also manufactures APIs. The company has prudently addressed relevant and growing therapeutic areas like gastrointestinal, cardiovasculars, diabetes, psychiatry, neurology, anti-bacterials, anti-infectives, and pain management, among others.

Currently 30 percent of the company's turnover comes from international business operations. Just as its competitors, Unichem is eyeing to penetrate the regulated markets. "When talking about regulated markets, we cannot afford to ignore the USA, as it represents 40 to 45 percent of the world market. Our second focus will be Europe," claims Dr. Prakash Amrut Mody. As far as the United States is concerned, Unichem will be filling its own ANDAs through its wholly owned subsidiary, and intends to exploit this market with its own marketing model. Unichem's ambition is to partner with other companies. "This strategy is not rocket science," Dr. Mody says. "But we can be among the first to spot opportunities, find the right partners and produce our own APIs." By doing this, Unichem expects to be able to obtain better margins than the ones it has in India. "We look for a suitable US acquisition or setting up our own marketing team only when we have a reasonable portfolio of ANDAs marketed in the United States."

The Indian API sector is expected to reach sales of $ 4.8 billion by 2010.

In terms of innovation, Unichem is not looking at new chemical entities but has projects being developed in the biotechnology area. "Hopefully in the future, we will be able to provide a lot of innovation in this area," says Dr. Mody." Unichem would rather take its expertise to foreign markets and partner with other companies in order to expand the reach of the company's products in rest of the world. Its aspiration is to become a $500 million company by 2010— growth it hopes to achieve through the interest in Indian companies and on some acquisitions in the domestic and international stages.

"Unichem believes its growth will be quite substantial," says Dr. Mody. "Organically it would not be possible to secure this kind of growth. We are not involved in contract manufacturing but in the contract research business where the company is concentrated in building some intermediaries for multinationals. Unichem is also looking for generic partners and providers of APIs and finished formulations." ■

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From Copycats to Innovators

"Among the sectors that have experienced the greatest transformation in India, the pharmaceutical industry is perhaps the most significant. India's WTO involvement during the last decade has encouraged our pharmaceutical companies to adopt a strategy of R&D based innovative growth."

Kamal Nath, the Indian Minister of Commerce & Industry, is very clear about a change in the sector, from a constellation of generic companies to an R&D hub. To Dr. R A Mashelkar, the Director General of the Council of Scientific and Industrial research (CSIR), the Indian pharmaceutical sector has indeed responded very well to the challenges of the new product patent regime. "Major pharmaceutical companies had already shifted their focus from imitative to innovative research, including new drug discovery. Ranbaxy, Dr Reddy's Laboratories, Workhardt, Nicholas Piramal, Cipla, and Lupin have created state-of-the-art R&D facilities so as to take the global challenges."

If we look at the Indian scenario, it has 6,000 pharmaceutical companies, but many of these are small and medium sized and can therefore not afford to spend any money on R&D. Thus, while Indian companies spent not even a fraction of a percent on R&D ten years ago, today the largest Indian companies are spending in the region of six to eight percent of their turnover on R&D. (The norm for major MNCs is 12 percent.) They already spend significant amounts in this key area, recognizing that growth will come primarily from their ability to innovate and bring new drugs to market. In 1995, the total R&D spent by the Indian pharmaceutical industry was about $30 million. By 2005, this number had gone up to $333 million.

"This is a significant increase and shows their commitment to move in a new direction," says Dilip Shah, General Secretary of the Indian Pharmaceutical Alliance."I see this trend towards innovation to go further. India will soon emerge as a hub for pharmaceutical R&D and manufacturing," adds Dr. Mashelkar.

Dr. Anji Reddy

Innovative skills

"In 1993, when I was President of the Indian Pharmaceutical Congress in Bangalore, I said to my colleagues, 'This feast will not last forever,'" remembers Dr. Anji Reddy, Chairman of Dr. Reddy's Laboratories. "There will be a patent law at some point. And you should get ready for it, or you will disappear." That is why the company started building its R&D structure as soon as 1993. Dr.Reddy recalls: "Back then, nobody wanted to come to India, so I had to do it by myself." Nowadays, Dr. Reddy's invests 12 percent of its revenues in R&D. "We are taking this step because if we just rely on our capability to produce cheaper products, we will always remain a pygmy in the pharmaceutical world. If you take a look at the statistics, the twenty-fifth research-based pharmaceutical company is still bigger than the number-one generics firm. I have always believed that India has innovative skills, which are second to none in the world," says Dr. Reddy.

