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New Patent Regime: Pharmaceutical Patent Protection vs. Public Health

IMRAN AHAD
Ph.D. Scholar
Department of Law, University of Kashmir, Hazratbal, Srinagar (J&K) India

ABSTRACT

The pharma patents are not only centralized to drugs but it is related to hiking of price. The pharmaceutical companies' main focus for most of their history has remained on developing new drugs to advance medical care. But during the last few years their return at this central task has steadily declined, which has not only put pressure on them to reduce research and development funding rather to enter partnerships that don't require the fixed costs of their own laboratories and employees. Though, India has a strong generic pharmaceutical industry which has witnessed immense growth in last few decades, the pharma industry has in many cases taken on strong MNC's on cases of proposed or alleged infringement of drugs that are patented investing huge sums of money. Initially under the Patents and Designs Act 1911 India had a product patent dominion for all inventions. But in 1970 with new Patents Act, pharmaceuticals and agro-chemical products were excluded from eligibility of patents.

Key Words : Public health, DOHA Declaration, Life saving Drugs, Compulsory Licensing

INTRODUCTION

The intellectual property law is essentially the outcome of the capitalistic economic system perpetuated by the western colonial powers in the industrial revolution. India being subjugated by colonial powers have to bear the brunt of capitalism in its nascent form. It had no choice but to be the part of the colonial hegemony power. The Indian pharmaceutical sector has come a long way, from being almost non-existent before 1970 to a prominent provider of health care products at present. The pharmaceutical industry has grown from mere US $0.3 billion turnover in 1980 to about US$21.73 billion in 2009-10. India now ranks 3rd in terms of volume of production (10% of global share) and 14th largest by value (1.5% of global share).[1] The leading global pharmaceutical firms are facing some challenging times as a significant number of patents for branded drugs are set to expire over the next five years. From 2011-2015, the total value (as measured by annual sales) of patent expirations is expected to be around $100 billion, a significant increase from $73 billion in patent expirations over the previous five years. Indian pharmaceutical companies can capitalize on this opportunity due to their first move advantage, strong process engineering skills and access to low-caste talent.[2]

Statistics of Patent Application Filing at Indian Patent Office-All Fields:

Patent system was implemented in India since 1970s

1. Dr. Mandar Madhukar Kodgule, growth of Indian pharmaceutical industry: impact of Indian, US and European patent laws and regulatory requirements available at http://www.ipapharma.org/pt/july2012/45-49.pdf last visited on 27-4-2013.
2. Mukul Gulati, The upcoming patent chief: implications for Indian pharma available at http://www.vccircle.com/byinvitation/2011/08/29/upcoming-patent-chiff-implications-indian-pharma last visited on 26-4-2013.

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where in, process patents were granted since then. Table 1, indicates 28064 applications (other than through PCT National Phase) were filed under the category of drugs during the term 1997 to 2010 which contributes to about 12% of total fillings.[3]

Per cent Year On Year Patent Application Filing At Indian Patent Office During 1997-2010 Drugs, Chemicals, Bio-Technology:

During the term 1997-2010, indicates patent application filings relating to drugs ranging from 9 to 22% based on year by year basis. The patent application filings are high during the transition period 1995-2005 wherein, India made a mailbox facility in accepting product patents as well. It is necessary to understand that several patent applications belong to chemical class and may also belong to pharmaceuticals. It is observed that patent applications relating to biotechnology are below 10%.[4]

Leading Indian Pharmaceutical Manufacturers:

The TRIPS agreement express these conditions in a way that is now widely used in national laws. TRIPS specify that patents should in principle be available for any inventions, where the products re process. Provided they are new, novel or involve inventive step. Patent law often provides for exception to the kind of subjective matter that can be changed. India's leading pharmaceutical companies are striving to compete not only in the domestic Indian market, but also in the global market for both generic drugs and original products. Sales for India's largest 200 pharmaceutical companies grew from $7.9 billion in 2004 to $8.6 billion in 2005, or by 9 percent. 21 By 2005, 9 of the top 10 Indian drug makers were Indian-owned firms accounting for more than 44% of total industry sales. India's top five pharmaceutical companies, in term of sales, are Ranbaxy Laboratories, Dr. Reddy's Laboratories, Aurobindo Pharmaceutical, GSK-India, and Cipla. These companies manufacture a wide range of generic drugs (branded and non-branded), intermediates, and active pharmaceutical ingredients (APIs).[5]

In terms of total sales, Ranbaxy Laboratories is India's largest pharmaceutical company and one of the world's top ten generic drug makers. In 2005, exports accounted for nearly 80% of Ranbaxy's sales and the US is Ranbaxy's largest market. Ranbaxy is a vertically integrated company with a presence across the pharmaceutical value chain, offering a range of unbranded and branded generics, active pharmaceutical ingredients, and biotechnology products. Ranbaxy markets its products in more than 100 countries, a sales presence in 23 of the world's top 25 pharmaceutical markets, and has manufacturing facilities in 8 countries. Cipla, India's second-largest pharmaceutical company, is best known for its anti-AIDs drugs, and Dr. Reddy's Laboratories, India's third-largest pharmaceutical company, also rely heavily on exports as its revenues.[6]

Need of Strong Patents Regime in Pharmaceutical Industries in India:

