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Big Pharma's R&D Booster Shot

In their quest to develop new drugs, Western pharmaceutical companies are increasingly teaming up with companies in China and India

by Pete Engardio and Ben Rissing

In the late 1990s, scores of U.S. multinationals were catching on to the cost-cutting benefits of sending work to Asia. Not Big Pharma. The industry was bulging with profits and confidence. Whatever money could be saved by shifting drug development work to India or China would have seemed inconsequential compared with the billions of dollars at stake in a potential new blockbuster.

What a difference a decade can make. Each month, it seems, a big Western pharmaceutical company announces a strategic tie-up with a company or research institute in China or India. In May, for example, Merck (MRK) signed a drug-discovery alliance with New Delhi-based Ranbaxy Laboratories that would pay the Indian company hefty royalties if the program leads to a commercial drug. Merck has struck similar co-discovery deals with India's Advinus and Piramal Life Sciences. Eli Lilly (ELI), GlaxoSmithKline (GSK), Johnson & Johnson (JNJ), Forest Laboratories (FRX), Wyeth (WYE), and Bristol Myers Squibb (BMY) also have recruited Indian partners to help develop new treatments for cancer, respiratory diseases, and heart conditions. In most cases, the multinationals are sharing technologies and biological insights that would have remained under lock and key a decade ago.

No new drugs from Asia yet

Outsourcing to China is taking off as well. Virtually every big pharmaceutical company is hiring contractors such as Wuxi PharmaTech (WX), Shanghai ChemPartners, and ShanghaiBio to do everything from synthesizing and analyzing new compounds to testing drugs on tissue samples and animals. And full-fledged discovery collaborations such as those in India are starting to appear. Eli Lilly, for example, signed on with Shanghai-based Hutchison MediPharma. Other partnerships have been formed but have not been publicly announced.

The offshoring of drug R&D will continue to grow. In a new study funded by the Ewing Marion Kauffman Foundation, a team of Duke and Harvard researchers found that outsourced research in India and China is becoming more strategically important to multinationals, and that drug patents by inventors based in the two nations have grown dramatically over the past decade. The team interviewed executives at 16 pharmaceutical firms in India and China and found most are planning for rapid growth.

When will a new blockbuster come out of India or China? It is far too early to say. It typically takes more than a decade to develop a newly discovered compound into a commercial drug that can win approval from the Food & Drug Administration, and most of the current strategic development deals are less than three years old.

Intense pressure for results

But Asia has made impressive progress. In a number of cases, Indian companies have achieved key research milestones months ahead of schedule on potential treatments for cancer, respiratory ailments, and metabolic disorders. India's Glenmark Pharmaceuticals, which does its own R&D, already has licensed drug candidates to Eli Lilly and Merck. Ranbaxy, which agreed to sell a majority stake to Japanese pharmaceutical company Daiichi Sankyo, is in Phase II clinical testing for what may be the next important antimalaria drug. Several India-developed compounds are entering clinical testing on patients in the West.

Indian outsourcing companies, meanwhile, are performing increasingly sensitive and complex work. Advinus, Piramal, Dr. Reddy's Laboratories affiliate Aurigene, and others are getting involved at the earliest stages of drug development. They are starting with "targets," enzymes or proteins in the human body that are believed to cause diseases, and helping design new compounds that can hit those targets. The Asian partners then supervise the development of promising compounds all the way into the early stages of human testing. Essentially, the Asian partners are sharing the financial risk as well as the potential rewards of drug discovery.

The forces driving Big Pharma offshore are gathering steam. Some key blockbusters, including osteoporosis drug Fosamax and cholesterol-lowering medication Lipitor, will soon go off patent and be exposed to competition from low-cost generics (BusinessWeek.com, 2/06/08). There is a dire shortage of promising new drugs in the pipeline to replace those moneymakers. Development costs in the West are skyrocketing, with pharmaceutical companies investing $1.2 billion on average for every drug that ever makes it to market. Pressure to cut development times, recruit global talent, and penetrate the huge growth markets for medicines in the domestic markets of India and China also are acute.

Return migration

These pressures have prompted big pharmaceutical companies to turn to outside partners to combine resources, share costs, and find new ideas. China and India, with their huge pools of scientific talent and ambitions to emerge as global biotech powers, are happy to oblige.

Neither Asian giant, however, is likely to become a major direct competitor to the U.S. and European drug industries in the foreseeable future. The companies doing outsourced R&D work lack the breadth of skills and experience required to develop and test their own drugs to treat complex diseases such as cancer and diabetes. Also, pharmaceuticals have one of the longest development cycles and regulatory review periods of any industry. Indian and Chinese firms are presently ill-equipped to independently navigate the lengthy, high-risk, high-cost clinical trials required to produce a commercial drug for the U.S. or Europe—and then market them globally.

But India and China must be taken seriously as major players in the future. These nations are rapidly building their capabilities through the return migration of top Indian and Chinese scientists who have amassed years of experience at U.S. pharmaceutical companies and universities. That is evident in the growing prevalence of Chinese and Indian inventors in global pharmaceutical patent applications. Since 1995, the Duke and Harvard study found, their contributions have grown fourfold. In 2006, 8.5% of all pharmaceutical patent applications filed through the World Intellectual Property Organization included an inventor located in China, and 5.5% included one in India.

Eventual competitors

The close interaction with multinationals, meanwhile, is helping Indian and Chinese firms learn to innovate. While such relationships rarely involve transfer of core intellectual property, they entail a significant sharing of knowledge about how to run long-term R&D projects and use state-of-the-art analytical tools and process methodologies that would otherwise take years to develop.

Eventually, the Indian and Chinese pharmaceutical industries will have to create their own proprietary drugs to sustain their growth. As labor and facility costs continue to rise, and as the Chinese and Indian currencies gain steadily against the U.S. dollar, the big cost gaps between East and West already are narrowing (BusinessWeek.com, 4/07/08). Firms such as Ranbaxy, Piramal, Biocon, and Dr. Reddy's, therefore, are using their profits from generics to fund their own internal research into original drugs. As Dr. Reddy's Chairman Anji Reddy puts it: "Drug discovery is the only way to become a major pharmaceutical player."

It could take a decade or more before Indian and Chinese companies master the entire drug-development process. Until then, their value as partners to Western multinationals will only increase.

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