The company is mainly into metabolic disorders, such as obesity and cardiovascular diseases. From the start, its main motivation has been to make affordable drugs so that everyone can have access to medicines.Lately, since Dr. Reddy's has entered the American and European markets, the company has also become deeply enthusiastic about finding an answer to unmet medical needs, such as atherosclerosis. Another example that has attracted enthusiasm and controversy is the Polypill (currently in clinical trials), for cardiovascular diseases.

"It is not innovation per se but it is incremental innovation," explains G V Prasad, CEO of Dr. Reddy's Laboratories. "It is also a market focused on innovation in the sense that the Polypill will respond to the needs of the vast majority of cardiovascular patients in a specific market place, the developing world. A company like Dr. Reddy's—with deep skills in active pharmaceutical ingredients (API), in formulation, and in marketing—is combining its expertise in this area to solve a significant problem in the developing world. It is not only a business opportunity; it is a breakthrough to make an impact on society. We are meeting an unmet medical need." To Dr. Reddy, the main advantage that India has to offer in this field is that Indian scientists are "hungry for glory." "They want to show the world what they are capable of doing," he says.

"If we just rely on our capability to produce cheap drugs we will always remain a Pygmy in the pharmaceutical world"

Innovation is also critical to one of the youngest CEO in the world, Malvinder Mohan Singh, CEO of worldwide generic company Ranbaxy. "It is clearly where we are heading. But this is a long-term game. It is not that you discover something today and tomorrow you have the results. We have close to 1,100 people in R&D, 300 of

Malvinder Mohan Singh, CEO & MD, Ranbaxy

which hold PhDs, and we spend a massive amount of money in this area. We spent over a hundred million dollars last year. We are strongly committed to R&D."

Ranbaxy aims to develop a business mix of generics and NCEs. Today, it has a NCE for malaria, which will be starting Phase II clinical trials soon and, if all goes well, should hit the market by 2009 or 2010. "We have a rich pipeline of products in different development stages and have established a research alliance with GSK. We are the only Indian company to have that kind of an alliance. I think that model is very good for us, I am looking at doing more alliances and hopefully in the next twelve months, we might announce something in that area."

Ranbaxy today has direct operations in 49 countries, which probably makes it the most global, if not among the top two, in terms of international spread.

"We do not see competition in terms of Indian companies; to us competition is global," Singh says. "We are not an Indian player. We are a global player based in India. India is just one more of our markets. We sell our products in over 125 countries and have manufacturing facilities in eight countries. Furthermore, 80 percent of our business is international and only 20 percent is domestic. The way in which we operate, our mindset and our multicultural workforce make us a global organization."

The discovery of new molecules

Torrent Pharmaceuticals has been part of the Indian pharmaceutical industry for almost five decades. It was originally conceived as an API and generic pharmaceutical company. It first specialized in anti-rheumatic and CNS drugs. Anticipating the changes following the patent law in 2005, the company set up a state-of-the-art research center in 1996. "The patent law provides opportunities for an R&D intensive company like Torrent to market its own molecules and capitalize on them in the global market," says Sudhir Mehta, Chairman of the Torrent Group. "Currently, we have more than 500 scientists working on drug discovery and development. I believe this is the only R&D center in India capable of conducting studies all the way from Phase I to Phase IV."

This center has not only developed several processes, products, and platforms for the generics business, but has also made excellent progress in developing new molecules. An example of this commitment has been its work on the AGE (Advanced Glycosylation End-products) Breaker compound. Another substantiation of its strong R&D capabilities is its alliance with AstraZeneca to conduct collaborative research for developing novel anti-hypertensive drugs. Currently, the company spends around eight to nine percent of its annual sales on R&D and has seven discovery projects in the pipeline: three in diabetes and related complications, one in cardio-vascular, two in obesity, and one in cerebro-vascular.

