PATENTS: INDIAN DRUGS AND PHARMACEUTICAL INDUSTRY

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ABSTRACT

Pharmaceutical industry is knowledge based and technology keeps on upgrading itself. The process of innovation is long and time consuming. There is a constant need for upgrading the technology. This results in growing need of protection of innovations. The Trade Related Intellectual Property Rights (TRIPs) Agreement was born to protect the interests of the industry, trade and services.

Although the government has to look at the interest of both the parties i.e. the manufacturers and the consumers, but the need of the poor masses cannot be ignored since they have to depend on the market for purchasing drugs, given the poor service delivery by both the public and the private hospitals. The scope of the ***Patents (Amendment) Ordinance, 2004*** *and* ***the Patents (Amendment) Act, 2005*** *will be tested in the coming days, along with success of the various schemes of the Government of India like the National Rural Health Mission (NRHM).*

Keywords: *Patent, Copyrights*

INTRODUCTION

Technology is inputs in the production process getting transformed into output. Ideas (particularly the innovative ones) improve the technology of production. There are various examples of ideas and technological improvements that can happen. Moore's Law (attributed to the former chairperson of Intel) asserts that the number of transistors that can be packed onto a computer chip doubles approximately every 18 months[i]. There are different attributes of ideas. *Ideas are non-rivalrous (indivisible) unlike most goods (which are tangible).* Suppose, I am consuming an idea, which you too are consuming, then the idea can be termed as non-rivalrous. But *ideas are considered as excludable or partly excludable*. Non-excludability means that once an idea is created everybody can use it; nobody can be excluded. There is always a cost associated initially to develop the idea, which can be termed 'fixed cost'. Once the idea is created it can be replicated and sold without any additional cost. So, *marginal cost of producing every extra unit of idea becomes zero*. Therefore, the firm which takes up the onus of creating and selling ideas should charge zero prices from the consumers, if one follows the principle of marginal cost pricing under perfect competition. But if the firm follows such a rule, then it cannot recover the cost of developing the idea, and can undergo losses. Therefore, it has to keep a price, which can at least recover the cost of developing that idea. So, it has to move away from the principle of perfect competition i.e. marginal cost pricing, and move towards the principle of imperfect competition i.e. price should be greater than the marginal costs. As the firm produces more and more of the idea, the average cost declines and the firm gets *scale-effect*. Due to fixed cost and zero marginal cost associated with the production of idea, there are increasing returns to scale. The institution of patenting, intellectual property rights and copyrights becomes important, to give the original inventor the incentive to create new ideas or to undertake R&D (Jones, 2002)[1].

Intellectual property laws deal with abstract objects, and not physical objects. Intellectual property rights are very much related to the market. They have an important role in constituting markets in information. Given the overtly economic character of intellectual property legislations, one possibility worth investigating is that economic theories, which may or may not be contradictory to one another, provides a justification for enactment of intellectual property rights. These rights can be different from each other in terms of legal detail and character. *A patent monopoly gives the owner rights against the independent discoverer of the same invention, while copyright offers rights against copying but does not prohibit the independent creation of the same work*. From the point of view of economics, property rights must be the best way to ensure that individuals devote sufficient resources to the creation of abstract objects. Intellectual property rights have to be based on the outcome of a cost-benefit calculation from the

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[1] Jones, Charles I (2002): Introduction to Economic Growth, 2nd Edition, WW Norton & Company

point of view of economic rationality. Patent statutes are meant to protect inventions (Drahos, 1996)[2]. *Protection is conditional upon satisfying various criteria of which novelty and inventiveness are two important examples*. According to historical facts, connection between intellectual property, science and economic development is contingent and local rather than necessary and universal. Imperial China for example achieved spectacular outcomes in science without relying on intellectual property rights (Needham, 1969)[3].

Pharmaceutical industry is knowledge based and technology keeps on upgrading itself. The process of innovation is long and time consuming. There is a constant need for upgrading the technology. This results in growing need of protection of innovations. The Trade Related Intellectual Property Rights (TRIPs) Agreement was born to protect the interests of the industry, trade and services.

