

THE INDIAN PHARMACEUTICALS INDUSTRY

Introduction

India's population is in excess of 1 billion, and its burgeoning middle class promises a huge market for life-saving and life-style drugs. The production costs of pharmaceutical products in India are estimated to be 50% less compared to developed countries, and India is rated first among the top-5 manufacturers of bulk drugs in the world and among the top-20 pharmaceutical exporters. Foreign investors seeking to invest in the Indian pharmaceutical industry must consider the unique features of the Indian market, the present and potential business models, the regulatory framework concerning the pharmaceutical business and IP protection in India.

Indian patent law

In 1995, India became a member of the World Trade Organization and a signatory to the Trade Related Intellectual Property Rights ("TRIPS") Treaty, which marked the beginning of the revolution in India's legal framework relating to IP protection. Further, India honored its promise to the world and ushered in a product patents regime for drugs and food products by enacting the Patents Amendment Act, 2005 (the "Amendment Act"). Prior to 2005, India's Patent Act, 1970 ("IPA") recognized only "process patents" as against "product patents," which allowed generic drug manufacturers to reverse engineer.

India is a member of the Paris Convention for the Protection of Intellectual Property, enabling international protection in convention countries. India is also a party to the Patent Co-operation Treaty ("PCT"). The pharmaceutical industry can obtain product patents in India because the Amendment Act permits the patenting of substances to be used as "food, medicine, or drugs." However, the mere discovery of a new form of a known substance that does not enhance the known efficacy of the substance cannot be patented. Although plants and animals in whole or part cannot be patented, microorganisms can be patented if they satisfy the patentability criteria.

In addition to the earlier provisions with respect to patent infringement, an applicant will be regarded as a patentee during the period between the publication of the application and grant of patent. However, infringement proceedings can be

initiated only after the patent is granted. Moreover, the defendant in an infringement suit must prove that he used a process different than the patented process in order to shift the burden of proof. Additionally, the patent holder of a mailbox application (applications filed between 1995 and 2005) cannot initiate infringement proceedings against Indian companies that have made significant investment and commenced production of the mailbox patent holder's product prior to January 1, 2005. However, the patent holder will be entitled to receive a royalty from such Indian enterprises for use of the patented invention.

Also, the Amendment Act provides for both pre-grant and post-grant oppositions. A post-grant opposition should be initiated within 1 year and a pre-grant opposition within 6 months from the date of publication. A compulsory license for the export of pharmaceutical products to countries that do not have the requisite manufacturing facilities can be obtained if the recipient country also provides a compulsory license or issues a notification to that effect.

Regulatory & legal aspects

The pharmaceutical industry is highly regulated in India.

The Drugs Controller General of India (“DCGI”), established under the Government of India’s Ministry of Health and Family Welfare, is the nodal agency that regulates India’s drug market including product safety and efficacy, clinical trials, market authorization, and post-market surveillance. The Drugs and Cosmetics Act, 1940 (“Drugs Act”) and the Drugs Rules, 1945 (“Drugs Rules”) regulate the import, manufacture, licensing, testing, distribution, and sale of drugs in India. The DCGI heads the Central Drugs Standard Control Organization and formulates policies in order to implement the Drugs Act. The DCGI also coordinates the activities of the different State Drug Control Organizations. Drug prices in India are regulated under the Drug Prices Control Order, 1995 (“DPCO”).

Features of the Indian Market

India’s pharmaceutical industry has a compounded annual growth rate of 13.7%, and employs 3,300,000 people.

The domestic pharmaceutical market is estimated to be worth US\$5.1 billion, and comprises of 60% Indian and 40% multinational companies. It consists of around 15,000 small-scale generic manufacturers and 260 research-based drug companies.

According to industry estimates, 13-14% of the products in the Indian market are patented. The industry manufactures almost the entire of range of therapeutic products and is capable of producing raw materials to manufacture a wide range of bulk drugs from the basic stage onwards.

Generics

The global generics market is growing significantly, and presents huge opportunities for developing countries like India. More than 90-95% of the drugs available in India and specified on the World Health Organization's List of Essential Drugs are off-patent. Further, drugs worth US\$40 billion were reported to have gone off-patent in 2005, and US\$70 billion worth of drugs are expected to go off-patent by the end of 2008. Considering the availability of quality manpower and low production costs, India expects to hold about 30% share of the increasing generics market.

Many Indian companies have approvals related to cardiovascular, anti-infective, or central nervous system stimulants from the United States Food and Drug Administration ("USFDA"), the UK's Medicine and Health products Regulatory Agency, and the South African Medicine Central Council.

Research & Development (R&D)

India's leading pharmaceutical companies have demonstrated their ability to engage in commercially viable R&D activities, and have become major players in the international market. In 2003, Ranbaxy Laboratories, which has several molecules under development, had an R&D expenditure of US\$52 million. Dr. Reddy's Laboratories recorded 11% of its gross turnover from R&D.

In order to promote R&D in the drugs and pharmaceutical sectors, the Department of Science and Technology and the Government of India have initiated several policy measures and tax incentives for strengthening R&D activities.