"Our growth strategy in the domestic market consists of two key elements," explains Mehta. "Firstly, we plan to record an aggressive growth in the key therapeutic areas in which Torrent is already present, through product and marketing differentiation. Secondly, we will start working in new therapies and molecules through our own research, in-licensing, and acquisitions." Although it is an extremely competitive and price-driven market, Mehta is very optimistic about Torrent's performance in India: "We are expecting to achieve a significant increase in our market share in the next five years by entering new therapeutic areas, launching new products and aggressively promoting our current product portfolio. This should help us position ourselves within the top five companies in the Indian Market."

Glenmark has been experiencing dramatic growth since 1998/1999. This is what gave the 28-year-old company the revenues and cash flow to finance its innovative branch.

"We believe the generics business will become commoditized in the long run, mainly because of the large number of players from India and China that are currently entering into the generics game. So we think it is essential for us to have innovation under our belt. Glenmark's long-term objective is to become an innovative company," says Glenn Saldanha, Managing Director & CEO of Glenmark Pharmaceuticals.

Although the company continues to be strong in the generics and APIs' space, it has, over the last five years, attained a leadership position in the drug discovery area in India. "This is the key change that we have been working for as an organization. A shift from branded generics into innovation," Saldanha explains.

Glenmark's first molecule was a compound for asthma and COPD called Oglemilast. It licensed it to Forest Laboratories in what has been the largest deal of its kind for an Indian company. The company expects to launch this drug globally in 2009. Glenmark also has developed a DPP-IV class molecule for diabetes called GRC8200. This molecule has just completed Phase I and has shown very positive results. Glenmark also is working on a compound for obesity called GR10389, and has three other compounds currently undergoing preclinical trials.

Torrent R&D Facility

Torrent spends up to 9% of its sales revenue in R&D.

"In the long term, the objective is to bring our products to markets other than US, Europe, or Japan," says Saldanha. "So whatever comes out of our NCE pipeline, we look for partners to market it in the regulated markets and we either market it ourselves or keep co-marketing rights with whoever we decide to partner for the rest of the world." ■

Becoming a Global Biotech Powerhouse

"The future of life sciences in India lays with biotechnology, as we have 200 research institutes, a very well trained English-speaking man power, and good biodiversity and a cluster of really good companies." As analyzed by Dr. Swati A. Piramal, Director-Strategic Alliances & Communications of Nicholas Piramal, Indian biotechnology has clearly gained global recognition and is being tracked for emerging investment opportunities. The rapidly disappearing appetite for risk capital in the United States and Europe has led to a sharp decline in the biotechnology sector in these regions, where survival lifelines are being provided by the lower cost research environs of the developing world.

Prashant Tewari

The "biotech queen"

The Economist called her the "biotech queen," Business World said she is "one of the richest self-made women in India," and Nature Biotechnology portrayed her as the most influential person in biotechnology outside of the United States and Europe. The Managing Director of Biocon, Dr Kiran Mazumdar-Shaw pioneered biotechnology in India. "In the future I would like to be known as someone who was able to develop a blockbuster biotech drug with a 'made in India' label for the global market," she says. Biocon's strategy is to focus on this niche market, as 40 percent of drugs in the approval pipeline today come from the biotech segment, and it is estimated that by 2015, 60 percent of drugs will come from this industry. "Biotech offers a lot of opportunities," says Dr. Shaw. "The research engine of the conventional pharmaceutical companies is slowing down, and it is becoming difficult to find drugs for diseases therapies. Therefore, they have taken a different approach to drug discovery; they look at targets and then see how to chemically antagonize them."

The most important milestone so far at Biocon was acquiring Nobex, now its US partner in an insulin program. "We kept them going for two years through an oral insulin program, but it was not enough to keep them going forever," Dr. Shaw recalls. "Consequently, they gave us an opportunity to buy them out. This acquisition demonstrates that Biocon is very focused and committed to innovation for new drug development. We are going to launch our first anti-cancer drug, which we are developing with Cuban technology and that have demonstrated very good clinical data. We are hoping to get it in the Indian market in the next few months. We are also developing an interesting antibody product, which hopefully we can market in India in the next couple of months," she concludes.