INDIAN PHARMACEUTICAL INDUSTRY

The Indian pharmaceutical industry has shown satisfactory progress in terms of infrastructure development, technology base and product use. It has shown domestic sales of US $ 4 billion and exports of over US $ 3 billion, during the fiscal year 2004-05, according to the Economic Survey 2004-05. The industry produces bulk drugs belonging to all major therapeutic groups requiring complicated manufacturing processes and has developed **good manufacturing practices** (GMP) compliant facilities for the production of different dosage forms. The **pharmaceutical industry is capable of developing cost-effective technologies in the shortest possible time for drug intermediaries and bulk actives without compromising on quality**, which is realized through the country's strengths in organic synthesis and process engineering. India has gained fame as a low cost producer of antiretroviral and supplier of the same to international organisations and more importantly to the needy patients in Africa.

The R&D effort in India has focused on development of new molecules. Rs. 150 crore has been provided under the **Pharmaceutical Research and Development Support Fund**. A **Drug Development Promotion Board** under the **Department of Science and Technology** has also been set up for the utilization of this fund. India's biotech research is concentrating on areas like vaccines, diagnostics, molecular and cellular biology, cell culture, fermentation and hybridoma technology. Recombinant vaccines (for typhoid, rabies and hepatitis B), HIV 1&2 diagnostics test kit and gene probe test for TB are some of the important areas where research is being carried out.

The number of drugs and pharmaceutical units in India has increased from 1,752 in 1952-53 to 20,053 in the year 2000-01, owing to various institutional changes (and laws), which has been discussed in the latter part of this article.

Government of India is honouring its binding commitment to change the Patents Act 1970 to conform to the **TRIPS (Trade Related Aspects of Intellectual Property Rights)** provisions. In this process, the Act has been amended twice in 1999 and 2002. On 26, December 2004, the Government promulgated the **Patents (Amendment) Ordinance, 2004**, followed by the amended Patents Rules 2005, issued on 31st December. The **Third Amendment to the Patents Act, 1970** was to be tabled in the winter session of Parliament in 2004, but the Government's justification for the Ordinance was that the TRIPs (Trade Related Aspects of Intellectual Property Rights) agreement under the **GATT** signed in 1994, required WTO members to make their domestic patent laws TRIPs compliant by 1st January 2005 or else face retaliatory measures from other WTO members. The main objective of the **Patents (Amendments) Ordinance 2004** was to introduce product patents for food, pharmaceuticals and chemicals, preventing others from manufacturing through different processes, without taking permission from and paying royalty to the patent holder. To make the Patents Act 1970 TRIPS compliant, the erstwhile NDA (National Democratic Alliance) government had carried out, among many others as well, ***two important amendments*—extension of term of patent protection from 7 to 20 years** and **grant of exclusive marketing rights[ii] to patents applicants or "Mail Box"** candidates even before approval of the patents and thus gave them a monopoly over the products ahead of completion of formalities.

One can conclude that the Ordinance is only a replica of the earlier 'Mail Box'[iii] Act. Thus ***(a)*** it simply states in general terms that a patent application has to show that there is novelty and an inventive step involved in the new product. But both the **Indian Pharmaceuticals Alliance (IPA)** and the **Indian Drug Manufacturers Association (IDMA)** have warned against the strategy of 'evergreening' of patents by allowing

[2] Drahos, Peter (1996): A Philosophy of Intellectual Property, Dartmouth

[3] Needham, J. (1969): The Grand Titration.

the filing of patent applications for new forms of older patented drugs and for new uses of older drugs, thereby trying to block the entry of generic drugs into the market[iv]. By allowing the 'evergreening' practice, off-patent drugs used for even common ailments, which are in the generic category could get patented and monopolised. Evergreening is possible because patentability is not defined. ***(b)*** A change in the procedure for filing opposition against a patent application has been made. However, by not making the opposing person/agency a party to the proceedings, the Ordinance, in the name of curtailment of delay in disposing of objection petitions, ensures that patents are by and large granted as a matter of course and denial would become an odd exception. ***(c)*** The clauses related to Compulsory Licensing and Government takeovers of patents have been left as vague as they are due to which the so called safeguard of public interest will in practise be nullified on two counts -- *one*, the procedure for Compulsory Licensing continues to be cumbersome and time consuming, and *two*, the royalty to be paid to the patent holder has no fixed ceiling (Kealay, 2005)[4].

