PATENT REGIME – EFFECT ON COMMON MAN*

The recent changes in Indian Patent Law have resulted in a resumption of the debate on the issues of product patents and their impact on a common person, which was first started in the early part of 1990's. One of the important issues that has been raised, and needs to be addressed is whether product patents would result in an increase in pharmaceutical prices, adversely affecting healthcare concerns in a developing country like India or not.

Till 1970, the law on patents, in India, was a colonial legislation, aimed at protecting the trading and manufacturing interests of that era, which were predominantly foreign. It is a fact that at the time of independence, in 1947, a substantial number of patents were held by multinationals. The law then in force namely, the Indian Patents and Designs Acts, 1911 allowed product patents, in all areas of technology and, for a term of 16 years from the date of filing.

The Patents Act, 1970, removed any form of product patent protection in three areas – pharmaceuticals, agrochemicals and food. Only process patents were permitted. The Parliament further restricted the term of patent, in respect of patents relating to drugs and foods to seven years from the date of filing in view of the social impact of such patents. Product patents were permitted in all other areas of technology without any restriction, for a full term of 14 years from the date of filing.

The patent system exists, essentially, as a compromise between the need to encourage and promote innovation and the need to prevent unjust monopoly. The result of a patent regime, favourable to domestic industry, resulted in a tremendous growth in the pharmaceutical industry in India. This was further emphasized in the Drug Policy announced in 1978. The 1980's, as I learn, saw a sudden boom in investment in the areas of bulk drugs. Indian companies had started providing most of the bulk drugs required in the country at a far lower cost than the cost of importation of bulk drugs made by multinationals. This resulted in its own set of disadvantages, including sickness in several bulk drug units due to excessive supply.

India's commitment to implement the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of GATT/WTO required three sets of amendments to the country's Patents Act. The first amendment was introduced in 1999, to put in place a mechanism for accepting product patent applications covering pharmaceutical and agricultural chemicals from January 1, 1995 (better known as the Mail-Box Provisions) and to provide exclusive marketing rights, if certain conditions were fulfilled. The second amendment was introduced in 2002 to bring the Indian Patents Act into conformity with all provisions included in Section 5 of the TRIPS Agreement relating to patents, barring a solitary exception. This exception, *viz*, introduction of product patents in the area of chemicals, pharmaceuticals, agriculture and food, is the principal subject matter of the third amendment, which has recently been made.

The real issue – whether the drugs would be affordable to common man, seems to have missed the consideration and the attention it deserves. In the entire debate on the impact of product patents on pricing and drugs, it has not, so far been, seen on whether the favourable patent regime prevalent earlier, did in-fact result in a reduction, or status quo in drug prices. The change in the global trade scenario and the economic compulsions of this changing scenario have

culminated in India becoming a signatory to the GATT and thereby subject to the TRIPS section, thereof.

In order to fulfill its international commitments, a system has been introduced where an applicant can now get patent protection in almost all the aspects of drug development – from molecules and processes going upto sequences. Undoubtedly, it is a big jolt to the pharma industry, but the question is, 'who is going to bear the brunt?' The experts feel that the price impact is likely to fall on consumers of the new regime and this is likely to be between Rs. 150 crores and Rs. 4,000 crores. For multinationals, the impact may not be so serious. In so far as Indian companies are concerned, they would not be able to release less expensive generic version of drugs.

*The Statement of Objects and Reasons appended to the Patents (Amendment) Bill, 2005, which has recently been introduced in the Rajya Sabha on 24*th March, 2005, takes note of adverse impact on the production and availability of drugs and medicines for the common man and the poor countries. The problem is going to be serious for the developing countries where a large number of population, suffering from killer diseases like AIDS and HIV or malignancy, would not be able to afford the prohibitive prices and would simply be deprived of treatment by such patented drugs. Even senior citizens, in developed countries, may have to move to neighbouring countries for availing life saving drugs and treatments.

