



India, China will create big demand for generics

By AMANDA BALTAZAR

While the generic drug industry flourishes in the United States under an unprecedented wave of patent expirations, the markets for generics also are growing in India and China.

Both of these countries house populations more in need of affordable drugs, and are desirable countries to set up shop—both for American companies and domestic ones.

There is huge potential for both India and China to grow. There are about 250 ongoing clinical trials taking place in each country, a nominal figure compared with the 10,000 that are under way in the United States.

Each country will follow a slightly different path going forward, since the generic manufacturers in each country have different strengths. “One can expect the Indian companies to be very active in expanding their distribution and regulatory capabilities globally, while Chinese players will continue to be a force to reckon with as low-cost suppliers of API [active pharmaceutical ingredients] and intermediates to the global generics industry,” said Bart Janssens, a Mumbai-based principal with The Boston Consulting Group.

In fact, according to Janssens, China and India are projected to be the fourth- and 10th-largest pharmaceutical markets in the world, respectively, by 2015.

Both domestic and foreign players will benefit from the growth potential, he said. First, the domestic generics companies will see demand for their products rise, as the population and life expectancy increase, along with incomes (especially since healthcare expenses mostly are covered by individuals). At the same time, the habits and diseases of those countries are starting to mimic the Western world. For example, more than 30 million Indians have diabetes, and more than 48 million suffer from hypertension.

The Indian pharmaceutical market, which is worth about

\$6.5 billion or 2 percent of the global pharma market, is attractive for U.S. companies because of the far more affordable cost of manufacturing and labor there. “The drivers of the lower cost base not only are lower direct input costs [labor, materials], but also lower capital costs [lower cost of infrastructure],” Janssens said.

Coming up, we’ll likely see

steady merger and acquisition activity in India, said Eric Bolesh, research team leader at Cutting Edge Information. These companies consolidate to get a broader stable of products, to get promotional capability, to get into new markets with drugs that are approved to sell there and also to acquire manufacturing and distribution capabilities in other countries.

The situation in India changed somewhat this summer, when Novartis challenged the country’s 1970 Patent Act and was subsequently denied a patent for its cancer drug Gleevec, leaving the door open for generic copies to be produced.

Novartis challenged a part of Indian law that refuses to patent small changes to a

drug. The pharmaceutical giant was seeking a new patent on Gleevec, which was rejected because the new drug is not significantly different from the previous version.

This is good news for Indian generic manufacturers because branded drug companies won’t be able to make minor changes to their drugs and receive more years of patents. It’s also good news for the cash-strapped Indian population which needs affordable pharmaceuticals.

China’s pharmaceutical outlook almost mirrors India’s, and pharmaceutical revenue is jumping more than 10 percent annually, according to Bolesh. A large portion of the Chinese population is poor, he added, and they too are in need of cheaper generic alternatives, while also providing a pool of cheap labor.

Bolesh said he expects to see more Chinese generics companies but expects many of them to become acquisition targets for larger international companies.

China hasn’t had the best press this year with reports of contaminated pet food and toys, but analysts don’t expect this to scare off American consumers. This, however, is largely because consumers are mostly unaware where their drugs are manufactured.

American companies also are unlikely to want to break the ties they have established with Chinese companies. “It takes a long time to set up supply chain logistics so that’s another reason [American companies] might not back off,” Bolesh said.

The Chinese drug industry, he added, also is heavily regulated, so faulty or dangerous drugs coming out of that supply is an unlikely proposition. “They’re struggling to get to the forefront of these industries ... so their manufacturing has to fall into line at some point with U.S. regulations.”

To be able to export or sell products in the United States, the production process, facilities and quality-control procedures need to be certified by the Food and Drug Administration, Janssens pointed out.

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