Where will Indian drug companies be in five years? Everywhere – if they innovate

This has been a busy winter for India's drug companies. Ranbaxy Laboratories Limited, the subcontinent's largest pharmaceutical firm with $1.17 billion in annual revenues in 2005, has been in the news for challenging global companies' patents on blockbuster drugs such as Pfizer Inc.'s cholesterol-lowering Lipitor and AstraZeneca's stomach ulcer drug Nexium. Although a U.S. district court ruled in favor of Pfizer last December, Ranbaxy appealed the decision.

Also last December, Nicholas Piramal India Ltd. announced it had signed a long-term manufacturing-related research and development services agreement with Pfizer International. And in February, Dr. Reddy's Laboratories, another leading Indian drug maker, acquired betapharm Arzneimittel, the fourth largest generic drug maker in Germany, for $570 million. Chairman Anji Reddy said the acquisition would help Dr. Reddy's Laboratories become a billion-dollar company by March of 2008.

As these moves show, India's pharmaceutical industry has arrived at a cross roads. Well-positioned compared with China as an arena for drug development and reliable, low cost manufacturing, India's pharma capabilities are strong and growing fast. Some large Indian players have already moved into global markets, and represent an emerging force as developers of generics.

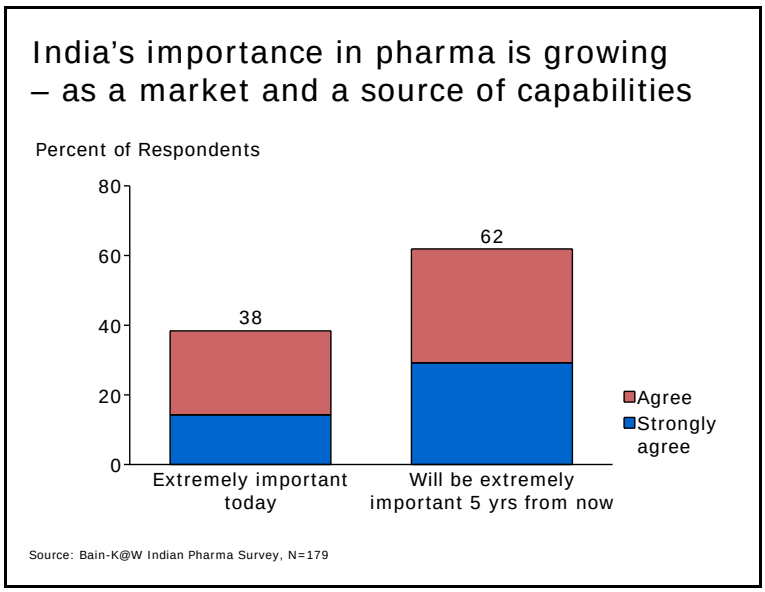
The involvement of global pharma companies as partners will speed the emergence of big Indian pharma companies in global markets. And the pace of investments and partnerships is picking up. Global pharma companies are attracted to India's capabilities, as well as its large and growing market. But alongside opportunity, India also represents threat to global pharma. For one, the largest Indian firms have excelled at reverse engineering and legal tactics to challenge the primacy of branded blockbuster drugs with low-cost generics. For another, despite moves by the Indian government last year to bring its laws into conformity with the World Trade Organization, concerns persist among global drugmakers over the lack of IP protection, lax restrictions on parallel trade and regulatory uncertainty. Moreover, from the outside in, global pharma companies don't see innovation as a key asset of Indian pharmacos yet.

The savviest global companies are partnering with Indian firms for cost-effective, highly skilled activities such as large-scale clinical trials and production of active pharmaceutical ingredients, with drug discovery and early development likely to follow. To reach India's vast market, global players are creating partnerships to provide affordable medicines, in some cases acquiring older products that are off patent.

