

Impact of revision of Indian Patent Law on Indian Pharmaceutical companies' business models

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Summary: In the midst of rapid development of economy achieved by the strong political leadership, the Patent Law in India was revised in 1970. Under the new Patent Law of 1970, product patent right, which holds the vital meaning for the pharmaceutical industry, was not protected. However, due to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which took effect in 1995, the Indian government was required to revise its patent law again to tighten patent protection. In 2005 the Indian government revised its patent law again into a new one which protects the product patent over 20 years. This paper analyzes that how the Indian pharmaceutical companies' business models have been impacted by the revision of the Indian Patent Law.

Current Status of the Indian Pharmaceutical Industry: Under the Indian Patent Law of 1970, which did not protect product patent right, the Indian Pharmaceutical industry had been flourishing. Pharmaceutical companies re-engineered medicines (which are on-patent in the other countries) and produced and sold these copied products. Due to the strategies, production and sales of Indian pharmaceutical companies' API and finished products had drastically increased. According to the Indian pharmaceutical industry association, the Indian pharmaceutical market in 2005 was \$5.8 billion. It occupies 1% market share of the world pharmaceutical industry of \$521 billion. Today, Indian pharmaceutical market is ranked as the 15th largest in the world in values and the 4th in volumes.

Features of Indian Pharmaceutical Industry: The Indian Pharmaceutical Industry has several unique features. There are 20,000 pharmaceutical companies around India. However, most of them are small to medium companies. The top 10 companies occupy 30% of the total market in India. The market is dominated by domestic companies: these firms occupy 75% of the Indian market. So-called "mega-pharma" are still struggling to enter the Indian Market.

India has a huge population of 1.1 billion. Although the total market is ranked as the 15th largest in the world, per capita consumption of drug remains merely \$5, which is 0.5% of the per capita consumption of a U.S. citizen that is \$915. However riding on the Indian' drastic economic development, pharmaceutical industry has successfully achieved an annual growth rate of around 8-10% over the past decade.

Impact on Indian model: Under the 1970 Patent Law, which is lack of product patent protection, the Indian Pharmaceutical industry had been flourishing. However, under the 2005 Patent Law, the Indian Pharmaceutical companies are no more allowed to produce on-patent products without paying patent royalty. Under the new patent system, Indian companies, especially large pharmaceutical companies in India, started seeking for new business models, including a vertical integrated model. Dr. N.N.Prasad, Director General of the Indian Department of Industrial Policy & Promotion, at an IP symposium held in Japan in December 2007, said that Indian Pharmaceutical companies launched new drug development efforts under the new Patent Law.

Major Indian Pharmaceutical companies: As mentioned above, there are 20,000 pharmaceutical companies in India. This paper focuses on the major Indian pharmaceutical companies. As mentioned above, the pharmaceutical market in India is still relatively small; however it has been expanding very rapidly. Using the revenues collecting from the worldwide sales, major Indian companies have been expanding their business by taking over world-class pharmaceutical companies around the world. Major Indian Pharmaceutical companies also have been expanding their R&D expenditure rapidly. Some companies set up their own R&D Centers, while the other companies have been recruiting researchers. Due to such efforts, pipelines of major Indian companies have been becoming very rich. This paper reviewed major Indian pharmaceutical companies' R&D strategies:

Ranbaxy: The company has four R&D centers around the country (India) which totally hold 1200 researchers. The firm has a very strong pipeline with 10 new drug candidates. The firm has been promoting collaboration with so-called mega-pharma such as GSK and Biel

Dr. Reddy's: The firm also has a very strong pipeline with eight new drug candidates. Currently four among them are on pre-clinical test, two are on Phase I clinical studies, and the other two are on Phase II. Their target diseases including metabolic syndrome,

heart diseases, and cancer. The firm is expecting that the firm's very first new drug will be put on the market in 2008/2009.

Lupin: Lupin has been putting an emphasis on R&D. The firm's R&D expenses in 2006/2007 was 1.3 billion rupees, or 6.7% of its total revenues. The firm's current pipeline includes four candidates: one in Phase I, two in Phase II and another in Phase III. The target diseases include: psoriasis, migraine and TB.

Sun: Sun has been putting an emphasis on R&D. The firm's R&D expenses expanded from 1.2 billion rupees in fiscal 2000/2001 to 2.9 billion rupees in fiscal 2006/2007. The ratio of R&D per revenues increased from 4% in 1993 to 12% in 2004/2005. The firm has two laboratories in Baroda and Mumbai. The firm's pipeline includes one candidate on pre-clinical studies and another in Phase I.

Patent application and granted:

Due to rapid expansion of R&D expenditures of pharmaceutical companies, the number of patent applications and granted have been increasing. According to the Patent Office in India, the number of patent application jumped up from 4824 cases in 1999/2000 to 28882 in 2006/2007. The number of patent granted also increased from 1381 cases in 2000/2001 to 7359 cases in 2006/2007.

Change of business model:

According to Mr. Arun Sawhney, API President of Dr. Reddy's, Indian Pharmaceutical companies' business models migrate from "wait to see" to "Vendor based outsourcing" to "partnership for end-to-end research" to finally "captive R&D Center." As mentioned above, some major Indian pharmaceutical companies have constructed their own R&D Centers. It seems they have been following the model and have been successfully migrated their models.

However, this model is limited to large companies with abundant resources. Vast majority of the Indian pharmaceutical companies that are small to medium companies do not have enough resources to launch its own new drug research. Thus these firms have no choice but holding their current business models. It seems the Indian pharmaceutical market will be divided into two groups: the one aimed to convert themselves into vertical integrated companies with new drug discovery and development; and the other one aimed at remaining as generic pharmaceutical companies. (end)

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