Intellectual Property Rights and the Indian Pharmaceutical Industry*

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Summary - The genesis of the Indian Patents Act 1970 is outlined. The expectations of the Indian Pharmaceutical Industry from the Act are described. Need for assessing the impact of the Act, particularly on the pharmaceutical industry of the country, is stressed. The Act having the shortest validity period of any patent in any country in the world, has probably caused a decline in the patent filing for pharmaceuticals. The type of patent system needed for the country is analysed. Recent developments related to patent laws in different countries are described. The Indian dilemma, whether to continue with a diluted patent act or move towards strengthening of intellectual property laws in line with many other countries of the world, is presented.

The recent raging controversies on the proposed Dunkel proposals at the Uruguay Round of Talks for amendments to the prevailing intellectual property laws of several developing countries, including India, to make them acceptable and reasonably consistent with those of the developed world continue to attract the attention of the concerned public, media, industry and policy makers in India. There have been several, often times, diverse opinions of matters of fact and more often on matters of interpretation of these proposals per se. Before these are discussed in detail, it is important to reaffirm our ideological support to the right to intellectual property and to the system of incentives and rewards to investors, which patents represent. This assertion is amply supported by the fact that we do have a patents act, even for food, drugs and medicines, however, weak and controversial. On the other hand, it is generally contended that the exclusivity to markets afforded by the patents system should not be used as an instrument of monopoly leading to economic domination by those, who, apart from their scientific and inventive capabilities, are blessed with adequate resources to discover and develop new therapeutic agents.

The Indian Patents Act 1970

Ever since the first exercises under the leadership of Justice Bakshi Tekchand and the later recommendations of Justice Rajagopal Iyengar who, in a balanced view of the overall scenario in the late fifties opined, “I consider that the Patents System is the most desirable method of encouraging inventors and rewarding them”, many more deliberations were held at various levels before the Patents Act 1970 came into force in 1972.

A cardinal feature of the Indian Patents Act 1970 is that it has discriminatory provisions for certain industrial segments in matter of product versus process patents, period of validity, automatic endorsement of the words ‘licences of right’ and stipulation of quantum of royalty payable in respect of licences. India was by no means the only country with such provisions. Many other developing countries opting to adopt such a policy for similar reasons prompted India to take such a stance. It was generally agreed, if not expressed in tangible terms, that discriminatory provisions were transitory in nature in view of the developmental status of these countries and that a fuller and more rigid patent system will become operational in course of time as we move up the development ladder and attain a competitive status in international markets. In addition, it was generally hoped that the Indian Patents Act 1970 will provide the necessary incentives for the 'Indian Pharmaceutical Industry' to achieve a competitive position in accelerating discovery and development of new drugs, at least in selected areas of relevance to India and other developing countries with similar socio-economic and morbidity patterns.

Time to Assess Impact of the Indian Patents Act 1970

It is more than two decades since the Indian Patents Act 1970 came into operation and the time now is ripe to introspect and evaluate the progress made by the Indian Pharmaceutical Industry in the field of R&D, manufacture and marketing of drugs falling under the category of 'patent-protected' and 'new' drugs. In the area of R&D, while meek and meagre efforts at a sub-optimal level were deployed for discovery of new drugs during the last two decades, nothing tangible or commercially rewarding has come out of these efforts. Apart from the relatively low and sub-critical investments in new drug research, other factors such as working in too many research areas thereby making our resources too thin, lack of clinical developmental expertise; and inadequate infrastructure support systems to transform a new drug research concept to commercial reality, contributed to this situation. It is to be realized that during the same period of the seventies and the eighties, the search for new drugs has become extremely expensive with figures quoted at almost US $200 million for each new chemical entity brought to the market. Recently, Mitchel Daniels of Eli Lilly estimated that it takes screening of 100,000 compounds to lead to 100 in the clinical trials, leading to 10 in the market, out of which only 2 generate profits. Such estimates emphasize that the gap is widening with respect to the capacity of countries like India to invest in new drug research.