The Patents (Amendment) Bill, 2005, introduced in the Parliament in March, 2005 with the objective of making the Patents Act compatible with India's international obligations, particularly under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) had the benefit of detailed discussion in both the Lower and Upper Houses, pertaining to issues like patentability of micro-organisms and the definition of 'pharmaceutical substance' to mean "a new chemical entity (NCE)" or "new medical entity (NME)".

EARLIER PATENTS SYSTEM

Production of modern medicines by domestic units started with the setting up Bengal Chemical and Pharmaceutical Works in 1892, which was followed by the establishment of Alembic Chemical work in 1907 and Bengal Immunity in 1919. Before the existence of Patents Act 1970, the patent law framed by the Britishers viz. **Patents and Design Act 1911 product patent system** was being practised. The prices of medicines and their availability were a serious issue during those times. According to the **Report of the American Senate Committee** headed by Senator Kefauver, the prices of antibiotics and other medicines sold by the MNCs in India used to be the highest in the world. During that period 85% of the medicines available in India were produced and distributed by the Multi National Companies (MNCs). **Hindustan Antibiotic Ltd. was founded in 1954**, in the first Five Year Industrial Policy Plan (1950-1955), with the technical assistance of the **WHO (World Health Organisation)** and **UNICEF (United Nations Children's Fund)**. Its goal was to reduce the country's dependence on external antibiotics drug supplies and provide supplies at lower prices than those posted by NMNCs. In the same way, the Government of India promoted drug production from domestic raw materials. Thus, local units started to produce sulfamides and anti-infectious drugs. In the **Second Five Year Plan (1955-1960)**, the company **Indian Drugs and Pharmaceuticals Ltd.** was set up to help in the production of low cost drugs with the technical help of the then **USSR** (Felker, 1997)[5]. Process patent system was introduced with short term of patent for only 5-7 years, with the enactment of Patents Act 1970. The licenses of right system were also provided to guarantee effective role of the domestic industry. Over a period the role of the domestic enterprises increased tremendously and virtually 85% of the pharmaceuticals produced and distributed in the country are being provided by the domestic enterprises (Keayla, 2005)[6]. Since the 1980s, the industry has grown rapidly due to the enactment of the Patents Act 1970 and announcement of the **Drug Policy 1978** (Lanjouw, 1997)[7].

The **Patents Act 1970**, India, had been conducive to the growth of pharmaceuticals and other industries, since it provided process patents (and not product patent) for pharmaceuticals and agro-chemical products in addition to food substances and other chemical based products. **Justice Rajagopal Ayyangar Committee Report 1958** provided a techno-legal-developmental critique

[4] Keayla, B.K. (2005): Patents (Amendment) Ordinance 2004: A Critique, Third National Colloquium on Economic and Social Implications of the New Patent Regime, presentation at the India International Centre 1, February.

[5] Felkar, G., Choudhuri, S., Gyorgi, K. and M Goldman (1997): The Pharmaceutical Industry in India and Hungary: Policies, Institutions and Technological Development, World Bank Technical Paper No. 392

[6] Keayla, B.K. (2005): Patents (Amendment) Ordinance 2004: A Critique, Third National Colloquium on Economic and Social Implications of the New Patent Regime, presentation at the India International Centre 1, February.