A wide range of opportunities

Although biotech is beginning to make a splash in India, there remain a limited number of companies with branded biologics in the works. To Prashant Tewari, Managing Director of USV, his company is indeed one of the few that have biotechnology patents. "We believe that in the area of biosimilars, intellectual property will be critical for penetrating regulated markets," he says. USV's biosimilar projects are focused on the regulated markets. They have therefore been designed bearing in mind intellectual property issues. "At this moment, we are undergoing a transition process that will take us from generics development into biotechnology," Tewari says. "In terms of technology issues, biotechnology is a much more complex area. After seven years of hard work, we have been able to develop this technology in-house. This effort has paid off. At the moment, we have three biosimilar products going into full scale manufacturing."

USV's next step will be to use these same capabilities and all that has been learned from this process to move into innovation. The project it is working on is called pegylation. Protein half-life in the body could thus be extended through pegylation. "I think that all together, we still only dedicate 10 percent of our work to this area," notes Tewari. "However, this will increase as we become more competitive in these capabilities. The proportion of our R&D investment will also increase in this field. Today it is 90:10, but it will become something like 75:25." Most of the technology related to biotechnology has been developed in-house, a difficult task: "As we start transforming USV into an innovator I think technology will be our biggest challenges," concludes Tewari.

Wockhardt decided to venture into the area of biotechnology 15 years ago and considers itself a pioneer. "During the last 15 years, we have developed the capacity to construct genes and to go all the way to large scale manufacturing," says Habil Khorakiwala, Chairman of Wockhardt. "I believe this is still a great opportunity, it was so 15 years ago and it is even more so today. At that time not many visualized that there would be these kinds of opportunities in biotechnology."

Two years ago, Wockhardt inaugurated its biotech park to create a manufacturing base for the worldwide requirements. "Thanks to our biotech park, we have been able to start exporting to some South American, CIS and South East Asian countries," says Khorakiwala.

Lastly, Wockhardt has been doing research on new chemical entities, mainly on anti-infectives, working in different areas and hoping everything goes as expected. "In the medium term, biotechnology will translate into considerable growth for Wockhardt," says Khorakiwala. "New drug discoveries will take more time." ■

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CRAMS: The Gateway to Indian Success

"Apart of the generic market, another avenue for the Indian pharmaceutical industry is Contract Research And Manufacturing Services (CRAMS), mostly for medium size players. In this regard, India's core capabilities, (cost differences and an abundance of "naïve" patients) augur well, as this is what global R&D players are looking for. Overall the contract research market is expected to rise by a CAGR 14 percent, from $12.8 billion in 2004 to approximately $25 billion in 2009.

The Indian pharmaceutical industry is betting big on the growing opportunity in the CRAMS segment. With international competition heightening, pharmaceutical companies worldwide are seeking to reduce production and research costs. Indian companies, with their strong chemical engineering capabilities and low costs, offer these advantages. According to analysts, global pharmaceutical manufacturing was estimated to be at $50 billion in 2004, out of which 30 percent was outsourced. This, along with the contract research segment estimated at about $6 to 10 billion, makes CRAMS a very lucrative opportunity. Also, what makes the case strong for future growth is the fact that the number of players focusing on this opportunity is still small. India has the potential to garner at least 35 to –40 percent global market share in this segment. With foreign companies increasingly leaning towards India, the chances of big growth in the future looks bright.

On the other hand, the pressures on global pharmaceutical companies to outsource are growing for a couple of reasons. One is an ageing population in the West straining healthcare budgets almost everywhere. Most US and European governments are thus looking for cheaper generics and lower cost drugs. Then, with new drugs becoming more difficult to develop, pharmaceutical companies cannot sustain large R&D spending unless new blockbusters are developed cheaper.

