The issue of encouraging medical research while keeping medical treatments affordable – is as yet unresolved. This paper first examines how implementation of the World Trade Organization’s (WTO’s) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) agreement initially restricted health access in developing countries and assesses whether these concerns have been subsequently addressed. It then examines the effects of patents on stimulating medical research, and discusses cases of market inefficiencies and failure. I address the effect of change from process patent to product patent after patent amendment act 2005 in pharmaceutical industry on health access and medical research in turn.

**Key words:** Patent, Product patent, Process patent, Pharmaceutical industry, TRIPS.

**INTRODUCTION**

Patent is a legal document granted by the government giving an inventor the exclusive right to make, use and sell an invention for a specified period of time. It is also available for significant improvements on previously invented articles. The underlying idea behind granting patents is to encourage innovators to advance the state of technology. According to the UN definition, a patent is a legally enforceable right granted by countries government to its inventor. Patent Law represents one branch of a larger legal field known as intellectual property rights. Patent Law centres on the concept of novelty and non-obvious inventions. The invention must be legally useful. The imitators and all independent devisors are prevented from using the invention for duration of patent.

There are some inventions and discoveries which are not subject to any patent. Issac Newton could not have obtained a patent on laws of gravity even if he was the first one to obtain it. Critics of the WTO often cast it as an obstacle to human health, particularly in the poorest nations. Patents are particularly important in the pharmaceutical and biotechnology industries because they provide a mechanism by which the extremely high product development costs may be recouped. Loss of market share is estimated to be ~40% within the first year after patent expiration. In addition, the pharmaceutical pipeline is “drying up” (ie, fewer new drugs are entering the market). Therefore, when the patent on a drug expires, brand-name companies are increasingly seeking patent extension for the drug through innovative products such as clinically superior formulations of the drug (eg, new drug delivery systems, controlled release) and chemico-pharmacological modifications (ie, improvements in the pharmacokinetics or side effect profiles, single isomer drugs, prodrugs). Patent protection is crucial to the innovative pharmaceutical industry. Innovative companies require the guaranteed period of market exclusivity afforded by patents in order to sustain drug prices, recoup research and development (R&D) expenditures and finance the development of new products. India’s proposed changes to its 35 year old patent laws will deny inexpensive generic drugs to millions of people in India and other developing countries, international humanitarian agencies and health activists have warned.

India’s patent act of 1970 granted patents on chemical processes but did not permit patents on drugs. This allowed Indian drug companies to reverse engineer molecules to produce generic versions of patented drugs. Health activists say the amendments would make it easier for companies to acquire patents on new uses of old drugs and on new combinations of old drugs. Under the new legislation, compulsory licensing that allows local companies to produce generic products would become difficult.

India as a member of WTO, tried to make its patent legislation TRIPS compliant by bringing into force the Patents (Amendment) Act 2005 w.e.f. 1st January, 2005 which provided for product patents - a long debated issue globally and nationally. The major concern arising out of these amendments is increased prices of drugs thus creating problems for the poor. Resolving such a problem would not be easy but other regulatory mechanisms could be put in place to control the drug prices. The major concern that the social and economic costs of introducing pharmaceutical patents are likely to outweigh the benefits in the case of most developing countries suggests a cautious approach to intellectual property protection in the area of pharmaceuticals. 

Arguably the most controversial aspect of the World Trade Organization’s Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) is over the issue of patents for pharmaceutical drugs. To their proponents, patent rights are essential to encourage innovation, as the virtual monopoly they create allows firms to extract greater profits from drugs that they invent. Opponents, however, point out that patents result in higher prices, making essential medicines less affordable.