For Indian companies, focus has been the key to growth. With pressure growing in commodity generics markets, the most successful Indian pharma firms have paid close attention to operating efficiency and cost structure. The companies that achieve full potential have opportunities to "double down" in a few key areas, by improving their penetration of vital markets in North America and Europe, for instance, and focusing on the most promising therapeutic and diagnostic areas.

Bain-K@W Survey

The scope of the opportunity is captured in a survey of 179 global pharmaceutical executives, conducted by Bain & Company and Knowledge@Wharton, with help from the Organisation of Pharmaceutical Producers of India (OPPI). With 45% of respondents from companies with headquarters in North America, the survey shows that global pharmaceutical executives believe India will figure prominently in their business five years from now. While 38% of respondents feel doing business in India is extremely important today, 62% expect it to be five years from now.



Eight out of ten respondents see India as an opportunity -- or both as a threat and an opportunity -- and they expect to see India become more of a potential market during the next five years. The survey also found that 35% of the respondents believe India is already an attractive market for products, while 58% maintain it will become one in the future. Also, six out of 10 respondents believe that Indian pharma firms will expand during the next five years, by taking on more risks, having greater product depth and developing substantially increased scale and vastly expanded expertise.

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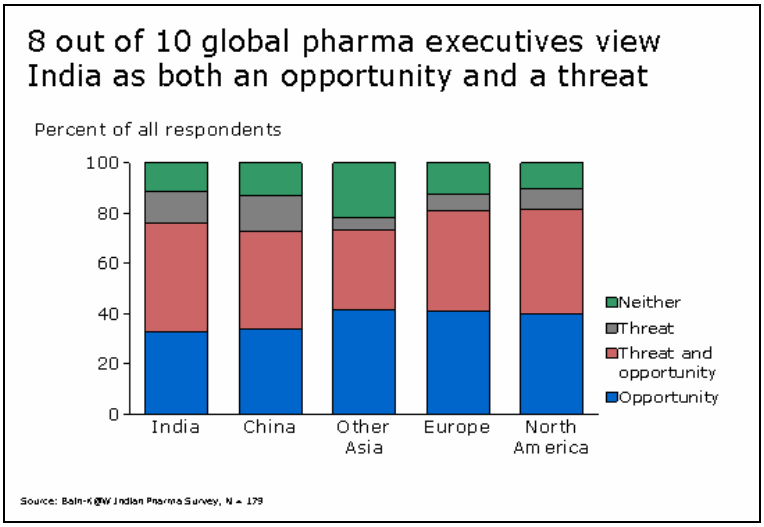


In the next five years, then, will India's pharma companies pursue a course of closer cooperation, or sharper competition with global pharma firms? "The answer is both," says Ashish Singh, managing director of Bain & Company India Pvt. Ltd. "But generics will continue to be a strong driving force for the Indian pharma industry, even as it brings them into direct competition with global players in the major markets of North America, Europe and Japan."

Singh sees a rapidly growing awareness of the Indian market both as a commercial market and a source of capability. Even three years ago, that was not the case, he adds. The general trend toward price consciousness in the developed markets is one important factor in the rising prospects of India's pharmaceutical sector, he believes. Patients, physicians and healthcare payers are increasingly willing to consider generics as a lower-cost alternative to branded medicines, says Singh. Equally important, he adds, big pharma companies recognize the need to look outside their traditional business models for new capabilities, even in areas that are strategic such as drug development and production. Pfizer's deal with Nicholas Piramal, for instance, would have the Indian health care and pharmaceutical company providing process development and scale-up services to Pfizer's animal health division.

As a market, India also holds appeal to global pharma companies, particularly as they confront slowing growth and pricing constraints in maturing markets of North America, Europe and Japan. Of course, the increasing visibility of companies like Ranbaxy has also raised awareness of Indian pharma capabilities – even though the company's tactics are regarded as a direct challenge to some leading global brands.

