An experiment in globalisation
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For the last two decades Nicholas Piramal, a drugs company based in Mumbai, has made a decent living by buying the rights to medicines developed in the US and Europe and selling them in India.

These days, however, the company has its sights set on much bigger targets. Swati Piramal, the director responsible for research, has given the company a challenge that - if met successfully - would rewrite the rules of the global drugs industry.

"The big pharmaceuticals companies say it costs them at least $800m to develop a new drug," she says. "Well, we can do it for $50m."

The obstacles facing the company are daunting, but Dr Piramal is brimming with confidence. "We are going to develop a cancer drug to prove it," she says. "We are hoping to turn the industry upside down."

With its combination of high-quality scientists and low costs, India has already become a significant player in the software and information technology industries. The streets of Bangalore, the country's IT hub, are lined with gleaming buildings built in the last few years to house companies such as Microsoft, General Electric and Dell.

Inspired by the revolution in IT, several Indian drugs companies have set out an ambitious game plan. By tapping the same low-cost pool of English-speaking scientists, they want pharmaceuticals to become the next phase in the shift of service industries to India.

Their fate over the next decade will be a fascinating experiment into how far globalisation can be pushed. If developing countries can genuinely compete in industries that depend on brainpower, such as pharmaceuticals, it will have profound implications for the corporate world.

The bold talk from India also comes at a time when many executives at large multinational drugs companies are in despair over the sector's future. Over the last decade, they have pumped ever greater sums into drug research, yet the number of medicines produced has not increased. Many admit that the industry faces a crisis in the productivity of its research. They are watching closely to see if India will emerge as a low-cost centre of medical research.

Indian success in pharmaceuticals would also raise political hackles in the US and could become more controversial than IT outsourcing has been. For many politicians in the US, it might be acceptable under the logic of globalisation that some manufacturing jobs shift to Asia. But by the same logic the invention of medicines such as cancer drugs - the ultimate value-added, capital-intensive economic activity - is supposed to take place in developed countries.

Indian has long boasted an army of talented chemists but for the last two decades they have been mostly focused on finding ways to copy other companies' drugs. Under a patent law dating from 1970 Indian companies have been allowed to sell versions of prescription drugs as long as they used a different manufacturing process.

That is all about to change, however. From the beginning of 2005, drug patents will apply in India as part of the World Trade Organisation's intellectual property rules. As a result Indian companies will no longer be able to rely on their lucrative domestic market. The search for new business models is being driven by necessity.

For a handful of Indian companies - including Nicholas Piramal, Ranbaxy and Dr Reddy's - the response has been to invest in innovation. They plan to harness skills in medicinal chemistry to shift from re-engineering other people's drugs to developing their own.
"India is moving centre-stage in the drugs industry," says Brian Tempest, chief executive of Ranbaxy, the Delhi-based company, which aims to have 40 per cent of its revenues from innovative products by 2012. "It will be like the scampering mammals taking over from the dinosaurs."

Cost is the key competitive advantage. Just as in the IT industry, India has huge numbers of trained scientists prepared to work at a fraction of European or US salaries. Indian companies estimate the cost of hiring a researcher is between one-third and one-fifth of the US rate.

Moreover, the Indians believe they can conduct clinical trials much more cheaply. Somesh Sharma, chief scientific officer at Nicholas Piramal, says that India’s huge population makes it much easier to find patients to take part in trials. When the company participated in the trial of a cancer drug developed by a US group, it finished its part four years ahead of its partner.

"It was an important experiment that proved we could do it," he says.

The drugs companies are also beginning to tap the huge diaspora of Indian scientists working in the US. By some estimates, 20 per cent of all the researchers working in the biotechnology industry in the San Francisco area are of Indian origin. The Indian companies cannot afford to lure back too many expatriates as they would soon lose their cost advantage. But by recruiting a few experienced executives they can transfer industry skills and standards to local scientists.

"There are lots of people who want to come back," says Kasim Mookhtiar, vice-president of new drug discovery at Ranbaxy. "We are now in a position to provide them with a career of their choice."