The most important international intellectual property agreement regulating remedies for intellectual infringement is the 1994 WTO agreement all trade related aspects of intellectual property rights. Pert III of the TRIPS agreement deals with enforcement of intellectual property rights. It usually indicates objectives but leaves considerable leverage to WTO member states on how to implement their enforcement obligations. Price of the patented product and their accessibility in India has been the focus of concern ever since the question of adopting product patent has come to front. The fundamental reason why pharmaceutical progress is dependent on IPR protection is the staggering cost of new chemical entity (NCE) development as a potential drug molecule and high attrition rate in the development cycle. Recent studies indicate that 1 out of 5000 molecules synthesized during applied research, eventually reaches the market. Without strong patent protection, pharmaceutical companies cannot attract the investment needed to conduct this expensive, high-risk research. The overall cost is further inflated if the opportunity cost of such high investment for such a long time with no guaranteed return is taken

3. Rau. B.S, Dr. Nair G.G and Dr. Appaji P.V, Current status of pharmaceutical patenting in India available at http://pharmexcil.org/uploadfile/ufile/5currentstatuspharmapatentingInIndia01jul2012.pdf last visited on 27-4-2013.
4. Ibid.
5. William Greene, The emergence of India's pharmaceutical industry and implications for the U.S. generic drug market available at http://www.usite.gov/publications/332/working_papers/EC200705A.pdf last visited on 26-4-2013.
6. Ibid.

into account. Without strong patent protection, fewer drugs will be developed and the flow of medicines to the public would be greatly slowed to the detriment of patients, public health and economic development throughout the world. Profits are diminishing due to imitation in drugs and pharmaceuticals.[7]

Another argument for strong patent regime has been that availability of newer life-saving drugs and devices can be ensured only through the implementation of the TRIPS Agreement. Study indicates significant increase in US exports to countries where intellectual property protection has been enforced. This leads to the growing realization that MNC's are keen to increase their stakes only in those countries where they can market their products under exclusive or monopolistic rights, i.e. technology-holders can exclude competition from domestic producers in importing countries or other foreign firms. Also, an agreement within the GATT/WTO facilities recourse to cross-retaliation for non-fulfillment of specific obligations. In simple words, countries failing comply with TRIPS could be subjects to trade retaliation if the WTO dispute settlement mechanism identifies the existence of a case of non-compliance within TRIPS Agreement.[8]

Social Desirability in Pharmaceutical Patents and Public Health:

In the last three decades the global gold rush for patents has been dominated by fillings for minor and mostly in consequential innovations at the expense of breakthrough innovations. In large part this is because weak standards in the patent laws of developed countries have explicitly encouraged the shift.

Patents are profitable for monopolists, but that much we knew already. But the important thing is to be kept in mind is the purpose of the patent system which is to benefit society through innovation. It makes no sense to grant patent monopolies inn medicines for the kind of innovation produced until it is mainly driven by the purpose to benefit the society.

Whatever one feels about patents and the "property rights" of monopolists, it is hard to fathom the defense of existing patents when millions of lives are at stake. Whatever religious altar one worships at, whether it be a more traditional religion, the religion of capitalism, or that of monopoly, there can be no excuse for allowing either the idea or reality of private property to interfere with the business of saving one's fellow man. If compensation for the taking of medical and pharmaceutical patents need be paid, so be it. But we can only hope that along with the great mass murderers of the 20th century – the Stalins and the Hitters – there is a special place in hell reserved for those who stood by and refused to act while those around them died.[9]

During the golden days of Indian Generics – India (as per the Patent Act of 1970) did not recognize patents as considered vital to human life-food and health. Therefore none of the pharmaceutical patents were valid in India, allowing Indian companies to manufacture generic medicines without licensing to the originators as long as the process used for manufacturing was different from that used by the original company. The Indian pharmaceuticals became experts in reverse engineering. This allowed Indian generics to compete in the world market most importantly by providing medicines at an affordable prize to areas of the world that badly needed them. The best example for this is the antiviral drugs manufactured by Cipla. These generics were made available in Africa as well as South America. The availability of these generics at an affordable prize no doubt had a great effect on curtailing the spread of the HIV epidemic.[10] So in case of epidemics and life threatening situation availability of a drug is solely humanitarian and it should be implemented as such. Whatever the loss incurred by the company might be, it cannot be worse than the loss of lives due to

7. Sajeev Chandran, Archna Roy and Lokesh Jain, implications of new patent regime on Indian pharmaceutical industry: challenges and opportunities available at http://www.niscair.res.in/sciencecommunication/researchjournals/rejour/jipr/fultextsearch/2005/july%202005/JIPR-vol%2010-july%202005-pp%20269-280.htm last visited on 26-4-2013.

8. Ibid.

9. Boldrin and Levine, against intellectual monopoly available at http://levine.sscnet.ucla.edu/paper/ip.ch.9.m1004.pdf last visited on 27-4-2013.

10. Athulaprabha Murthi, compulsory licensing—does it affect the pharma companies? Available at http://www.indiabioscience.org/article/compulsory-licensing-%E2%80%93-does-it-affect-pharma-companies last visited on 27-4-2013.

unaffordability of the life-saving drugs. It is time to turn around and protect the person for whom the drugs are actually manufactured rather than the profits (which seems to be the only direction companies are heading in).[11]

Conclusion:

Pharmaceuticals are health inputs and are not to be treated as par with consumables. For want of money, no one should be deprived of medicines and suffers morbidity & mortality due to diseases. The drug makers say that profits fund the research that produces break through treatments. The warn that without grant of patents on several big money drugs, their ability is to develop new drugs will be severally hampered and the strong patent regime is important to protect the profits that they need to keep the innovative product moving through the pipeline. But there is no proof of a link between patent and innovation. Drug companies focus on developing the most marketable drugs instead of the most urgently needed medication. So patent in pharmaceuticals only boost company's profits not to encourage the innovation needed to address the worlds unmet medical needs. Further History has repeatedly shown that innovation can strike without patents. Just look at Penicillin or Polio vaccine, Jonas Salk answered, "There is no patent, and could you patent the sun".

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11. Ibid.