With low-cost manufacturing and abundant scientific talent as historical strengths, and a lack of strong patent laws and bureaucracy as the legacy of a developing nation, India was traditionally viewed by global drug firms as a base for manufacturing and a vast commercial market rather than as a center for research and development and drug discovery. Indian companies had the reputation of being copycats, which, while not a very flattering label, enabled them to supply the domestic market as well as other low-income countries with inexpensive drugs that were copied from innovator companies. Indian companies could do that because they had to observe foreign patents on the manufacturing process, but not on the

final pharmaceutical products. That allowed them to alter the manufacturing process and produce generic versions of foreign branded drugs even while they were under patent.

Changes on the Horizon

The landscape of the pharmaceutical industry in India saw a major change early last year, however, when the country amended its Patent Act to include drug patents, and not just the manufacturing process. The amendment could be one reason that many observers expect Indian companies to become more active global players in the next five years, according to Ranjit Shahani, vice chairman and managing director, Novartis India Ltd., and president of OPPI.

The amendment, which brings Indian laws in line with World Trade Organization requirements, means that big generic makers, such as Ranbaxy or Cipla Ltd., as well as smaller companies will no longer be able to make inexpensive copies of foreign drugs patented after 1995. At the same time, the new laws allow global companies to set up R&D facilities in India and take advantage of its scientific talent and low costs without the fear of being under-priced before the expiration of patents**.**

Shahani says global drug companies face a lot of pressure to reduce costs and speed up development. According to Bain research, it costs drug companies nearly $1.7 billion to bring a new drug to market. Shahani believes this makes low-cost countries with a large pool of scientific talent attractive to the pharma industry. Moreover, global companies can take advantage of the time difference and follow the sun, so to speak, speeding up the development process. So launching a product two years or more in advance could mean big money, he adds.

Sandoz, the generic arm of Swiss drug maker Novartis AG, is well-positioned to take advantage of the new patent laws with an over-the-counter research facility in Thane, near Mumbai. Shahani expects other global companies to follow suit. The size of the Indian domestic market is more than $7 billion in sales and the industry exports drugs worth some $4 billion a year, he points out. India has emerged as a reliable source of quality medicine at affordable prices, Shahani adds.

The Quest for the Global Generic Market

While the new patent laws may attract global drug firms to India, its own firms' leaders have larger global ambitions, especially in the rapidly growing market for generics.

Ranbaxy, for instance, entered the U.S. market in the mid-1990s, and now sells more than 100 products. Its strategy has been to challenge patents of innovator drugs in foreign courts. Even if it ends up losing the challenge, it has the opportunity to be the only generic manufacturer for six months after the patent expires. Ranbaxy has 19 patent challenges, including Lipitor, filed against U.S. companies, which, if successful, will bring in $2.3 billion in revenues, according to a spokeswoman in its Princeton, N.J., office. Although the United States District Court for the District of Delaware ruled in favor of Pfizer, upholding its patent rights on active ingredients of Lipitor last December, Ranbaxy has appealed the decision.

Under U.S. Food & Drug Administration regulations, the first company to file a challenge on a patent gets a six-month exclusivity window, during which time the generic's price can be as high as 80% of the original drug's, Bain's Singh points out. Thus, although a company like Ranbaxy can spend up to $13 million on a single patent challenge, it could potentially make a profit of at least $2 billion if that challenge helps it obtain a six-month window on a blockbuster drug such as Lipitor, which has annual sales of some $10 billion, he adds. "That is a huge return on investment." Prices tend to drop rapidly after the first six months as more and more competitors enter, and could fall off to about 15% to 20% of the original price. That results in many companies exiting the market after a while, and the prices settle at a slightly higher level, Singh notes.

In other words, the generic drugs business is cyclical, which is why companies like Ranbaxy need to have several patent challenges filed at one time to be able to beat the cycle of low prices. Ranbaxy reported recently that its earnings took a hit in 2005, with its U.S. revenues dropping 22%, to $332 million, mainly due to erosion in U.S. generic prices. "The only way to beat the cyclicality is to have more than one six-month window in a year," says Singh. But patent challenges often require years of legal maneuvers, and such challenges have been issued against drugs all the way into 2013, he adds. This method of entering the U.S. market "favors big companies, such as Ranbaxy, since they need financial depth to file several patent challenges at a time."

