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Indian Pharmaceutical Sector in the Regime of Intellectual Property Rights

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ABSTRACT

Philosophical attitudes of Intellectual Property Rights [IPRs] have historically ranged between two extremes-on the one hand we may distinguished the co called natural rights view of the IPRs, best encapsulated in the Hegelian dictum that "an idea belongs to its creator because the idea is a manifestation of the creator's personality or self [Hughes 1988], on the other , there is a unilitarian view stressing the role of innovations in promoting industrialization by local diffusion of knowledge [Anderfelt, 1971 and Machlup, 1958]. National IPR laws usually embody aspects of both views, with 'strong' IPR regimes setting greater store by the natural right view point and 'weak' regimes emphasizing the other end of the spectrum.

INTRODUCTION

The Uruguay Round witnessed a marked polalisation of views on IPRs with the industrial west spearheaded by the US, taking up the cudgets for strengthening IPRs globally and third world countries offering spirited resistance to the US initiatives. US concerns about IPRs have found outlets both in its bilateral relations with other countries as well as its initiatives on multilateral fora such as OECD and GATT. The US led initiatives in GATT have largely succeeded in establishing a new world order, more attuned to the advanced countries view point and under such circumstances as to whether the bilateral initiatives have become superfluous, especially in view of their questionable conformity to the GATT legal framework [GATT, 1989].

The main bilateral initiatives are (i) Section 337 of the US Tariff Act of 1930 as amended in 1988, (ii) Section 301 of the US Trade Act of 1974 as revived in 1984 and 1988, and (iii) The Super 307 and Special 301 mechanism created by the Omnibus Trade and Competitiveness Act of 1988. These sections provide for various measures of retaliatory action by the US on the trade front mainly, as a countercheck to violations of IPRs in other countries and have been invoked quite regularly (mostly against LDCs) since their coming into effect [UNCTAD 1990, and Kalinsky 1989]. The negotiations which started between America and LDCs in 1980s culminated into Uruguay Round. The final outcome represents a definite victory for the industrialized countries viewpoint and all indications are that all the LDCs are going through a prolonged and painful period of adjustment in their Intellectual Property Rights.

The Uruguay Round began in April 1986 and ended with Dunkel proposals signed by 117 countries in April 1994. Out of the seven areas covered under the Dunket Draft, Trade Related Intellectual Property Rights [TRIPs] is the most controversial issue which is aimed at a creating a new uniform system of patents all over the world. While the prime impetus to strengthening global IPRs in the Uruguay Round has cause from the pharmaceutical sector in industialised countries, patent protection is of relatively recent origin [U.K in 1949, France 1960, Germany 1968, Japan 1976, Switzerland 1977, Italy 1978, Sweden 1978 and so on]. In the significant part of the third world, patent protection for pharmaceuticals is weak, with some countries (like India) providing only process patents, others (like Mexico and Zambia) no patents at all. This weak protection is alleged to have imposed substantial losses in pharmaceutical industries in the developed world-according to the estimates of US Pharmaceutical lobby [PhRMA, 2002], it currently loses more than $ 1.7 billion annually because of India's insufficient intellectual property protection.

It is a well documented fact that IPR protection is of far greater significance in the pharmaceutical sector than other sectors of the economy because the development of new products is very expensive and regulatory approval takes eight to ten years (in US) and also because imitation is considerably easy with easy short invitation lags.

The debate on Intellectual Property Rights in the pharmaceutical sector have assumed significant importance because of its socio-economic relevance especially among developing countries. The major steps relating to TRIPS as given in Dunkel Draft Text that affect Indian Drug Industry are as under :

i. The process patent gets replaced by the product patent.
ii. The patent term gets extended to 20 years.
iii. The import of patented product is considered equivalent to working of patent.
iv. In case of alleged infringement of the patent, the burden of proof shifts to the accused.

INDIAN PHARMACEUTICAL INDUSTRY AND TRIPs

Drugs and pharmaceuticals has always been regarded as "essential Product" in India and one of our former prime ministers was probably echoing this popular sentiment when she declared at a WHO meeting that "medical discoveries will be free of patents and there will be no profiteering from life and death" (quoted by Gadbaw and Kenny, 1988). As such drug prices have been under heavy surveillance since 1962 when Drug Price control order [DPCO] was passed. About 74% of the durgs and formulations were under perview of DPCO and thus subject to price control. The relatively low prices of drugs in 1970's and 1980's compared to the world level were due to these strict price control. While discussing Indian Pharmaceutical Industry [IPI], three points of time are important. These are : 1900-1970, 1970-90 and the decade of 1990's.