The Statement of Objects and Reasons, appended to the Bill, holds out certain hopes. It says that the Bill has been so designed as would take advantage of certain beneficial provisions contained in Doha Declaration on Public Health, according to which the TRIPS Agreement does not prevent the member countries from having measures to protect public health and in particular, to promote access to medicines for all. The SOR also claims that inspite of introduction of Product Patent System for Drugs and Medicines, the fundamental rights of citizens guaranteed by Articles 14, 19 and 21 of the Constitution are not taken away, rather they are ensured. Also, care has been taken not to prevent or interfere with the obligation of the States under Directive Principles of State Policy to protect, promote and improve living and health standards of the people.

The debate generated is welcome. I hope this Seminar would notice and critically analyse the shape of events to come from very many angles. From the point of view of common man and the business industry, the critical issue of relevance, is the availability of products within the reach of common man. From the point of view of the lawyers and judges, much would depend on how the legal system works under the patent regime, how the matters as to registry of inventions are dealt with and how the courts adjudicate upon and administer the law. Issues, as to pre-grant and post-grant opposition of product patents, are going to generate a lot of pressure on the regulatory and adjudicatory system. It may appear that the current system of patenting is undoubtedly favourable to the multinational companies, as they are apparently the proprietors of most of the technologies. The system has dropped the problematic issue into the lap of the Indian companies to accept and advance their own indigenous Research and Development and introduce their own products.

Certain key issues of concern have arisen in the light of the recent amendments. The first and the prime question is the availability of essential drugs, specially the life saving drugs, to the under-developed and developing countries and to senior citizens and also to not so affluent persons even in the developed countries; secondly, the pharmaceutical companies mainly target the urban population and do not reach out to the rural segment; thirdly, the pricing policy, in drugs and medicines manufacturing industries does not necessarily bear a correlation between

the actual manufacturing cost and the price; fourthly, very few understand and realize that the philosophy of the patent system is not to create perpetual or unjust monopolies; it is meant to encourage inventions and innovations while protecting social interest as well.

Co-related issues also arise. Can the alliances, partnerships, tie-ups or mergers, with strategic planning, enable the domestic pharmaceutical industry to meet the challenges posed by resurgent multinational companies? Can the cost factor be controlled by the government, stepping in through extending liberal financial assistance, for the purpose of research and development either within the government or academic institutions or domestic pharmaceutical industrial houses?

Economic reforms in the country cannot be planned in isolation without considering the reciprocal impact of the patents regime. One such example is the introduction of Value Added Tax. Yesterday's newspapers have highlighted the partial rollback by Delhi Governmentm making an announcement that all life saving drugs and devices, certain vaccines, medical devices and anti T.B. drugs, as also Ayurvedic and Unani medicines are to be exempted from Value Added Tax.

Perhaps, the solution lies in providing adequate safeguards in terms of licensing provisions and strict drug pricing control mechanisms to prevent, creation of unjust monopolies, at the cost of health safety measures. Negating product patents of pharmaceutical products may be counter productive as the domestic industry may feel satisfied merely by replicating at a lesser cost and maintaining its prices rather than involving into research and development and facing competition.

At the end, the whole issue bails out to the need for striking a judicious balance between international treaty obligations, protecting indigenous industry, encouraging research and development and the realities in life of the common man.

As the competition intensifies in the market, more and more disputes over proprietary rights, ownership of patents, market access and pricing will arise, which would multiply in proportion with the competition intensifying in the market. Not only the business and industry and the consumer activists but also the judiciary and the lawyers have to be well informed and innovate. The new regime has set forth challenges before us. The choice is ours. We can gear up to derive the maximum benefits or we can sit silent and lose all that we have gained so far. The age old saying of survival of the fittest has once again assumed relevance and significance. In this background, the Seminar of the day is welcome as a service to the society and the nation. Discussions and deliberations on the Patent Law as it stands today and the amendments, recent and upcoming, shall help the Government in identifying problematic provisions and finding out solution, in the interest of the common man and the national economy.

* Inaugural speech delivered on the occasion of the Seminar on 'Product Regime – Effect on Common Man' on 15th April 2005, at New Delhi.