Another way for Indian companies to enter the generic market is by filing Abbreviated New Drug Applications (ANDAs) with the FDA. These applications allow companies to sell drugs that are already off patent and on the generic market. During the past year, Ranbaxy has filed 26 ANDAs with the FDA, according to its spokeswoman. Shahani of OPPI sees the global generic market as a huge opportunity for Indian companies. "Almost $60 billion worth of drugs will lose their patents in the next five years, and India has a significant opportunity to get a share of that pie," he says.

Even so, the ride is hardly smooth. Patricia M. Danzon, a health care systems professor at Wharton, explains that while the "U.S. generic market is huge, some very strong players already are in the market. And the successful players seem to succeed by having a broad line of offerings." The supply-chain dynamics of the generic drugs industry call for strong relationships with pharmacies and large wholesalers who are the main customers. These customers are powerful and prefer to deal with only a few suppliers for all their generic drugs, Danzon says, which makes it difficult for companies to enter the market. Indian companies do not have any unique strength in this market that gives them a leg up over the competition, she adds.

Singh, however, points out that companies like Ranbaxy can be counted among the large generic players. Not only do they have a broad portfolio of products, they also have strong relationships with their customers, he says.

For instance, Ranbaxy Pharmaceuticals Inc., a U.S.-based subsidiary of Ranbaxy, won the Supplier Award for outstanding performance in the first quarter 2005 from the world's largest retailer, Wal-Mart Stores Inc. By 2007, Ranbaxy hopes its U.S. division will bring in 50% of the corporation's revenues, up from the current 36%. This might seem an aggressive goal, but

it is consistent with recent performance: Ranbaxy's U.S. sales increased nearly 10-fold between 1999 and 2003, going from $42 million to $412 million.

New Paths to Profits

Singh believes that profitability in the generic drugs market will diminish over time. Not only are more entrants vying for the business, but the innovator companies have started learning how to hold on to their drugs after patents expire. One tactic is for the patent holder on a branded drug to authorize a generic drug company that lacks first-to-file exclusivity to manufacture the drug for six months after the patent expires, and split the profits. "At a minimum now there are two players in that six-month window, and there could be three or four. That is killing the profitability of that opportunity."

Indian drug firms that pursue a strategy of challenging patents are less likely to be tapped as authorized generic makers, Singh predicts, and Shahani agrees. "The whole idea (of authorizing a generic drug maker) is to block the Indian companies from coming in," Shahani adds. Danzon notes that the authorized generics market still represents a relatively small part of the overall generics industry, and it is unclear if Indian companies have any special advantage there. But that may be changing. In February, U.S. drug maker Merck & Co. Inc. authorized Dr. Reddy's to sell generic versions of its cholesterol-lowering drug Zocor and prostate formula Proscar, both of which are going off patent this year, provided another generic maker gets the six-month exclusivity.

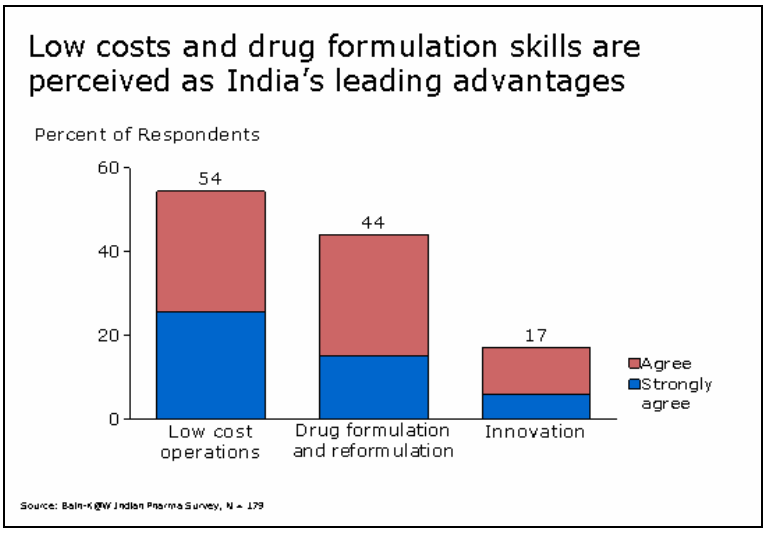
In addition to trying to become authorized generics companies, Indian drug makers could enter niche markets, such as specialty drugs that are hard to manufacture, says Singh. Such drugs do not attract many competitors and thus the pricing is generally higher. Last August, for instance, Aurobindo Pharma Ltd., an Indian firm, won tentative approval from the FDA for purchase and use outside the U.S. for zidovudine, a drug used to treat HIV-1 infection under the President's Emergency Plan for AIDS Relief.