Thus, while total allocation for R&D by industry in India remained at the level of 1.5 to 2% of its turnover (compared to 15 to 20% in developed countries), bulk of it was spent on process and technology development, particularly by the industrial research units.
And, what has been our contribution in these areas?

It has often been averred in the Indian industry circles that Indian Pharmaceutical Industry has contributed substantially to process development. While this is true in terms of production of a number of bulk drugs, hardly any of the processes used would qualify for innovative and therefore patentable processes per se. This is not to belittle the achievements in this area, but only to emphasize that innovative component which should be the hallmark of any R&D based industry is missing from these processes. Most of these processes, therefore, would have been anticipated in process patents of companies who had no recourse to product protection. What has been achieved, therefore, is technology development and implementation rather than creation of new scientific knowledge, based on which cost-effective indigenous and innovative processes could have been developed.

With regard to the availability of new drugs still under patents to the Indian patients, we have scored notable achievements with practically all new drugs reaching the Indian market with very little ‘drug lag’ between the first introduction abroad and the launch in India. This is remarkable, since, in the recent past, the innovating companies opted not to register their new products unless they had imminent marketing plans. That meant that the Indian companies had to access clinical and sometimes even pre-clinical documentation on their own and submit them for registration. Often, clinical trials also had to be undertaken to meet the requirements. Products such as Atenolol, Diclofenac, Alprazolam, Cimetidine, Ranitidine, Famotidine and host of others were launched by Indian companies far ahead of their original innovators. What is even more creditable is that processes for a number of bulk drugs required for these new products were developed, in some cases with the assistance of some of the national laboratories. It is not that the processes used were the best and the most cost-effective, but never mind, together the higher margins afforded by the respective formulations, companies were able to milk in more than reasonable profits without having to bother about paying royalties or licence fees to the original innovator. As a consequence, the consumer benefited too, since product pricing could be done on cost basis without having to provide anything for the research costs, which were absolutely essential and responsible for the product in the first place. This situation has often been quoted as one of the major benefits accruing from the diluted patent protection embodied in the Patents Act 1970. Moral justification for this scenario is difficult, unless one invokes the questionable basic right of developing countries to expropriate developed countries’ resources without paying for them.

The Indian Patents Act 1970, therefore, cannot be credited with providing a fillip to R&D in either new drug research or innovative process development. Rather, it has helped selected companies to quickly establish markets without let or hindrance and the consumer getting the latest drugs at prices far below than those prevailing in other countries. However, valid patents in those countries provide opportunities to patentee companies to command prices which the market can bear. In the process, the patentee companies in countries with strong patents are able to plough back the derived profits into further R&D for the discovery of new drugs, a luxury which the Indian com-
companies can never afford under the prevailing scenario.

What Sort of Patent System does India Need?

There are a number of Indian companies moving to the threshold of globalization of their activities after consolidating their presence in the domestic market. These companies have also developed a reasonably strong science and technology base which can be used as a nucleus to build a strong R&D based industry. One of the basic problems these companies face is that of protecting their technology and process details from horizontal and free transfer to competitors through manpower. The R&D results of any company become freely available to other parties through this mechanism. There is no machinery available in the country which can prevent such pilferage of knowledge and research results. This is a matter which requires immediate attention, if R&D investment is to be encouraged, and the industry is to be developed along ethical lines. In other words, even before discussing the merits or otherwise of the international laws on intellectual property, we need to find ways and means of rewarding the Indian inventor and protecting him from domestic piracy by vested interests. Even in countries of the former iron curtain, which did not, in earlier days, respect intellectual property rights, there was a system of issue of inventor's certificate which not only provided domestic protection for inventions, but also bestowed special privileges to the inventors. In fact, a carefully evolved system of safeguarding the technology and know-how from transfer to competition through unfair means has to be developed and implemented in the interest of industrial development. Patents, of course, do not provide for protection of technology and know-how which are outside the scope and purview of intellectual property rights, as they are today.