"CRAMS is important for the development of our business on two fronts," explains NR Munjal, Managing Director of Ind-Swift Laboratories. "Firstly, it provides our scientists with the required skill sets to go up on the value chain. And secondly, it allows us to finance our investment in R&D and infrastructure." In that regard, the company recently inaugurated an R&D center employing 250 scientists and has also been investing heavily on manufacturing infrastructure. "They will be on the look out for new CRAMS opportunities," explains Munjal. "We expect 20 percent of our revenues to come from CRAMS in the near future. We will be opening a new plant soon which will be entirely dedicated to exports and which will have great potentiality for contract manufacturing." Ind-Swift expects this plant to obtain USFDA approval later this year.

Vimal Kumar, joint MD, Shasun.

Partners for innovators

There has been a spate of tie-ups and acquisitions by companies in the CRAMS segment in India. Another recent example has been Mumbai-based Nicholas Piramal's acquisition of UK's Avecia Pharmaceuticals for £9.5 million. A global custom-manufacturing player, Avecia Pharmaceuticals' focus is on providing custom chemical synthesis and manufacturing services for innovator pharmaceutical and biotechnology companies.

"In the area of contract manufacturing services, our strategy is completely different from our Indian peers," explains Dr. Swati A. Piramal, Director-Strategic Alliances & Communications. "We do not enter the generics market or file ANDAs nor bust anybody's patents. Our approach is to be a partner for innovators." The manufacturing of the company takes place in three locations: Canada, UK and India. This allows the company to manufacture across the whole value chain.

Shasun's increasing focus on CRAMS should stand it in good stead. The famous Ibuprofen manufacturer has been investing in its CRAMS business for some time and has offerings across the value chain. "Since 1999 we have shifted our focus towards contract research and manufacturing services and customized synthesis," notes Vimal Kumar, joint managing director of Shasun Chemicals & Drugs."In that same year, we gave our first steps in collaborative research and development by signing a deal with Austin Chemicals. The close relationship that we have established with this company has allowed us to establish relationships with multinational companies like Eli Lilly."

The company has put in place a multi-product facility for manufacturing and a new R&D facility to capitalize on the CRAMS opportunity. "We expect a 50 percent growth in the CRAMS segment revenues in 2006. The CRAMS division should constitute about 10 percent of the overall business," says Vimal Kumar. "Our philosophy is to enter into partnerships with companies that are looking to outsource manufacturing and R&D. We believe in partnering them rather than competing with them."

Shasun has, in that regard, established strong relationships with several large pharmaceutical companies, such as Eli Lilly, GlaxoSmithKline, and Reliant Pharma. These tie-ups are expected to lead to higher contracts for the CRAMS division. Shasun's earnings are estimated to grow at 13 percent, driven by CRAMS and formulations.

"CRAMS is a long-term story," says Kumar. "Since most of the players in the segment have entered into long-term agreement with their partners abroad, earnings volatility is likely to be less of an issue going forward." ■

"The American dream of Sun Pharma"

Sun Pharma is one of the hottest pharmaceutical companies in the country today. CEO Dilip Shanghvi has been recognized as one of the top 20 richest self-made men in India: "We stand today sixth as per the IMS ranking," he says. "We are very well positioned in the domestic market. Sixty percent of our turnover comes from our business in India and 40 from exports. We have hardly any share of the US market, nor any share in the European or Japanese markets. These markets represent a great opportunity for our growth."

The United States has been one of the company's preferred markets. Sun has acquired four companies there, and recently, the manufacturing facilities of Able. "We wish to use this facility for filing controlled substance products in the US market. Therefore it gives us the ability to introduce a range of products that would otherwise be very difficult to export out of India," explains Shanghvi. And Sun Pharma continues to look for attractive opportunities to acquire businesses in the United States. "We look to license our products through partnerships and market them this way," Shanghvi adds. According to Shanghvi, regulatory procedures, marketing, and distribution infrastructures between the two countries remain quite different. But India is, to him, an excellent field of experimentation before penetrating foreign markets. "Some of the skills or expertise we have in India can be used in these markets. But we have to acquire new sets of skills to successfully penetrate regulated markets. If you want to succeed in the USA, you can't export the Indian model, but rather, adapt to the market you are looking at."