[7] Lanjouw, J.O. (1997): *"The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and the Suffering"*, Centre Discussion Paper No. 775, Economic Growth Centre, Yale University.

of the well accepted fundamental grounds on which the limited patent monopoly was being granted by all countries as part and parcel of their political economies—the crucial rationale being that patents and their limited monopoly rights are ultimately granted and given legal protection for making them available for national development by encouraging potential inventors for undertaking 'R&D of possible industrial use' and consecutively giving rise to viable technological-industrial development. The two Enquiry Committees namely **Bakshi Tek Chand Committee-Patent Enquiry Committee (1948-50)** and **Justice Ayyangar Committee-Patents Revision Committee (1957-59)**, recognised that although India had a patent system in some form or the other, the country did not derive much benefit from the previous or the then existing systems (Damodaran, 2005)[8]. The first investigation into the pharmaceuticals market in a Third World country was carried out by the **Hathi Committee**, which was formed in February, 1974 by the Government of India and chaired by Jaisukhlal Hathi. One of its principal conclusions was that brand names were responsible for the large number of unnecessary and often irrational formulations on the market [9].

The introduction of the **MRTP Act** and the **FERA** reduced the level of foreign direct investment (FDI) in the pharmaceutical sector in the 1980s. However, with the adoption of trade liberalisation measures, the limit for automatic approval of FDI was first raised from 40 to 51 percent and subsequently to 74 percent and in 2001, it was raised to 100 percent.

HEALTH SITUATION IN INDIA

The major cause of concern in the health area in India is the vast population, which now exceeds 1,000 million. HIV/AIDS, which has emerged as one of the most serious public health problems in the country, has made countless victims. In mid 2001, the total number of HIV cases was around 3.97 million, which has now reached the level of more than 5 million. HIV/AIDS is also accompanied by social stigma, which leads to other social and psychological problems. Because of this reason, detection of such cases and timely treatment becomes rather difficult. To overcome this problem, creating community awareness is being emphasized. To eliminate leprosy, a rigorous media campaign was launched due to which the prevalence rate declined from 57 % per 10,000 population in 1981 to 3.74 cases per 10,000 population in March 2001. The objective was to reach elimination at national level by 2004. As regards activities under the revised national tuberculosis control programme the population coverage increased from 120 million to more than 440 million in 2001 with the help of a World Bank assisted project. The government is planning to expand its coverage to 700 million population[11].

Diseases like smallpox and Guinea-worm disease have been eradicated from the country, and polio is on the edge of being eradicated. Leprosy, Kala-azar and Filariasis are expected to be eliminated soon. There has been a considerable drop in the total fertility rate and infant mortality rate. The success of these initiatives is seen in the progressive improvement of many demographic /epidemiological and infrastructural parameters over time as reflected below.

INDIA HEALTH SCENARIO: ACHIEVEMENTS BETWEEN 1951 AND 2000

India: Health Policy

The main objective of the **Health Policy** announced by the **Government of India in 2002** is to achieve an acceptable standard of good health for the people. The goal would be to increase access to decentralised public health system by establishing a new infrastructure in deficient areas, and by upgrading the existing infrastructure. Importance has been given to ensure a more equitable access to health services across the social and geographical expanse of the country. Emphasis will also be given to increasing the aggregate public health investment through a substantially increased contribution by the Central government. It is expected that this initiative will be to strengthen the capacity of the public health administration at the state level to render effective service delivery. The contribution of the public sector in providing health services would be significantly enhanced, particularly for the population group, which can afford to pay. Primacy will be given to preventive and first-line curative initiatives at the primary level through

[8] Presentation by Mr. AD Damodaran in February, 2005 at the India International Centre on the occasion of Third National Colloquium on Economic and Social Implications of the New Patent Regime.

[9] Hathi Committee, *Report of the Committee on the Drugs and Pharmaceutical Industry, Ministry of Petroleum and Chemicals*, Government of India, New Delhi, April 1975. For a more detailed study on the current state of affairs regarding patents, **see:** Report of the Technical Expert Group on Patent Law Issues, December, 2006 (aka Mashelkar Committee Report), or go to: http://patentoffice.nic.in/ipr/patent/mashelkar_committee_report.doc.

increased allocations. Emphasis will be laid on rational use of drugs within the allopathic system.