Validity Period for Patents in India

The Indian Patents Act 1970 has the shortest validity period of any patent in any country in the world. The basic question is whether the stipulated period of 7 years from the date of filing or 5 years from the date of sealing, whichever is shorter, provides any semblance of protection or exclusivity. Even for innovative process developments, this period is much too short. This, in turn, means that the short validity period provided in the Indian Patents Act 1970 is equivalent to not having any patent protection at all. On the other hand, in return of the privilege of patent protection, the inventor is obliged to disclose the details of his invention so that any one skilled-in-the-art can practice it. The main reason why patent filing for pharmaceuticals came down dramatically, was not the lack of product protection, but was this unfair short validity period. Regardless of the final outcome of the on-going deliberations on revision of the Indian Patents Act, one of the immediate pre-requisites is to apply uniform validity period for all product segments, including pharmaceuticals. The duration of 14 years embodied in the Indian Patents Act 1970 is not inconsistent with the duration in many Paris Convention countries since even among them patent terms vary from 15 years (as in the case of China, Japan and South Korea) to 20 years as in UK and some other countries of Europe. In addition, in some countries the term starts from the date of application, in some others, from the publication and in yet others like the USA, from the date of grant of the patent. Patent term-extensions are also possible in
many countries, e.g. the UK, the USA, Japan, Australia, etc., due to either inadequate returns or delays in registration of the product. The critics of the patent system, particularly in the area of drugs have the following general allegations against patents:

- Patents lead to monopoly in the market place
- They are used, in many cases, as pre-emptive and defensive tools more for warding off competition from the field than for commercialization.
- They are not often worked in the country.
- They lead to high pricing for products.

Patents and Monopoly

The grant of monopoly to a patentee is part and parcel of the system; the monopoly, however, is provided for a limited period as a reward to the inventor for his inventive contribution to the society. Therefore, use of patents as instruments of limited monopoly is not by chance but by design. As far as drug patents in India are concerned, this concept was not acceptable since monopoly of any kind or for any period has been anathema to concepts of economic justice.

Product versus Process Protection

Patent protection afforded to inventors in the pharmaceuticals field falls into three categories:

i) Countries which provide process as well as product protection, e.g. the USA, Canada, Australia, Austria, EEC countries (except Greece, Portugal, Spain), Israel, Japan, South Korea, New Zealand, Sweden, Switzerland and Taiwan;

ii) Countries which provide only process protection, which means the product can be marketed without infringement if a different process is used for manufacture. These include China, the former Comecon countries, Finland, Greece, Portugal, Spain and most of South America; and

iii) Those countries which have little or no protection for pharmaceuticals, e.g. Brazil, India, Turkey, Indonesia, etc.

Some of these countries have recently introduced a stronger patent legislation and more have already joined or are actively considering joining the countries in the first category. There are differences in other aspects also between these countries. The USA is one of the few countries which follow the system of 'first-to-invent' rather than of 'first-to-file' for establishing priority. In addition, in some countries like the USA, only the inventors themselves can file the application while in some other countries, the inventor is entitled to minimum benefits even when patent is assigned.

In most of the countries where only 'process patents' are allowed a unitary process can be claimed in the application. Thus, during prosecution divisional applications are filed to protect individual processes in separate applications. This requirement has several implications since in countries where working of the patent is a pre-requisite for maintaining patent rights, the patents covering unused processes become open for compulsory licencing or get revoked.

Compulsory Licences and Licences of Right

Provision of issue of compulsory licence in cases where the needs of market are not adequately met or where the patents are not
worked, has been a notable feature of patent laws in many countries, including Paris Convention countries. There is also a provision for the import of patented products for 'crown use' or for the benefit of the public in many countries like the UK. These provisions have also been fully invoked in recent years in certain countries, e.g. in the UK and Canada, much to the chagrin of the innovator companies. In addition to this, in India, a special provision under 'Licence of Right' authorises any third party to acquire a licence for the manufacture of a product if the same has not been made within 3 years of the grant of a patent. In actual practice, there has been hardly any case of the exploitation of these provisions in India partly because very few fresh applications for pharmaceuticals were being filed in India in recent years. Therefore, it was a free-for-all in the domestic market with little need to obtain licences from the innovating company, let alone payment of any royalty.

