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Critical Analysis of the Role of Indian Patent Law in Progress of Indian Generic Pharmaceutical Industry

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Abstract: *Indian pharmaceutical industry has grown significantly in last six decades mainly because of weak patent law that allowed pharmaceutical industry to reverse engineer patented molecules. After Independence, the Indian pharmaceutical industry was completely dominated by multinational companies (MNCs) and drug price in India was among the highest in the world. In 1970, the Indian parliament passed the Indian Patents Act 1970 with provisions to allow only process patents for pharmaceutical molecules and new chemical entities (NCEs). The Indian Patent Act 1970 was the main reason for the fast and continuous growth of the Indian pharmaceutical industry which until 2005 engaged in generic product development; hence there was no significant activity in patenting in India. In 2005, the Indian Patent Act was amended to include a 'product patent' regime to make Indian patent law compliant with TRIPS. This shifted the Indian pharmaceutical industry's focus from generic products to research-based 'NCEs' and 'novel drug delivery products.' The post TRIPS erasaw vigorous activity in patenting in India.*

Keywords: Patents, Intellectual property rights, Indian Patent law, pharmaceutical Industry.

I. INTRODUCTION

The Indian pharmaceutical industry is one of the developing world's largest and most developed, ranked fourth in terms of production volume and 13th in terms of domestic consumption value.[1] The Indian pharmaceutical industry has achieved this growth in a brief period. At the time of India's independence in 1947, Western multinational companies (MNCs) dominated India's pharmaceutical market and controlled the larger share of the market primarily through importation. At that time, Western MNCs held about 99 per cent of market shares of all pharmaceutical products protected by patents in India and domestic Indian drug prices were among the highest in the world. The Indian pharmaceutical industry has come a long way since the Indian Patents Act 1970 came into force in April 1972. The goal of this Act was to foster development of the indigenous pharmaceutical industry and to guarantee that the local public had access to low-cost drugs.[2] The Indian Patents Act 1970 replaced the scheme for IP protection which reflected the British colonial era and ended India's recognition of Western style 'product patent' (i.e. molecule patent) protection for pharmaceuticals, agricultural products, and atomic energy. The change of product patents to process patents for pharmaceuticals allowed Indian companies to reverse engineer or copy foreign-patented drugs without paying a license fee to originator patent owners. This helped the Indian industry to build up significant competencies and offer many cheaper 'copycat' generic versions legally in India if they used a production process that differed from the patented process in India. This legislation protected process patents for just seven years instead of the usual 20-year patent term in Western countries. The Indian pharmaceutical industry grew and prospered in a highly regulated environment, with the Indian government's price control governing a significant number of pharmaceutical formulations and bulk drugs.[1] This scenario also led to a decline in the development cost of new pharmaceutical products and to successive increases in competition between the industries in the Indian pharmaceutical market, which directly affected the cost of medicines in India.[4] The 1970 Act remained unchanged until 2005, giving a period of 35 years in which the Indian pharmaceutical industry was able to perfect its scientific and manufacturing capabilities, allowing many of its leading

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companies to move up the value-added chain. The Indian pharmaceutical industry now consists of large, medium, and small-scale companies, and is one of the world's most price competitive industries.

II. METHODOLOGY

The study has been conducted based on data from secondary sources such as books, relevant Acts, websites, news reports, research material available online. It is purely based on doctoral research method.

III. INDIAN PHARMACEUTICAL INDUSTRY AND WTO

The World Trade Organization (WTO) is the international organization dealing with the rules of trade between nations. WTO's TRIPS Agreement introduced IP rules into its multilateral trading system and India, being a founder member, automatically became a TRIPS signatory. TRIPS made it mandatory for India to add product patent protection for pharmaceutical products from 1 January 2005. This led Indian pharmaceutical firms to invest more in the R & D of new chemical entities (NCEs) and novel drug delivery products, resulting in a major change in India's pharma patent scenario. As a result of TRIPS compliance, a 20-year term is now available in India for any pharmaceutical product or process invention. Compulsory license provisions are also now TRIPS-compliant, and the government may grant such licenses only on the merit of each case, after giving the patent holder an opportunity to tell his position. In addition, no discrimination is permitted as between imported and domestic products in the case of patent infringement and, in the case of process patents, the burden of proof rests on the party that allegedly infringes.[5] The Indian Patent Act's provisions for product patents thus shifted the focus of the Indian pharmaceutical industry from generic products to innovation-based patentable R & D, generating huge investments by the Indian pharmaceutical industry in innovation-based research and patenting.