Dr Mookhtiar, who used to run a research department at Bristol-Myers Squibb in Pennsylvania, also believes that this brain-drain of Indians is the most effective argument against political criticism in the US. "When I graduated from the Indian Institute of Technology in Bombay, from my class of 160 people, 120 went to the US," he says. "Indians have made a huge contribution to the US. It cuts both ways."

Yet despite the verve and optimism, the obstacles facing the Indian companies are immense. Pharmaceuticals executives estimate that only one in 10 drugs that enters clinical trials actually makes it to market. Over the last two decades, hundreds of biotechnology companies have been set up in the US and Europe staffed by well-trained scientists. Only a handful have actually managed to develop a drug.

The large pharmaceuticals companies manage this risk by conducting trials in dozens of different drugs, which they hope increases their chances of a few successes. The odds, however, are stacked heavily against smaller companies.

Dr Reddy’s is a good example. The Hyderabad-based company was the first in India to try to build its own research operation a decade ago. It did have one drug for diabetes in late-stage clinical trials, but that failed 18 months ago. No Indian company has more than three molecules in clinical trials.

Ranbaxy’s attempts to lure high-profile Indians from the US have not always gone smoothly. Rashmi Barbhaiya, a former Bristol-Myers Squibb scientist hired to run its research department, left earlier this year after falling out with the senior management. The company has also opened a laboratory in the US, prompting rivals to claim that it could not find the necessary skills in India.

While India has great strengths in chemistry, some executives say it is harder to find people trained in molecular biology. Researchers complain about the bureaucracy; until recently, they say, it was difficult to get regulatory approval for animal experiments.

Moreover, drug research does not depend solely on talented scientists. As more has been discovered about the links between genes and disease, research has come to rely heavily on expensive equipment such as gene sequencers. The big increase in the cost of research in the US and Europe has partly been the result of these investments.

Despite their big cost advantages, the Indian companies do not have huge resources to spend heavily on research. While western companies spend more than 15 per cent of their huge revenues on research and
development, the top Indian companies spend around 5 per cent. Ranbaxy has a research budget of $60m, Dr Reddy's closer to $40m. The entire revenue of the Indian drugs industry is less than the $7bn a year Pfizer alone spends on research.

"Are you really trying to tell me that the entire global industry is putting down its money badly?" asks Ranjit Shahani, managing director of Novartis in India. "To go from copying straight to innovation is some leap."

There is a chance that one of the Indian companies could make it with a successful drug. As Indian entrepreneurs are quick to point out, many of the big companies in the industry today were transformed by one drug - for instance Glaxo, with its ulcer pill Zantac. But it is a long shot. The likelihood is that they will not turn themselves into research-based companies in one swoop.

As a result, most have a "plan B". Rather than try to jump straight up the value chain from selling generics to developing their own drugs, the Indian companies are developing less ambitious strategies. There is a number of ways the companies can move into more value-added areas and acquire skills without betting everything on one or two projects.

Generics are still part of that strategy. With prospects for the Indian market weak in the long term, a number of Indian companies are pushing into international generics markets, where they can take advantage of their low-cost manufacturing. They are attractive businesses in their own right, but also good ways of funding research.

Producing generic versions of biotechnology drugs, which regulators are expected to allow soon, could also be an interesting market. Indian companies such as Biocon in Bangalore, for instance, have developed the ability to manufacture these drugs, which are much more complicated than pills, and have lower labour and land costs than most potential rivals.

Indian companies are also focusing on lower-risk types of research that play to their strengths in chemistry, such as devising new ways of delivering established drugs. Ranbaxy is already receiving royalties from Bayer of Germany after developing a once-a-day version of Cipro, its antibiotic.

Dr Reddy's tried to use these skills to challenge to Pfizer's Norvasc, a $4bn-a-year blood pressure treatment. The company developed a version of the same drug that used a different salt in the formulation, hoping that this would allow it to evade Pfizer's patents. An initial court ruling went in its favour, but Pfizer won the appeal.

The company is now taking a different tack, acquiring a portfolio of established dermatology products that it hopes it can improve using its chemistry skills.