**ORIGIN**

The term patent originated from the Latin term literae patentes (letters patent) which means open letters. The origin of patent law in India can be traced back to the law and practice on patents in the United Kingdom. The Indian Patent Act 1970 is modelled on the British Patents Act 1949. But there are stark differences between these two acts. The Indian Patent Act 1970 granted Process Patent. Product Patents were not granted for food, medicines and chemicals before the Act was further amended in 2005 in full conformity with TRIPS regulations which mandated Product patents. As law, the patent term is 20 years, but it is roughly 16-18 years in case of drug patents, as they have to pass the FDA regulations, before coming in markets. When the patent expires, generic companies come up with the generic version of the same drug and sale in the market with very low price. Thus, to be in the competition, innovator companies try to extend the drug life time. This is known as extension of the known drug for longer time protection. With the advantages of cost competitiveness, ability and experience in reverse engineering, availability of skilled scientific and engineering personnel and the capability to produce raw materials for a wide range of drugs from the basic stage, the industry delivers the entire range of therapeutic products. McKinsey & Co. predict that India’s pharmaceutical market could reach a size of USD 20 billion by 2015, becoming one of the top 10 drug markets in the world.

**PATENTS ACT 1970**

Patents Act 1970 in its original form does not differentiate between Process and Product patents for medicines, food and chemicals. One of the important features of the Act was that it did not provide product patents for the three mentioned industries. In addition the Drug Price control Order, 1970 put a cap on the maximum price that could be charged and ensured that the life saving drugs are available at reasonable prices. The Act of 1970 safeguards the interests of the inventor and consumer in a even-handed manner. The Act has been promulgated in keeping with the Socialist Principles outlined in the Directive Principles of State Policy ( Art 39 of the Constitution ), such as India, whose 1970 Act of...
Parliament granted “patent rights only to manufacturing processes, rather than to the end products themselves,” allowing Indian firms to ‘reverse engineer’ the production process and manufacture generic copies of drugs. Therefore with a regulatory system focused only on process patents, helped to establish the foundation of a strong and highly competitive domestic pharmaceutical industry which in the grip of a rigid price control framework transformed into a world supplier of bulk drugs and medicines at affordable prices to common man in India and the developing world. These provisions were in part a response to the lack of protection for pharmaceutical products in countries. Patent filing process can be carried on different patent offices located at Delhi, Chennai and Mumbai.

INTRODUCTION OF PHARMACEUTICAL PRODUCT PATENTS

Scenario Pre-TRIPS

The Indian Pharmaceutical industry is one of the largest in the developing world and is ranked as the fourth largest in terms of production and 13th largest in terms of domestic consumption value. Over the past 30 years Indian drug industry has emerged from almost non-existent to a world leader in the production of generic drugs. With the changes brought about by the patents act of 1970, Indian drug manufacturer The amendments introduced in the Patents Act exhibit the essence of patentability in the pharmaceuticals and chemicals is inventive ingenuity, novelty and non-obviousness. The amendments introduced in the Patents Act exhibit the essence of patentability in the pharmaceuticals and chemicals is inventive ingenuity, novelty and non-obviousness.

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The new amendment was not to affect the drugs which were in the market prior to 1995. As far as those drugs which were produced between 1995 and 2005, they will have the right to continue to produce them in return for the payment of a fixed royalty to the patent holder. The main problem arises for those drugs which are now being manufactured and patented. The only way by which such drugs can be manufactured in India is by way of compulsory licenses. Such compulsory licenses are granted by the government on grounds such as non availability, high prices, public interest etc. The process ought to be simple and easy but the problem lies in the fact that the procedure has been left very ambiguous by the new Act. The immediate and the most drastic effect that TRIPS compliance and introduction of the new Act of 2005 will have will be with respect to the health sector in India. The patients are the ultimate beneficiaries of the pharmaceutical research and development. By denying product patents India will be able to encourage bulk generic drug production at cheap prices. However generics are not the only solution to counter the problem of access to medicines. Generic production of drugs will not necessarily result in the innovation of new and more effective drugs and by not acknowledging innovation India will run the risk of not having access to future medicines which will in turn affect public health. Denying patents and allowing the generic companies to freely copy the new drugs cannot be the solution to deliver medication to the patients too poor to buy them, be it rural or urban India. The actual problem lies in the fact that the product patents not only increase the cost of the drugs and medicines, but that most of them fail to introduce research and development in the neglected diseases. Lack of access to affordable medicines was a reason for the vast majority of deaths that took place due to HIV/AIDS in the developing countries. Hence while on one side the introduction of product patents will help in development of new and more effective drugs, the problem still remains that the research and development undertaken by the drug manufactures evade the neglected diseases and the diseases which are region specific such as medicines for malaria and tuberculosis which are found prevailing in developing countries like India.