Comparison of International Prices vis-à-vis Indian Prices: Some Selected Products Retail Prices in India and Wholesale Prices in Other Countries Considered (Prices converted into Indian Rupees)

Drugs, Dosage and Pack	Prices in India (Rs.)	Prices in Pakistan (Rs.)	Prices in Indonesia (Rs.)	Prices in UK (Rs.)	Prices in USA (Rs.)
Anti- infectives					
Ciproflaxin HCL 500 mg 10's tabs	29.00	423.86	393.00	1185.70	2352.35
Times Costlier		**14.55**	**13.55**	**40.89**	**81.12**
Norflaxin 400 mg 10's tabs	20.70	168.71	130.63	304.78	1843.66
Times Costlier		**8.15**	**6.31**	**14.72**	**89.06**
Ofloxacin 200 mg 10's tabs	40.00	249.30	204.34	818.30	1973.79
Times Costlier		**6.23**	**5.10**	**20.45**	**49.34**
Cefpodoxime Proxetil 200 mg 6's tabs	114.00	357.32	264.00	773.21	1576.58
Times Costlier		**3.13**	**2.32**	**6.78**	**13.83**
Anti-Ulcerants					
Diclofenac Sodium 50 mg 10's tabs	3.50	84.71	59.75	60.96	674.77
Times Costlier		**24.20**	**17.07**	**17.42**	**192.79**
Rantidine 150 mg 10's tabs	6.02	74.09	178.35	247.16	863.59
Times Costlier		**12.31**	**29.63**	**41.06**	**143.45**
Omeprazole 30 mg 10's cap	22.50	578.00	290.75	870.91	2047.50
Times Costlier		25.58	12.92	38.71	91.00
Lansoprazole 30 mg 10's caps	39.00	684.90	226.15	708.08	1909.64
Times Costlier		**17.56**	**5.80**	**18.16**	**48.97**
Cardiovasculars					
Atenolol 50 mg 10's tabs	7.50	71.82	119.70	NA	753.94
Times Costlier		**9.58**	**15.96**	**--**	**100.52**
Amlodipine Besylate 5 mg 10's tabs	7.80	200.34	78.42	338.28	660.21
Times Costlier		**25.68**	**10.05**	**43.37**	**84.64**
Anti-Viral Fungal					
Zidovudine 100 mg 10's caps	77.00	313.47	331.65	996.16	895.90
Times Costlier		**4.07**	**4.31**	**12.94**	**11.63**
Lamivudine 150					
Zidovudine 300 mg 10's caps	274.00	NA	NA	4767.02	4988.62
Times Costlier		--	--	17.40	18.21
Anti-histamine					
Ceterizine 10 mg 10's tabs	6.00	35.71	57.50	262.19	927.29
Times Costlier		**5.95**	**9.58**	**43.70**	**154.55**
Anti-Anxiolotics/ Psychotics					
Alpramazoo 0.5 mg 10's tabs	7.00	160.57	31.05	NA	446.81
Times Costlier		**22.94**	**4.43**	**--**	**63.83**
Fluxetine 20 mg 10's caps	25.80	444.53	143.40	395.79	1416.42
Times Costlier		**17.23**	**5.56**	**15.34**	**54.90**
Anti-Cancer					
Boposide 100 mg injection	190.00	554.69	242.90	1217.43	6210.30
Times Costlier		**2.92**	**1.28**	**6.41**	**32.68**
Cholestrol Reducer					
Atorvastatin 10 mg 10's tab	39.00	NA	565.95	537.74	1102.92
Times Costlier		**--**	**14.51**	**13.79**	**28.28**
Simvastatin 10 mg 10's tabs	35.00	283.05	187.00	537.74	1149.79
Times Costlier		**8.09**	**5.34**	**15.36**	**32.85**
Antiasthmatic					
Salmeterol 25 mcg					
Fluticasone 50 mcg inhaler	210.00	NA	782.65	1628.25	NA
Times Costlier		--	3.73	7.75	--
Urology					
Sildenafil Citrate 50 mg 4's tabs	48.00	NA	1356.93	1614.89	1744.93
Times Costlier		--	28.26	33.64	36.35

Conversion rate of exchange considered

Increased access to tried and tested systems of traditional systems of traditional medicine will be ensured. Private players will also be included to play a key role through public-private partnerships (PPP). NRHM (National Rural Health Mission) is the driving vehicle for giving effect to the mandate of the National Common Minimum Programme. The Second phase of Reproductive and Child Health (RCH-II) Program, launched on April 1, 2005 for a period of 5 years, is trying to improve the performance of family welfare in reducing maternal and infant morbidity and mortality, and unwanted pregnancies, and thus lead to population stabilization[10].