These approaches are less glamorous but lower-risk than innovating new molecules and can help build up expertise in the development process.

The other strategy being adopted by Indian companies is not to compete head-on with the US and European industry but to collaborate. By partnering with multinationals on research projects, Indian companies can devolve some of the heavy development costs as well as learn more about how to manage research projects.

GV Prasad, chief executive of Dr Reddy's, says the company will not conduct late-stage clinical trials itself because the costs are too high. Its diabetes molecule in phase II trials has been licensed to Novo Nordisk, the Danish company.

Ranbaxy has entered into a different type of alliance with GlaxoSmithKline, the UK-based multinational, which allows it to benefit from GSK's extensive research infrastructure. GSK has invested billions of dollars in an early-stage discovery process that produces hundreds of possible ideas for drugs every year. Ranbaxy will get access to some of those leads and, if they prove viable in smaller trials, GSK will conduct the late-stage trials. Ranbaxy would then get a royalty on sales.
The multinationals are not talking about considerable outsourcing of drug research to India in the near future, but such alliances give them a window to view India's progress.

For all the potential growth that they predict, however, India's pharmaceuticals entrepreneurs are in a hurry. Like many other industries in India, they feel the hot breath of Chinese competition on their necks.

"We have about 10 years to make this transition," says Dr Sharma at Nicholas Piramal. "If we do not make it by then, we shall be overtaken by China."

**IT EXPERIENCE HOLDS LESSONS FOR SECTOR**

Many in India believe the country's drugs companies stand at the cusp of rapid growth - but for reasons that differ from those that transformed its information-technology industry.

The key difference will result from a robust patent regime that will be implemented next year. The law will apply intellectual property rules, protecting companies' drug discoveries, thereby encouraging domestic and foreign companies to invest in research. By contrast, the IT industry's explosive growth in India happened without regulation.

If the law is effectively enforced, Indian - and foreign - drugs companies could be able to climb the "value chain" far earlier than had been the case for their IT cousins.

Another difference is the gap in human resources. India's pharmaceuticals sector needs, but appears to lack, the mature biomedical community that commercial research requires.

"The academic contribution is particularly crucial in drugs innovation because so much flowers from researchers who can nurture drug discovery. But India's university-based research departments are not market driven," says Nermeen Varawalla, vice-president at PRA International, a US clinical trials company set to open a testing centre in Mumbai. Yet, Dr Varawalla says, the best pharma companies are still dependent on a global network of Indian scientists.

Nevertheless, Indian pharmaceuticals companies can learn much from the experience of their IT cousins. First, India's IT companies jumped into low-end and low-value services, while pharmaceuticals companies must "fight commoditisation of their services", says Ferzaan Engineer, chief executive of the Indian arm of Quintiles, the US clinical trials group. "We've got abundant home-grown chemistry skills and a mature IT industry to offer data-mining services based on, say, cardiovascular monitoring."

One sign of high value services in pharmaceuticals is the emergence of back-office clinical trials facilities. These offshore outsourcing services are far removed from the less complex tele-sales that have made their IT counterpart the fastest expanding segment in technology services.

Second, big Indian pharmaceuticals companies have responded to the patent law, not only by declaring their research and development ambitions, but also by installing the technology and plant that have met US regulatory requirements. That strengthens their hand in global competition, making them stronger than most of the early IT service companies.

Third, huge R&D costs have led Indian companies to collaborate, not only with global industry leaders, but also with other Indian companies and across sectors. Raghunath Anant Mashelkar, the government's chief scientific adviser, cites an alliance between 18 public-sector research bodies and Tata Consultancy Services - a private company - that yielded software for bioinformatics at a fraction of the usual cost.

Fourth, Sunil Mehta, vice-president of Nasscom, the Indian IT trade lobby group, says Indian pharmaceuticals companies "should follow our lead and speak in the language of global customers". But perhaps IT's biggest lesson for pharmaceuticals is showing the necessity a to create network of advisers, investors and lobby groups. "That will position Indian pharma for the huge healthcare opportunity in US and Europe, where high costs are forcing suppliers to turn to India."