Unlike in the developed countries, the lack of the penetration of medical insurance makes the people directly affected by the increase in the prices and hence decreases the affordability. The patent system makes the lives of the people outside the sphere of social security, which forms majority in the developing countries, impossible.

A product patent system will make India dependent on the multinational companies for technology and for permission to produce the patented drug. Exorbitant prices will be charged and the Indian pharmaceutical industry will become subservient to the MNCs. They will lose the position that they had gained in the wake of the Act of 1970.

PATENTS AMENDMENT ACT (2005)

The Patent Amendment Act 2005 passed by the Parliament in its budget session of 2005 brings the Indian Patent Act in full conformity with the intellectual property system in all respects. This replaced an ordinance promulgated on December 2004 to meet WTO obligations. Some of the major amendments have been introduced in Sections 2 and 3 which are as follows:

Section 2 of the Patent Act is the definition clause:

According to Section 2(j) invention means a new product or process involving an inventive step and capable of industrial applications. (ja) inventive step means a feature of an invention that involves technical advancement as compared to existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in art. Thus an invention in order to be patentable, should:

(i) involve an inventive step capable of industrial application;
(ii) which should involve technical advancement as compared to the existing knowledge or having economic significance or both; and
(iii) be not obvious to a person skilled in art.

Section 3 outlines various situations where an invention (properly so called) can be not patentable. Section 3(d) of the Patents Act 1970 has been amended under the new Act to prescribe a class of discovery which cannot be subject matter of patent; it reads as follows:

(d) mere discovery of a new form of known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least employs one new reactant.

Product Patents have been extended to fields of technology such as drugs, food and chemicals but granting of patents are subject to restrictions as mentioned above (Section 3(d)). This section prevents frivolous inventions from being patented.

The amendments introduced in the Patents Act exhibit the essence of patentability in the pharmaceuticals and chemicals is inventive ingenuity, novelty and
existence of industrial application or economic significance of the new product or process.[12]

Patents work differently in different industries. However, in the pharmaceutical, chemical and biotechnology industries the patent normally equals the product, and protects the extensive investment in research and clinical testing required before placing it on the market.[13]

THE GLOBAL INSTITUTIONS RESPONSIBLE FOR ADMINISTERING THE PATENT SYSTEM

National patent offices

Every country with a patent system has a national patent office where claims of inventors may be made a matter of public record. As mentioned above, in many countries there is an examination before an inventor is given any substantive rights. In other countries patent claims are registered but detailed examination is delayed until a dispute over infringement arises. However, even in these countries a search of the prior art is often conducted as a part of the registration process, and the search results are published so that members of the public can access the claims made by the registrant.

The World Intellectual Property Organization (WIPO)

Headquartered in Geneva WIPO is the specialized United Nations Agency that serves as a clearinghouse for administration of most of the global intellectual property treaties. It is the principal forum for negotiation of new patent treaties and the leading provider of technical assistance to developing countries in the field of intellectual property rights. WIPO was created in 1967 as the successor organization to the International Bureau for the Protection of Intellectual Property, which had been in existence since the 19th Century. WIPO currently has 179 member states.