IV. POST TRIPS GROWTH

Today, the Indian pharmaceutical industry can produce almost every type of medicine locally, from headache pills to complex antibiotics and cardiac compounds. Nor are its activities restricted to the domestic market. When India joined the WTO in 1995, its pharmaceutical exports were less than US$600 million; and by 2005, its exports had grown to US$3.7 billion. Currently, Indian pharmaceutical companies produce over 20 per cent of the world's generic drugs (by value), offering some 60,000 finished medicines and nearly 400 bulk drugs used in formulations worldwide. India has the world's third-largest active pharmaceutical ingredient (API) manufacturing industry, valued at nearly US$2 billion in 2005. Currently, India's drug industry produces more than 400 different APIs and is among the world's top five API producers, accounting for about 6.5 per cent of the world's API production.[1] Before 1995, product patents for pharmaceuticals were not available; only process patents were granted in India. At that time, the Indian pharmaceutical industry was engaged in the development of generic versions of MNC molecules manufactured by alternative process, bypassing MNC process patents. Since the Indian pharmaceutical industry was not willing to perform innovation-based research and patenting, the number of patents filed with the Indian Patent Office was relatively low. After the TRIPS Agreement and the 2005 patent law amendment, it became necessary for the Indian pharmaceutical industry to progress towards innovation and research, since the new product patent regime prohibited the development of 'copycat' generics in India. With very few options left to them, most Indian pharmaceutical companies actively taken part in this transition, launching their own R & D centers for the APIs, producing novel as well as generic formulations. The research-oriented approach boosted the numbers of patents filed and increased the generic marketing of various therapeutic classes of drugs—including some of the blockbuster drugs—in India, the USA, and Europe.

V. FINDINGS AND DISCUSSION

India's US$9.4 billion pharmaceutical industry is growing at the rate of 14 per cent per annum, reflecting the country's position as one of the largest and most advanced among the developing countries. The US market is still the most lucrative market for Indian pharmaceutical companies, led by its market size and by the number of blockbuster drugs going off patent. An estimated US$45 billion of drugs went off patent in 2007 in the US alone. While the big Indian companies such as Ranbaxy, Sun Pharma, and Dr. Reddy's are increasingly focusing on tapping the US generic market, outsourcing in the fields of R & D and manufacturing is the next best event for the Indian pharmaceutical industry.

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Spiraling development costs abroad, expiring patents, low R & D costs in India, and market dynamics are driving the MNCs to outsource both manufacturing and research activities to the Indian pharmaceutical industry. Additionally, the Indian Government's decision to allow 100 per cent foreign direct investment into the drugs and pharmaceutical industry is expected to aid the growth of contract research in the country. Foreign MNCs are showing an active interest in India's pharmaceutical sector: companies such as Glaxo Smith Kline, Pfizer, Mylan, Daiichi, Alcon, and Apotex are making substantial investments in R & D,either directly—by setting up their own research centers—or through mergers and acquisitions.

VI. CONCLUSION

Presently, in terms of the global market, the Indian pharmaceutical industry holds a modest one to two per cent share, but it is growing at a rate of about 10 per cent per annum. The Indian pharmaceutical industry has already gained a foothold in the global pharmaceutical market scene with its innovatively engineered generic formulations and APIs and now seeks to become a major player in outsourced clinical research and contract manufacturing and research.[7]The growth of the Indian pharmaceuticals market will be influenced by six trends over the next decade:
the doubling of disposable incomes and the number of middle-class households;

- expansion of medical infrastructure;
- greater penetration of health insurance;
- rising prevalence of chronic diseases;
- adaptation of product patents; and
- aggressive market penetration driven by the relatively smaller companies.

Presently, the Indian pharmaceutical market is ranked14th in size in the world but by 2015 it will have reached the top ten, overtaking Brazil, Mexico, South Korea, and Turkey. The USA and China are expected to\ add US$200 billion and US$23 billion, while India, Japan, Canada, and the UK are expected next in line, with growth expectations in the range of US$13–14billion during the next decade. Thus Indian patent law has played a significant role in growth of Indian generic pharmaceutical industry providing affordable medicines across the globe and India.

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