**Patents and Prices**

One of the most convincing arguments against introducing a strong patents system for drugs is that in the absence of 'product patents' monopoly and exclusivity in India, drug prices are low, in fact, among the lowest in the world. This contention is only partly true. Prices of pharmaceuticals vary widely among countries, even among those who are members of the 'strong patent league' or the Paris Convention. Within the EEC countries, in some countries like France, prices are the lowest in spite of the fact that France, prices are the lowest in spite of the fact that France is a protagonist of strong patents system. It is also common to have a differential pricing system even for patented products for different target publics. It is true that companies would like to harmonize prices globally, but, in practice, this is never possible or even attempted. In addition, prices can vary depending on cost of production, tariffs, grade margins and a host of other country-specific cost-related factors.

Contrary to the public belief in India, many countries, even among the free market countries, have Government-sponsored price control mechanisms aimed at keeping drug prices low, without denying legitimate costs and returns on investment to the producer. To implicate the patent system as the prime reason for high drug prices, is neither correct nor fair. Particularly, India, which in spite of all the professed economic liberalization, will always have controls on prices of the essential drugs at least. It, therefore, follows that the price factor can not be invoked as a critical and determinant factor in our decision to strengthen our Patent Act.

What is not acceptable is the consequent bureaucratic lingerings leading to delays in industrial activity and the denial of the prices based on legitimate costs of production, including R&D costs and adequate returns on investment.

**Global Developments in the Patents Area**

The recent pronouncements by the US Trade Representatives that some of the countries including China, Thailand and India may be subject to sanctions under the Special 301 provisions of the US Trade Law has added a new dimension to the debate on the intellectual property laws in these countries. It is true that the USA and other countries of the strong patent league would like all the countries to fall in line with their patenting systems. Wild claims...
have been made that the US companies were losing $80 billion because of infringement of intellectual property rights, particularly by developing countries. Attempts are also being made even to implement a highly impractical internationally harmonized patent systems.

Basically, the pressure on India with reference to its Patent Act is related to

i) restoration of period of validity to preferably 20 years;
ii) introduction of product patents and reversal of the burden of proof;
iii) dilution of compulsory licencing provisions;
iv) removal of licences of right clause; and
v) extension of patentability to biotechnology, agricultural or horticultural inventions.

While the US stand on these issues at the moment appears to be more or less inflexible, Dunkel Draft proposals are not so. They should be considered as just the beginning for further negotiations and discussions. Whether the Uruguay Round to Talks is the right forum for these discussions is also a matter of dispute. In any case, it is unlikely that the present plan for finalizing all pending matters, including Trade Related Intellectual Property Rights, will fructify before the end of the year as planned.

While a number of countries have acceded to the norms of the international intellectual property laws, some other countries such as China, India, Brazil, Argentina, Thailand, Turkey, etc. are planning for the future course of action. For example, a draft intellectual property bill is pending legislation in Argentina to provide stronger patent protection for pharmaceuticals. As in India, the national industry fears that it will lead to price hikes and negation to its growth plans. The Government in Argentina feels that it has to face this new reality and keep pace with the rest of the world. Turkey which has no pharmaceutical patent protection so far, is contemplating introduction of the system. It is also felt that updating its drug legislation to bring it in line with that of the European Community might make its membership, for which it is aspiring, easier. In Brazil, a stronger patent draft law is under the active consideration of the Parliament. The national industry in this country is hoping for a long gestation or grace period before the new law becomes effective to enable reworking its strategy in the changed situation. Amendments proposed include pipeline protection for products which have not been marketed in Brazil. As per the present proposals, a third party can stop a patent from being granted if it can prove that it has taken serious steps to market the products in Brazil. Yet another proposal is to make products included in WHO's essential drugs list non-patentable. Similarly, biotechnology products are excluded from patentability. China has more or less accepted in principle the norms of the international systems.