The draft Pharmaceutical Policy, 2006 proposes to create an IP cell within the Ministry of Chemicals and Fertilizers. Further, electronic filing of patents is also proposed.

Exports

Indian pharmaceutical exports are of excellent quality, and reasonably priced. An increasing number of Indian companies are attaining international standards and approvals from agencies such as the USFDA. Current estimates suggest that 40% of the total production is exported, out of which 65% is formulations and 45% is bulk drugs. Products such as sulphur-methoxazole, amoxycillin, ampicillin, menthol and ibuprofen are the top ten products in terms of export turnover. Indian pharmaceutical products are exported to a large number of countries, including the US, Japan, Canada, Germany, France, as well as Latin American and other developing countries.

Imports

Currently, imports of pharmaceuticals are limited to a few life-saving drugs like anti-cancer, cardio-vascular and anti-hypertension drugs. Drugs may be imported from anywhere in the world, provided the DCGI approves the import, and the drug is not on the restricted list of the EXIM Policy. The import or manufacture of new drugs in India is regulated under Part XA of the Drugs Rules, while Schedule Y of the Drugs Act lays down the norms for clinical trial in India.

Pricing

The DPCO regulates drug pricing in India.

The National Pharmaceutical Pricing Authority (“NPPA”) collects the data on raw materials, compositions, packing materials, process losses, overhead allocation, technical data, etc., and makes recommendations to the Ministry of Chemicals and Fertilizers (the “Ministry”). The Ministry fixes ceiling prices of some active pharmaceuticals and formulations, and issues notifications on drugs and formulations that are “scheduled” to the Drugs Act. The NPPA is criticized for its lack of transparency in recommending drugs prices. The Government of India is currently in the process of revisiting the Pharmaceutical Policy, 2002, and proposes to change the method of determining price-controlled drugs and the

pricing formula. The draft Pharmaceutical Policy, 2006 proposes new ceilings on trade margins for wholesale of generics and branded drugs.

Under the Drugs Act, certain drugs such as antibiotics can only be sold in licensed outlets to customers who have a prescription. The government proposes amending the Drugs Act in order to create a list of drugs that can be sold legally without a doctor's prescription.

The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 regulates the advertisement of drugs and pharmaceuticals.

Investing in the Indian pharmaceutical industry

Foreign Direct Investment

FDI is allowed up to 100% under the automatic route in the pharmaceutical sector. The only requirement is filing a report with the RBI within 30 days of investment. An investor can choose from a wide range of investment vehicles into India.

Outsourcing to India

Many global pharmaceutical companies already outsource their research, manufacturing and clinical trial activities to India. Further, considering that only a few Indian pharmaceutical companies have dedicated R&D activity and obtain patents, the large export market held by generic drug manufacturers may be adversely effected. Additionally, the restrictions on patenting merely a new use of known substances will prevent the generic drug manufacturers from patenting innovations on salts and esters. Such manufacturers will find it difficult to invest in aggressively in R&D, and will be forced to shift their strategies and collaborate with the innovators as marketing arms or licensed manufacturers.

Clinical trials

According to a recent *McKinsey* report, the global clinical trial outsourcing opportunity in India is estimated to be US\$2 billion by 2010. One-third of global clinical trial activities are being conducted in developing countries like India. India is able to provide a large patient population, well-trained professionals, and 40% reduced clinical trial costs than developed countries.

Legal & regulatory framework for clinical trials in India

The DCGI regulates clinical trials in India. “Clinical trials” are defined as systematic studies of new drugs in human subjects to generate data for discovering and verifying the clinical or adverse effects of the drug in addition to determining the safety and efficacy of the new drug. Schedule Y to the Drugs Act provides for the manner in which such trials should be conducted:

Phase I, “Human Pharmacology,” involves a preliminary evaluation of the safety of the drug on healthy volunteers.

Phase II, “Therapeutic Exploratory Trials,” involves efficacy trials on a small number of patients.

Phase III, “Therapeutic Confirmatory Trials,” involves an assessment of safety on the basis of large-scale multi-centric trials.

Phase IV, “Post-Marketing Trials,” is related to assessment of the drug subsequent to approval by the licensing authority.

Contract manufacturing

According to industry surveys, the contract manufacturing market for global companies in India is estimated at US\$900 million by 2010. The Drugs Act defines the term “manufacturing” as a “process for making, altering, ornamenting, finishing, packing, labeling, breaking up or otherwise treating or adopting any drug with a view to its sale or distribution, however excluding retail.”

Drug manufacturers in India must comply with the Industries (Development and Regulation) Act, 1956. A renewable license from the Central government is required to manufacture a limited number of drugs such as those that use recombinant DNA technology. Such a license is required for each drug and manufacturing location in India.

Under the Drugs Act, a drug is required to meet certain quality standards before it can be imported, manufactured, stocked, sold, or distributed. The products must display its ingredients in the prescribed manner on the label or container and other

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standards prescribed under the Drugs Rules. General standards have been laid down concerning tablets, capsules, liquid orals, injections and ointments.