The period 1900-1970 signified the dominance of multinationals in this field. Most of the firms were engaged in repacking the formulation produced by the multinationals. The Patent Act . of 1911 was in practice. Hence the indigenous firms were legally prevented from manufacturing most of the new drugs introduced by the MNCs. Drugs were mainly imported from abroad. However, the second world war and the introduction of Sulfa drugs and Penicillin gave an impetus to Pharma industry. By 1952, a few drugs like tetanus anti-toxin, PAS and indocblorhydroxy quinoline were produced in India from their basic stages [Narayana, 1983]. The setting up of public sector units and technical institutes contributed to the growth of the industry. Still, the import content of the basic drugs was high due to which drugs prices in India were the highest in the world.
The second period of 1970-90 is very significant for IPI since the Patent Act of 1911 was amended in 1970. The Patent Act 1970 provided process protection. This brought revolution in the IPI in India. By 1972, over 100 essential drugs covering a wide spectrum of therapeutic-droups like antibiotics, Sulfa drugs, anti-leptrotic drugs, analgesics, antipyretics, vitamins, tranquillisers, photochemicals and various other pharmaceutical chemicals were produced in India [Narayana, 1983]. Table 1 shows the increase in the production of bulk drugs and formulations before and after 1970's.

Table 1: Value of Production of Bulk Drugs and Pharmaceutical Formulation (Rs. in Cr.)

YEAR	BULK DRUGS	FORMULATIONS
1950-51	2	8
1965-66	18	150
1975-76	113	544
1980-81	240	3148
1991-92	900	4800
1995-96	1822	9125
199-200	3777	15850
2000-01	4344	17843

Source : 39th IDMA Annual Publication 2001. IDMA Bulletin XXXII [2001] World Bank Technical Paper No. 392.

Besides this the export of drugs both to developed and developing countries increased from Rs. 8.46 cr. in 1970 to Rs. 6631.0 cr in 1990-00. The limit of Foreign Direct Investment [FDI] in IPI also increased from 40% to 51% and later to 74% in 1997.

As most of the firms are engaged in the production of finished formulations, investment in research and development [R & D] is low. Due to the decline of public sector the investment in R & D from public sector has gone down. The investment in R & D in 1999-00 is just 2% of the sales turnover [Rs. 32,000 lakh] in public sector and just 0.35% of the sales turnover in the private sector [Malhotra, 1989].

India accounts for 8% of the world's pharmaceutical production and is fifth largest country in the world after the US, Japan, Europe and China in terms of volume of production. This all shows the heterogeneous nature of IPI in India.

IMPLICATIONS OF TRIPS FOR INDIAN IPI

India as a signatory of W.T.O. had to make several amendments in the existing Patent Law to provide for product patent. Patent will be granted both for products and processes for all the inventions in all fields of technology, which includes pharmaceutical sector [In India only the process patent was existing]. The patent will be for 20 years from the date of application [Compared to seven years under the 1970 Act]. In the case of dispute the responsibility to prove lies with the accused [in 1970 Act., the responsibility is with the patent holder].

A bill was introduced in parliament in December 1999 to bring about amendments in Indian patent Act 1970. The bill was then revised by joint parliamentary committee [JPC] and it submitted a revised bill with a few changes in December 2001. This bill has been approved by the parliament in May 2002. The Exclusive Marketing Right [EMR] system has not yet been abolished. A third amendment will be necessary by the end of 2004 to replace EMR system. In order to implement these policy changes India has been allowed a transition period of 5 years that will end on Jan. 1, 2005.

Within India mixed reactions prevails regarding to product patent. Some argue that monopoly status to few will restrict the competition and adversely affect R & D and new product development in the country. This will also lead to high prices of drugs and medicines will be inaccessible to majority of population. But another segment of the industry says that TRIPs allow some level of flexibility and a right mix of TRIPs along with existing policy guidelines will be favorable to the country [Watal, 2001 & Cullet, 2001]. In view of the problems faced by LDCs in the health sector, Doha declaration is very important which recognizes the rights of member countries to protect public health.

DOHA DECLARATION ON HEALTH

Doha declaration is a direct consequence of the multiple controversies concerning patents in health sector, in particularly in the context of HIV/AIDS epidemics. It is recognized by now that developing countries which already face constraints to access to medicines due to lack of resources and insufficient health infrastructure; will be in grave difficulty due to new patent regime. A country's right to protect public health gets severaly restricted due to TRIPs agreement. USA and South Africa were virtually on the urge of trade dispute due to a South African law which grants its citizens access to affordable, generic forms of HIV/AIDS drugs. Point to remember is that nearly 70% HIV/AIDS patients live in Sub-Sahara Africa. Attempts to open up access to potential life saving medicines have been met with economic pressures by the pharmaceutical sector, threats of trade sanctions and political arming by developed countries.

