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India Expands Role as Drug Producer

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HALOL, India — Below an ancient hilltop temple to Kali, the Hindu goddess associated with destruction and change, Sun Pharmaceutical Industries churns out generic versions of cancer drugs and epilepsy medications bound for the United States.

Business is so brisk that Sun, with revenue of 41 billion rupees (\$880 million) last year, predicts sales will grow 20 percent this year and is expanding its Halol factory.

“This site specializes in making difficult things,” Sampad Bhattacharya, Sun’s vice president in charge of operations, said during a recent factory tour. The blue and gray concrete building, which will be nearly 800,000 square feet after the expansion, would not look out of place in the pharmaceutical manufacturing centers of New Jersey, except for the herds of cattle and buffalo wandering nearby.

India’s drug industry — on track to grow about 13 percent this year, to just over \$24 billion — was once notorious for making cheap knockoffs of Western medicines and selling them in developing countries. But India, seasoned in the basics of medicine making, is now starting to take on a more mainstream role in the global drug industry, as a result of recent strengthening of patent law here and cost pressures on name-brand drug makers in the West.

And while the Indian industry has had quality-control problems, it nonetheless benefits from growing wariness about the reliability of ingredients from that other historically low-cost drug provider — China. The United States is India’s top export customer for drugs.

India is becoming a “base for manufacturing for the global market,” said Ajay G. Piramal, the chairman of Piramal Healthcare, a drug maker based in Mumbai. Eventually, in Mr. Piramal’s perhaps overly optimistic forecast, only the very first and very last steps of the business — molecular drug discovery and marketing — will be run by the West’s global drug giants.

Those companies “don’t create much value” in the steps in between, he said.

It is not only Indian executives, though, who are bullish about the pharmaceuticals industry here. Analysts, research groups and consultants have been making similar predictions in recent months.

Big pharmaceutical companies have come calling, too. This year, Mr. Piramal sold his generic drug business to Abbott Laboratories for \$3.7 billion, the latest in a string of takeovers and joint ventures here. Daiichi Sankyo of Japan helped kick off the foreign drug push into India in 2008 by buying a stake in

Ranbaxy Laboratories, this country's biggest drug maker. Last year, among other deals, GlaxoSmithKline formed a partnership with Dr. Reddy's Laboratories; Pfizer tied up with Claris Lifesciences; Sanofi-Aventis took control of Shantha Biotechnics, and Bristol-Myers Squibb opened a research center in India with Biocon.

"There is a lot of good talent at a much lower price in India," said Jim Worrell, the chief executive of Pharma Services Network, a Charlotte, N.C.-based consulting firm that is organizing tours of Indian factories for Western pharmaceutical executives who are considering outsourcing some of their business. "What I see happening now is manufacturing and even packaging and even formulation are moving to India," Mr. Worrell said.

The shift to pharmaceuticals is part of a subtle, broader shift in the Indian economy. Moving beyond less sophisticated, outsourced services like telephone call centers, India has been advancing up the business value chain, particularly in law and medical diagnostics. Now it is showing a flair for manufacturing, particularly in goods demanding high-skill production and superlow prices.

Until recently, pharmaceuticals has been "an incredibly arrogant industry that has never outsourced," said Sujay Shetty, an associate director with PricewaterhouseCoopers in Mumbai. But over the next several years, he predicts, "everything in the value chain will move to different parts of the world that are cheaper," with India a major beneficiary.

The next opportunities for India could come at the more sophisticated end of the drug making spectrum, including research and development for the world's drug giants and even development of proprietary medicines.

"We can crack the problem of patented drug discovery in India at a much lower cost" than in the West, predicted Mr. Piramal, who held onto his research and development operation, Piramal Lifesciences Limited, when he sold the rest of his company to Abbott.

At Piramal's main laboratory in north Mumbai, about 300 scientists are researching new drugs aimed at inflammation, metabolic disorders and cancer. Mainly because of lower wages, if it costs big pharmaceutical companies "\$1 billion to \$1.5 billion to discover a new drug, we can do it in a tenth of the cost," Mr. Piramal predicts.

G. V. Prasad, chief executive of Dr. Reddy's Laboratories, said that Indian drug makers had the "ability to handle product development on a massive scale at a low cost." Dr. Reddy's original diabetes drug has completed Phase 3 clinical trials — the last step before seeking Food and Drug Administration approval — the farthest of any of its peers.

Meanwhile, at Sun's stucco and glass laboratory in Gujarat, surrounded by white, pink and yellow bougainvillea, 650 scientists, backed by tons of expensive machinery and 10,000 animals in cages, are at work breaking down drugs with the aim of rebuilding them in cheaper ways with fewer side effects.

Revolutionary science is not only about developing a brand-new product, said T. Rajamannar, executive vice president of Sun Pharma Advanced Research. It also means learning how to make an existing drug "very efficiently," he said.

For all the potential, though, India's drug industry has a long way to go to fulfill its promise. India exported about 384 billion rupees (\$8.3 billion) in drugs and services for the pharmaceutical industry in the 2008-9 fiscal year, according to government figures, up 25 percent from the year before. Recent growth, though, has been shadowed by quality problems. The F.D.A. cited Ranbaxy for manufacturing violations several times in recent years, and in February ordered a review of the company's

global manufacturing operations.

In May, Sanofi-Aventis recalled vaccines made by Shantha Biotechnics that were distributed to the World Health Organization after users complained about white sediment in the vials. In June, after floating matter was found in some plastic IV bags, Pfizer recalled injectible drugs made by Claris Lifesciences and sold in the United States.

Intellectual property is also an open question. Trying to change its outlaw image as a maker of illegal knock-offs, India toughened its patent laws in 2005. But dozens of intellectual property suits are still being fought between Indian and foreign firms in courts around the world. And big pharmaceutical companies still find securing protection of their intellectual property in India difficult.

Meanwhile, outright counterfeit drug making remains rampant in India, executives and analysts here say. A study this year of pharmaceuticals from Indian wholesalers found that 3.6 percent of the “drugs” had no active ingredients whatsoever.

All of which is why some drug executives in the United States say that their Indian peers may be too optimistic about their industry’s prospects.

“Cost is one issue, and yes it is important, but there are two other critical factors: intellectual property and quality and safety issues,” said Panos Kalaritis, the chief operating officer of Irix Pharmaceuticals, a Florence, S.C., contract research and manufacturing company, which competes with Indian laboratories and factories.

The F.D.A., in response to India’s growing influence, has opened two offices in this country — in Delhi in early 2009 and another in Mumbai in June of last year. When fully staffed, the offices will have between them a dozen full-time employees, including inspectors and technical specialists, which is comparable to the F.D.A.’s presence in China.

Among other measures, the Indian offices will enable the F.D.A. to “verify that important products and the way they are manufactured meet U.S. health and safety requirements,” an agency spokeswoman said in an e-mail message.

While China is the undisputed low-cost maker of a multitude of consumer goods, India may have a rare edge in the drug industry. India’s long tradition of generics has fostered a robust educational system here for pharmaceutical scientists, as well as longer experience dealing with Western regulators.

The F.D.A. has issued about 900 approvals to plants in India to import drugs or raw materials for the industry to the United States, the vast majority in recent years, compared with more than 300 such approvals for China.

Indian companies have “a lot to offer and the cost advantage is huge,” said Swetha Shantikumar, a research analyst in Chennai with Frost & Sullivan, who predicted more buyouts of Indian firms by global giants in the near future. Chinese firms “don’t have the technical capacity to produce sophisticated drugs,” said Ms. Shantikumar.

“If you want to make simpler drugs like aspirin,” she said, “you manufacture them in China.”