CONCLUSION

Although the government has to look at the interest of both the parties i.e. the manufacturers and the consumers, but the need of the poor masses cannot be ignored since they have to depend on the market for purchasing drugs, given the poor service delivery by both the public and the private hospitals. The scope of the **Patents (Amendment) Ordinance, 2004** and **the Patents (Amendment) Act, 2005** will be tested in the coming days, along with success of the various schemes of the Government of India like the National Rural Health Mission (NRHM).

ENDNOTES

[i] Gordon Moore made his famous observation in 1965, just four years after the first planar integrated circuit was discovered. The press called it "Moore's Law" and the name has stuck. In his paper *Cramming more Components onto Integrated Circuits* in Electronics, Volume 38, No. 8, April 19, 1965, Moore observed an exponential growth in the number of transistors per integrated circuit and predicted that this trend would continue. Through Intel's relentless technology advances, Moore's Law, the doubling of transistors every couple of years, has been maintained, and still holds true today.

[ii] **Meaning of Exclusive Marketing Rights:** EMRs grants exclusively to an international company to market a product in the field of pharmaceuticals exclusively in the Indian market. The Patents (Amendment) Act grants EMRs for 5 years. Thus, the Act is a prelude to putting in place an updated product patent regime in India in line with the WTO (World Trade Organisation) requirements (which envisage allowing product patents from 2005). There are basically three conditions on which EMRs are granted: the new chemical entity should be filed after January 1, 1995: the product should not have been marketed earlier in India; and compulsory licensing wherein the government could reserve the right to allow three or four companies to license and manufacture the same product in case of a major demand-supply shortage. Thus, EMR is almost like a product patent. The critical difference is that the EMR is issued in lieu of the government screening the company's patent legislations. So it could mean that two companies with patent application for similar drugs could be granted EMRs.

[iii] **Meaning of Mailbox:** Mail Box is a box in which all the applications for the pharmaceutical and agricultural chemical products will be submitted. This box will be opened in 2005. Till that time no examination of applications will be possible.

[iv] Examples of **Charges of Patenting Trivial Changes**

Case 1: *"Substantially Pure" (Fexofenadine Hydrochloride)*

- Patent (US 4,254,129) was granted to Aventis in 1979.
- Aventis obtained second patent (US 5,578,610) in 1996 claiming 'substantially pure compound' which was indeed the product on the market, extending its patent life to 2006.
- This is a case where first the patent is obtained for the compound without any reference to purity. Thereafter, a patent is sought for a 'substantially pure' compound. The second patent becomes a hurdle for generic products, as they are also 'substantially pure'.
- Now, if the legislation were to permit patenting of trivial changes (substantially pure), fexofenadine hydrochloride would become eligible for product patent as a post-1995 molecule.
- Total sales of product in India: Rs. 30 crore.

Case 2: *"Particle Size" (Oxcarbazepine)*

[10] For more detail, go to: http://indiabudget.nic.in, (Economic Survey 2006-07).

- Patent (US 3,642,775) was granted to Novartis in 1970.
- Novartis obtained second patent (US 20,030,190,361) in 2003 claiming 'particle size' of certain specifications.
- This is a case where first the patent is obtained for the compound without any reference to particle size. Thereafter, a patent is sought for a 'particle size' compound. The second patent becomes a hurdle for generic products.
- Now, if the legislation were to permit patenting of trivial changes (particle size), oxcarbazepine would become eligible for product patent as a post-1995 molecule.
- Total sales of product in India: Rs. 16 crore.

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4. Hathi Committee, *Report of the Committee on the Drugs and Pharmaceutical Industry,* Ministry of Petroleum and Chemicals, Government of India, New Delhi, April 1975
5. Jones, Charles I (2002): Introduction to Economic Growth, 2nd Edition, WW Norton & Company.

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