The Initiator of TRIPs America too was in trouble after Anthrax attackes in the USA following 11 September, 2001 attack on the US. The US government threatened Compulsory licensing [CL] for the Bayer antibiotic Ciprofloxacin (Cipro). Canada too followed America and it ordered a generic drug manufacturer to produce Cipro in violation of Bayer's patent. The pharmaceutical industry accused the government of violating its own patent laws.

Such experiences led America and other developed countries to recognize that developing countries face a number of crippling public health crises and "TRIPs should be interpreted in a manner supportive of a nations right to protect public health and access of medicines to all". This strengthens the position of the countries that want to take advantage of the existing flexibility within TRIPs. In other words, the declaration does not open new avenues within TRIPs but confirms the legitimacy of measures seeking to use to the largest extent possible the inbuilt flexibility found in TRIPs.

The declaration focuses mainly on questions relating to the implementation of patents, such as compulsory licensing. Compulsory licensing has long been used as a tool to Regulate the exclusive rights conferred by patents. In other words, patent should not creat a situation where a protected medicine in not available to the public because of non-health related factors. Indian Patent Act 1970 provided compulsory licensing and licenses of right. The TRIPs agreement has not done away with the notion of compulsory licensing but provides a more restrictive frame work that the current regime in force in India. The recognition in the Doha Declaration that TRIPs member states can use the flexibility provided in the agreement and can, for instance, determine the grounds on which compulsory licenses are granted must thus be understood in the context of a generally increasing restrictive international patent regine. The declaration has been hailed as a major step forward in the quest for making the TRIPs agreement more responsive to the needs of the

developing countries and more specifically all individuals unable to afford the cost of the patented drugs. In fact, it addresses a number of important issues related to the implementation of medical patents. The Doha Declaration remains an important instrument in India for India was among the most vocal developing countries at the ministerial conference in putting forward developing country's interests. Doha has also allowed developing countries not to provide patents in pharmaceutical sector until 2016. The developing countries can use the in built flexibilities found under TRIP's to their advantage and can mitigate the adverse affects of the new patent regime.

SUGGESTIONS FOR INDIA AND DEVELOPING COUNTRIES

a. Under Article 27(1) of the TRIPs agreement patents will have to be provided for inventions, which are "new, involve an inventive step and are capable of industrial application". This provides some flexibility. A developing country like India can interprete these terms so as to restrict the number of patents [Correa, 2000 & Abbott 2001]. New dosage forms, formulations, combination of existing molecules etc. : patents should not be given to these.

b. Due to economic reforms the public sector is withdrawing from the production of medicines. This has reduced investment in Research and Development. Investment in R & D is important from the point of view of the patentability of new drugs. Developed countries are engaged in research that concerns their people, e.g., melanoma, Leukaemia, Cancer etc. However, third world deseases such as Malaria, Tetanus and Lymphatic Filariasis have so far not attracted their attention. Developing countries should invest in this area. This will help them inventing new drugs.

c. Article 31 of the TRIPs agreement provide limited exemption to patent rights. Developing countries can amend their patent laws which allow compulsory licensing under many circumstances discussed under the heading "non-commercial use", "government use", "national emergency etc.

d. Developing countries should also consider the option of production of drugs using process capabilities. Also, since, most innovations are developed on earlier innovations, firms that can reverse engineer the patented product, can cross license the product that is subsequently developed. This can reduce the competition as well as prices.

e. Developing countries are always in resource crunch. With scare resource, these countries can produce off patented drugs or can produce drugs which are specified for developing countries and are much in demand. Most drugs are short in supply, but the technology to produce such drugs however is already available among producers. Given the fact that many of the developing countries do not have adequate production facilities, production of essential and off-patented drugs by units will open up a wider generic market.

f. Doha declaration is very important in the sense that developing countries can make suitable changes in their patent laws.

g. The I.P. system can help to establish differential prices for drugs for developing and developed countries. A policy of lower prices in LDCs and high prices in developed countries can be adopted.

h. The developing countries should also improve health infrastructure in their countries to improve access to medicines and health care.

i. The countries should use Bolar exceptions. Bolar exceptions permites the pre-market testing of generic products during the patent term so that they can be marketed immediately upon expiry of the patent.

Given the importance of the issues at stake, the debate concerning the impact of medical patents on access to drugs is unlikely to subside in the near future.

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