The World Trade Organization (WTO)

The World Trade Organization was established in 1994 in Marrakech following the successful conclusion of the Uruguay Round of Trade Negotiations. The predecessor to the WTO was the General Agreement on Tariffs and Trade (GATT). A key reform of the Uruguay Round was the Agreement on Trade Related Aspects of Intellectual Property Rights, known as TRIPS, codified as an annex to the treaty establishing the WTO. It is important to recognize that the TRIPS Agreement was intended to create a more equitable system of international trade. Wealthy countries agreed to reduce barriers to imports of price competitive imports from abroad while developing countries agreed to open their markets to the high value added exports of the developed nations. These high value added exports disproportionately consist of technology in which much of the value is intangible and must be protected by strong intellectual property regimes to be effectively exploited. Pharmaceutical products constitute one of the most important categories of high technology products.

Among the major requirements of the TRIPS agreement are the following:

• WTO Member States must provide a level of rights equal to those provided in the major global intellectual property treaties administered by WIPO, including the Paris Convention on Industrial Property.

• WTO member states may not discriminate among technologies in providing patent protection, meaning that exceptions to patent protection in many countries for pharmaceutical products must be eliminated.

• WTO member states must provide patent protection for at least 20 years from the date of filing a patent application.

• WTO Member States must provide effective judicial enforcement of intellectual property rights.

• A TRIPS Council was created to coordinate WTO policy in the area of intellectual property rights and to manage the resolution of disputes among states on implementation of TRIPS obligations.

SPECIAL PROBLEMS OF PHARMACEUTICAL PATENTS

Most importantly, unlike industries which produce products requiring expensive and complex manufacturing infrastructures, the patented products of pharmaceutical companies can be easily and cheaply replicated by copiers with little capital investment. Since capital investment in the pharmaceutical industry disproportionally is directed to laboratory research and clinical trials rather than the manufacture of the final product, patent exclusivity is the only effective way to protect and receive a return on that investment.[84]

Patent protection is crucial to the innovative pharmaceutical industry. Innovative companies require the guaranteed period of market exclusivity afforded by patents in order to sustain drug prices, recoup research and development (R&D) expenditures and finance the development of new products.[135]

Unlike other products, however, medicines are required to undergo a strict regimen of tests and evaluations to determine their safety and efficacy before they can be sold commercially. The testing process is rigorous and time-consuming, involving animal and clinical trials of each prospective new drug. Much of the testing takes place after a patent for a drug has been applied for and results in significant lag between the invention of the drug and its sale to the public. Meeting government-imposed regulatory requirements consumes part of the period of patent protection, so that this is shorter for the pharmaceutical sector than for other industries. Innovative companies have responded to this disadvantage by lobbying vigorously for measures to strengthen the patent system and for changes to the regulatory process that would decrease the time involved in obtaining marketing approval for a drug.

CONCLUSION

It is important, in particular, that the scope of patentability be congruent with public health policies, and that governments be aware that unduly expanding what can be patented may distort competition and reduce access to medicines. Patents over minor developments may be effectively used to discourage or block competition, as generic producers, purchasing agencies and consumers, especially in developing countries, generally lack the substantial technical and financial resources needed to challenge wrongly granted patents or defend against infringement claims.

The major concern arising out of these amendments is increased prices of drugs thus creating problems for the poor. Resolving such a problem would not be easy but other regulatory mechanisms could be put in place to control the drug prices. Indian government can make use of price controls, its bargaining power as a large purchaser, and compulsory licenses in the meantime to ensure that the process does not proceed more quickly than is desirable.

Indian pharmaceutical firms may also suffer with the lack of Indian jobs. This fear is by no means far-fetched, but there are lots of reasons to have a faith that Indian industry would be able to compete with global players. Such as an educated, well-trained scientific workforce and a 40 year old R&D base as a backbone of current successful Indian Pharmaceutical industry. Moreover, by passing such reforms that would encourage the development of venture capital, India’s government can make certain that funding will be available for the country’s nascent biotechnology industry, an industry that holds the promise of making significant contributions to India’s economic growth and public health.

REFERENCES