Thailand's amended Patents Act is due to come into force any day now, even though there are still more unresolved issues. While product patents will be allowed for 20 years, compulsory licences will be possible in special cases and the Act does not provide pipeline protection which means the first products to benefit from patent will not come before the first decade of the next century. A new committee will monitor the effect on Patent Legislation on drugs prices.

The Indian Dilemma

While most countries of the world who had little patent protection for pharmaceuticals
are moving towards strengthening their intellectual property laws on their own volition or due to pressure from their trade partners from the developed world. India, on its own, has taken very little initiative to amend its laws. This is primarily due to the fact that by and large public opinion favours a highly diluted Patent Act, under the impression that the Patent Act of 1970 has enabled the national industry to grow, drugs to be made available in adequate quantities and the prices kept down. Yet another often-mentioned contribution has been in the field of self-reliance in technology for conventional formulations and a large number of bulk drugs. At the same time, the Patent Act 1970 has not led to any growth in R&D or innovative products. The question now arises whether in view of current developmental status of the Indian Pharmaceutical Industry, the impact of protective industrial policies for four decades, Indian technological capabilities and the availability of abundant scientific manpower, India is ready to move into the international arena and be a global force in this industrial segment. One of the necessary pre-requisites for achieving this goal will be to graduate from its present position of basically a copy-cat industry to an R&D-based industry with adequate protective mechanisms for intellectual property. To achieve equal status in trade and marketing, the rules of the game have to be modified to be consistent with those of its trading partners. In addition, India’s dependence on foreign financial resources makes it imperative that policies are evolved to match those of the other donor countries. Discussions on TRIPS at the Uruguay Round to Talks where trade-related matters will be tied to our intellectual property laws, have also forced us to consider new proposals for amending our existing Patents Act of 1970. The compromise Dunkel Draft proposals embody extension of term of the patent, provision for protection of products including importation to be considered equivalent to working, reversal of burden of proof on the infringer, etc., which are basic to the intellectual property laws of the developed countries. A gestation period of 10 years is also suggested for implementation of product patents.

As a matter of principle, the provisions of any proposed new legislation should not foresake the interests of the Indian public. At the same time, there is no need to feel that it is all or none situation. Even within the framework of the Paris Convention, several countries have differential provisions without upsetting the basic philosophy of reciprocal rights to their citizens and outside inventors, which is the hallmark of the Convention. Apart from this, the other aspects are still negotiable, even if India decides to join the Paris Convention. The issues on which India should not compromise, but should continue to negotiate are:

- 'Working of the Patent' to be made mandatory for keeping the patent alive;
- Importation of the product not to be treated as equivalent to working of the patent;
- The right to compulsory licences on terms to be common for all patentees and licensors; and
- Burden of proof of infringement to be on the patentee.

Subject to these situations, India will stand to gain by joining the Paris Convention since it provides certain privileges like provision of priority rights in other member countries and perhaps even common examination facilities at a later date. The provision for compulsory licences will enable Indian companies to enter into formalized licencing agreements making the state-of-art technol-
ogy available. It will also enable us to invest our resources for more creative innovations rather than for re-inventing the wheel which is the practice today.

In the area of biotechnology, already there are basic differences in perceptions, even among the developed countries. Opposition to the genetic 'Onco Mouse' of Harvard University and the NIH Patents on genetic sequences discovered under the Human Genome Project for which specific utility has not been established, agro-related and transgenic plants, etc. are rampant even among countries claiming strong intellectual property rights and are members of the Paris Convention.

As long as laws are aimed at protecting intellectual property and help national economic policies, disputes will rage from time to time, which works to protect, for how long to protect and to what extent. Ultimately, the objective of the patent system should be to provide returns to the inventor and encourage transmission of the benefits of the innovation to the economy. Several countries including China, Thailand, Turkey, Brazil, Argentina, etc. are on the threshold of introducing changes. It would be useful to arrive at certain common approaches together with these countries to meet the challenges and to avoid strong polarization of interests between the developed and developing, between the North and the South and the scientifically less and more advanced countries of the world.