Challenges Ahead

The new patent laws also mean that global pharmaceutical companies, which in the past limited their activities to manufacturing or joint-ventures in India, will now be able to invest more in research and development facilities for new drug discovery. A number of global players, including GlaxoSmithKline, Merck, Novartis, AstraZeneca and Pfizer, have a significant presence in India today. Shahani points out that India already has the highest number of U.S. FDA-approved facilities (84) outside the U.S. "The FDA should have a permanent office in India," he says, only partly in jest.

But other challenges lie ahead. While tighter patent laws and global market conditions open the doors for Indian drug companies to become more active players on the global stage, the Bain-Knowledge@Wharton survey also reveals growing concerns over these developments. More than half the survey respondents say they are concerned with the lack of intellectual property protection in India. Although the new patent laws meet WTO requirements, doubts linger over whether the laws will be enforced. Many also expressed concern about lack of control over parallel trade as well as regulatory uncertainty.

More importantly, only 17% of the respondents believe that innovation is a key asset of Indian drug companies. With laws changing in their home market and the global generic business becoming tougher, Indian companies will have to become more innovative. "For 35 years, Indian companies were doing reverse engineering, but in terms of drug discovery, nothing happened," says Shahani. Now many Indian companies have local research centers, but that is inadequate, at least in the short run, because drug research and discovery have a high failure rate.



Indian companies will have to get creative if they want to move away from the generic business, says Singh. Biogenerics — generic versions of biological products — could be an attractive market. But Singh notes that it requires heavy investment and entirely new capabilities in manufacturing, regulatory expertise and distribution. Similarly, Singh believes that drug discovery and development, another path that some Indian pharma firms are pursuing, leads them away from their business strengths and advantages.

The most effective course of action, Singh suggests, is for Indian companies to focus first on achieving the full potential of their core business. That requires increasing their operating efficiency, and paying particular attention to improving cost structure. Second, says Singh, Indian pharma companies have an opportunity to "double down" in a few key areas, by improving their penetration of vital markets in North America and Europe, for instance, and focusing on the most promising therapeutic and diagnostic areas. Finally, Indian companies should pick their spots to expand. Specialty and branded generics, for example, are an area where several Indian companies have opportunities to lead. But Singh believes they will need to move quickly to acquire the right targets before the next wave of consolidation occurs.

Some seem to be on that path already. While Dr. Reddy's Laboratories chose to become an authorized generic maker and an acquirer, Ranbaxy is working on specialty products and new drug delivery systems, which it said would make up a significant portion of its expected $5 billion revenue in 2012. Nicholas Piramal is focusing on contract manufacturing.

These companies may be small by global standards – contrast, for instance, Ranbaxy's $1.17 billion revenues in 2005 with Pfizer's $51.3 billion in the same year – but their ambitions are not. Their expansion efforts not only showcase the readiness of the top tier of Indian pharmaceuticals to become global players, but they also point to a maturing of the Indian drug market, where competition and new patent laws are forcing drug companies to either bulk up their presence in other markets or innovate. It's strong medicine, but if Indian drug companies want to expand their global reach, they will have little choice but to take it.