BUSINESS

Reinventing an industry

Two years after a radical change that brought India’s patent laws into line with international trading rules, the country’s drug makers are taking a new direction. Apoorva Mandavilli reports.

Kiran Mazumdar-Shaw is India’s uncrowned queen of biotechnology. She started her company, Biocon, in a garage in 1978 with just Rs10,000 (US$225) in working capital and has built it into the country’s largest biotech company, with 1,800 employees and revenues last year of $180 million.

Said to be the richest woman in India, Mazumdar-Shaw was in the spotlight last September when her Bangalore-based company launched the first new drug to be developed, tested and taken through approval by an Indian company. The drug, BIOMAb-EGFR, is a monoclonal antibody for treating head and neck cancers.

This could be the harbinger of a brighter and more innovative future for India’s drug industry, which until recently relied on supplying cheap ‘generic’ copies of drugs — many of which were still under patent elsewhere.

That all changed in January 2005, when India brought itself into compliance with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) — international rules that forbid the copying of patented drugs.

The transition has gone smoothly. “Companies are playing by the rules,” says Frederick Abbott, a professor of international law at Florida State University who knows the Indian drug industry well.

Few of India’s estimated 20,000 drug companies have been driven out of business so far. But there’s little sign that many are ready to follow the trail blazed by Biocon and develop patented products of their own. There are fewer than 100 new compounds in various stages of development in the entire Indian industry. Most companies lack the resources to do their own research and instead are fighting for tiny pieces of the generics market.

“There’s a change now for the better,” says Pradip Bhatnagar, Ranbaxy’s vice-president for drug discovery. “There’s nothing we don’t have — knowledge, good people, infrastructure, experience.” But he admits that genuine innovation remains rare. “Although the scientists are there, the inquisitiveness that’s required for medicinal chemistry or drug discovery is not,” Bhatnagar says.

Ranbaxy is one of the world’s top 10 generics manufacturers, with 2006 sales of $1.2 billion. Last year, the company spent about $85 million on research and development, including a collaboration with Geneva-based Medicines for Malaria Venture to develop a synthetic form of the antimalarial drug artemisinin.

“With our purchasing power here, it equals about $400 million to $500 million,” says Bhatnagar. However, the investment in research has squeezed Ranbaxy’s profit margins. Generics, Bhatnagar says, will always remain a part of the business.

Trouble at home

Even there, Ranbaxy faces growing competition. Generic drugs are currently worth about $40 billion worldwide and with so many best-selling drugs soon coming off patent, that is expected to double. Multinational generics producers such as Israeli company Teva Pharmaceutical Industries and Sandoz, a German subsidiary of the pharmaceutical giant Novartis, are expected to expand their Indian operations. “Indian companies have an advantage but it’s marginal because everyone else is coming,” says Cidambi.

Research-based pharmaceutical companies that had left India because of its lack of patent protection are also returning, often in alliance with local partners. American companies Bristol-Myers Squibb and Pfizer, as well as the British firm AstraZeneca, have signed contract-research deals with Biocon. UK-based GlaxoSmithKline has entered into a broader alliance with Ranbaxy, and Novartis from...
Switzerland and Denmark-based Novo Nordisk are collaborating with Dr Reddy’s on developing drugs for diabetes.

In the short term, Indian firms need these partnerships to help run large clinical trials, position their drugs in the United States and Europe — and bring in money. Biocon has subsidiaries that do contract research in early drug development and help conduct clinical trials. These companies account for 15% of its revenues and 25% of its profits. “If we had built Biocon as a stand-alone company, it would have been very expensive and almost unaffordable,” says Mazumdar-Shaw.

There are still some disincentives to foreign companies setting up in India. The Drug Controller General of India has been slow to approve new drugs and it still has arcane rules mandating, for example, that every drug be tested for its effect on male fertility. And although the law has been changed to protect patents, it doesn’t shield trade secrets or proprietary information.

But as the competition increases, local companies will need to learn fast. “It’s going to be a real battle,” says S. V. Kapre, executive director of the Pune-based Serum Institute of India, the world’s largest manufacturer of DPT (diphtheria, pertussis and tetanus) and measles vaccines. “We’ve always had the philosophy of making something from scratch,” he adds. “We don’t want to be bottlers and fillers for somebody else.”