EMERGING ISSUES IN PHARMACEUTICAL PATENTS IN INDIA

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Abstract

Internationally, the matters related to intellectual property are on the brink of revolution in modern times. The existing structure of IPR regulations are I accordance with the Trade Related Intellectual Property Rights (TRIPS) agreement governed by the WTO. Under Patent's Act, 1970, patent is a grant from the government to the inventor for a limited period the exclusive right to make use, exercise and vend his invention. The patent (amendment) Act, 1999 was a revolutionary step covering Exclusive Marketing Rights (EMR), compulsory licensing, protection of security of patents by govt. etc. The challenges and revolution in pharmaceutical industries are briefly discussed.

Patent is another form of Intellectual Property Rights other than the trademark, copyright and design. It creates an exclusive right I favor of the patentee. He can deal with this property right either by using it himself or convey the rights to others by the grant of license or assignment of his rights to others for valuable consideration. This involves the principle of mutuality and contract. The object of patent law enshrines the encouragement to do scientific research, new technology and industrial progress. The price of the grant of monopoly is the disclosure of the invention at the patent office which after the expiry of fixed period of the monopoly passes into the public domain as rightly embarked by Supreme Court in *Bishwanath Prasad vs. Hindustan Metal Industries*[2]

Relatively, the entity of patent greatly involves the newly inventions. An invention to be patentable must be a new and useful method or manner of manufacture. It involves two separate conditions viz. it is a method or manner of manufacture and secondly, is it new and useful? In order to entitle an inventor to a grant of a patent both these conditions must be present.[3]

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[2](1979) 2 SCC 511
[3]AIR 1983 Bom 144

Pharmaceuticals include medicines i.e. the products chemicals in nature. They must be of mineral, vegetative or animal origin. However the question remains as to whether products derived from human being, as blood and its derivatives, mother's milk, organs or portions of organs may be considered as medicine. The product free from contamination, are less costly and less toxic to human beings i.e. human insulin used during the treatment of diabetes, alpha interferon used as antiviral and human growth hormone used to treat dwarfish. In India, patent grant is confined only for the process of manufacture of substance such as food, medicine ad drug under section 5 of the Act.[4]

INITIAL TRENDS IN PHARMACEUTICAL SECTOR

The patent policy adopted by India enabled it to hold a big partnership in the International Pharmaceuticals Market (IPM). The patent policy of 1970 dramatically changed India's condition. In 30 years, the Indian pharmaceutical industry is valued at USD 70 billion compared to a mere USD 2.1 million before 1970. Currently 24000 pharmaceutical companies are licensed in India, out of which 425 bulk drug companies are manufactured within the country. Indian production accounts for nearly 50% of the world production. Several companies like Ranbaxy, Dr. Reddy's and Cipla have the potential to become billion dollar companies within the next two years.[5]

As rightly marked by the then Prime Minister Indira Gandhi at the World Health Assembly in 1982- " The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death"

The Uruguay Round of GATT (General Agreement on Tariffs and Trade) negotiation[6] was crucial for all sectors of India's economy, agriculture and pharmaceutical industries. They asserted that patent protection would benefit the developing countries like India by encouraging FDI and introducing large research and development in this sector. A similar report of The Economic Times[7] tells that the industry witnessed a three-fold growth in the last years. There is a

[4]Indian Patents Act, 1970
[5]Damanjeet Ghai-Patent Protection and Indian Pharmaceutical Industry: International Journal of Pharmaceutical Sciences Review and Research Vol. 3 Issue 2 July-Aug 2010 Page 44
[6]September 1993,concluded in December 1993
[7] 21 June 2010

cautious optimism within the Bio-Tech industry, the continuous development and research bring succor for the industry.

A COMBATING SITUATION FOR THE PHARMA INDUSTRY

At the time of the amendment of the Act[8], the developing countries like India were given a grace period of 10 years for technologies previously unprotected in its market. During that interim period of ten years, all patent applications were put in a 'black box'. However, pharmaceutical corporations were granted power to apply for a Exclusive Marketing Rights (EMR) for their product for five years only even before the country in question has fully phased into the new patent protection system. The Act provides that the product must have been registered for a patent and has received marketing rights in any of the WTO member countries. The Indian Pharmaceutical Market is currently valued at 72,069 Crore INR as in 2013 as against 65,654 Crore INR in 2012. Though the market value has seen an increase, the sector overall has experienced a slowdown with its growth going down to 9.8% from 16.6% in 2012. This slowdown can be attributed the new drug pricing policy and the regulatory interventions. The industry is witnessing additional challenges like delays in clinical trial approvals, uncertainties over the FDI policy, a uniform code for sales and marketing practices and compulsory licensing.[9] The industry is facing stricter regulations on manufacturing management and quality practices in international markets.

In India, the biggest challenge to pharmaceutical industries exists as the patent law of India did not provide patents for products rather it only provided for process patents. In the case of a product, the patent lies in the ultimate end product while in the case of a patent for process it doesn't lie in the end product. That is, a same product can be projected for a new patent by developing it by different process.

Ultimately, the Indian Pharmaceutical Industry is slowly being conquered by the foreign industries by the use of the EMR under the TRIPS agreement of WTO. By this, there exists the probability of cost increase of pharmaceutical drugs also. The domestic market which has boomed over the years may collapse and driven out of business. Recently, the US is putting

[8]Indian patent (amendment) Act, 1999
[9]http://www.pwc.in/press_release/cii_pwc_report_pharma_industry Last visited 28.4.16 21:02:24

pressure on India to strengthen its laws with respect to pharmaceuticals which would protect the big firms' patents on particular drugs. Consequently, the Indian firms won't be able to market generic versions of patented drugs. Also, the countries which are using India made drugs will also suffer.[10]

Consequently, the International conventions has generated much grudges rather than developments between the producing developing countries and developed countries, generated controversy between US and Japan. The developed countries have secured such benefit by forcing the developing countries to ratify the GATT (TRIPS agreement). The international convention has opened many questions as to dividing markets exhaustion of rights, competition or anti-trust law etc. which needs a considerable discussion.

CONCLUSION AND SUGGESTIONS

The introduction of patent will lead to price increase. Based on studies made in Italy, India and Argentina such increase may reach to 100% or move for products under patents, depending on the prior pricing level, the elasticity of demand and other factors. The developing countries national research & development infrastructure is weak which leads to slow innovation.

The EMR will have a growing impact on pharmaceutical industries in coming years. But the Govt. of India should introduce effective regulatory mechanisms for checks and balances on the availability, access and price of essential drugs. The Govt. should strive to develop research facilities for the introduction of new drugs. The new liberalized drug policy has removed import restrictions. The TRIPS provisions are not preventive or remedial in nature but exploitative in nature. Also, the less developed countries must be given exemption for patent rights in certain basic drugs or compulsory licenses for production. After all, it's a high time to look forward for regularizing its own marketing policies with regard to foreign investments and policies in order to secure the downfall of domestic pharmaceutical industries.

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