INTELLECTUAL PROPERTY RIGHTS AND PATENT LAWS IN INDIAN SCENARIO IN RELEVANCE TO INNOVATIONS AND LICENSING POLICIES

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ABSTRACT

Intellectual Property Rights are constituted as one of the exceptions to the market mechanism meant to offer incentives to the private sector in certain fields where competition and free access are not deemed to provide appropriate incentives for innovation and development and are considered as an important legal mechanism to foster economic development by subsidiary technology transfer. The basic aim of conferring an intellectual property right is to give social recognition and economic incentives to its holder. It is a kind of social contract between society and the inventors, for making improvements as well as developing substantive new innovations. IPRs are limited monopolistic rights excluding others not authorized from commercial exploitation of the invention. The main legal instruments for protecting IPRs are patents, copyrights, trademarks, Industrial designs, geographical indications integrated circuits and plant breeder's rights.

LAW OF PATENT IN INDIA

The history of Patent law in India starts from 1911 when the Indian Patents and Designs Act, 1911 was enacted. The present Patents Act, 1970 came into force in the year 1972, amending and consolidating the existing law relating to Patents in India. The Patents Act, 1970 was again amended by the Patents (Amendment) Act, 2002 and Patents (Amendment) Act, 2005, wherein product patent was extended to all fields of technology including food, drugs, chemicals and microorganisms. After the amendment, the provisions relating to Exclusive Marketing Rights (EMRs) have been repealed and a provision for enabling grant of compulsory license has been introduced. The provisions relating to pre-grant and post-grant opposition have been also introduced.

TRIP'S AGREEMENT

India's industrial patent regime began to change slowly with its accession to the World Trade Organization (WTO) in 1995[i]. The agreements that accompany membership in the WTO cover goods, services, and intellectual property rights (IPRs)[ii]. One of the most important agreements within the WTO is the Trade-Related Aspects of Intellectual Property (TRIP'S) Agreement, which mandates that all WTO members adopt and enforce certain minimum standards of IPR protection. In 1986, when the negotiations for setting up the WTO began, India and other developing countries including Brazil and Argentina strongly opposed it on the premise that protection of IPRs fell within the mandate of the World Intellectual Property Organization (WIPO).

By 1989, other developing countries changed their stance because of various coercive measures taken by the United States, and India was left alone in its opposition. Thus, India faced with the unviable alternative of remaining completely outside the WTO system was forced to sign the TRIPS Agreement and join the WTO in 1995. However, in the process, India also managed to extract crucial flexibilities with respect to patent laws that had the result of restricting the effects of the changes originally mandated by TRIPS.

It is a well-accepted fact that India's objections to the TRIPS Agreement benefited many developing countries, since all of them were provided transition periods of several years by WTO to make their laws fully TRIPS compatible. Even though India was not required to comply with the product patent requirements of TRIPS until 2005, it was mandated to create a mailbox for the filing of patent applications that would be examined when the 2005 changes came into effect.

India's WTO entry, although a very important step, cannot be attributed as the sole reason for changing its patent/IPR laws. Thus, it is possible that when India became a member of the WTO in 1995, the economic liberalization policies it implemented four years before played some role in diluting India's stiff opposition to including IPRs within the ambit of the WTO. After the economic liberalization, India was in a much better position to align its policy interests with the fundamental philosophy of the WTO.

MEANING & NATURE OF PATENT LAW

The term patent usually refers to a right granted to anyone who invents or discovers any new and useful process, machine, article of manufacture or composition of matter or any new and useful improvement thereof. The additional qualification utility patent is used in the United States to distinguish it from other types of patents (e.g. design patents) but should not be confused with utility models granted by other countries. Examples of particular species of patents for inventions include biological patents, business method patents, chemical patents and software patents.

Some other types of intellectual property rights are referred to as patents in some jurisdictions: industrial design rights are called design patents in some jurisdictions (they protect the visual design of objects that are not purely utilitarian), plant breeder & rights are sometimes called plant patents and utility models or Gebrauchsmuster are sometimes called petty patents or innovation patents. This article relates primarily to the patent for an invention, although so-called petty patents and utility models may also be granted for inventions.

Certain grants made by the monarch in pursuance of the royal prerogative were sometimes called letters patent, which was a government notice to the public of a grant of an exclusive right to ownership and possession. These were often grants of a patent-like monopoly and predate the modern origins of the patent system. For other uses of the term patent see notably land patents, which were land grants by early state governments in the USA, and printing patent, a precursor of modern copyright. These meanings reflect the original meaning of letters patent that had a broader scope than current usage.

A trade secret is information that can be used in the operation of businesses or other enterprises and it is sufficiently valuable and secret to afford an actual or potential economic advantage over others. A trade secret may consist of a formula, pattern, compilation of data, computer programme, device, method, technique, process or other form or embodiment of economically valuables information. The (USA) Semiconductor Chop Protection Act of 1984 is intended to protect such situation by allowing designers of new semiconductor chip products to register them at the Copyright Office which will give the exclusive right to manufacture and distribute them in the United States for ten years.

FOUNDATION OF THE PATENT SYSTEM IN INDIA

The basic purpose of the Patent system is to encourage innovation and the improvement of industrial techniques. In return for the disclosure of his invention the inventor is given a monopoly in the use of it for a period of 20 years after which time it passes into the public domain. It is not mandatory to obtain a patent in order to protect a new invention; the inventor may instead choose to keep the detail secret. Indeed, not all technical developments are patentable. Tricks of the trade, detailed process specifications and modes of operation which do not involve an inventive step may, therefore, be unpalatable, although they are capable of protection as trade secrets or know how. As a matter of public policy, discoveries, scientific theories and mathematical methods are not patentable. Products whose novelty reside in the design and not in the function are not patentable but may be protected either as a registered design or by means of copyright or by means of unregistered design right.

The Patent law of India has the following salient features that decide whether a patent will be granted or not:

(a) **The object:** The object of patent law is to encourage scientific research, new technology and industrial progress. The price of the grant of the monopoly is the disclosure of the invention at the Patent Office, which, after the expiry of the fixed period of the monopoly, passes into the public domain.

(b) **Inventive step:** The fundamental principle of Patent law is that a patent is granted only for an invention which must have novelty and utility. It is essential for the validity of a patent that it must be the inventors own discovery as opposed to mere verification of what was, already known before the date of the patent.

(c) **Useful:** The previous Act, i.e. Act of 1911, does not specify the requirement of being, useful, in the definition of invention, but courts have always taken the view that a patentable invention, apart from being a new manufacture, must also be useful.

(d) **Improvement:** In order to be patentable, an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement, and must independently satisfy the test of invention or an inventive step. It must produce a new result, or a new article or a better or cheaper article than before. The new subject matter must involve "invention" over what is old, mere collocation of more than one, integers or things, not involving the exercise of any inventive faculty does not qualify for the grant of a patent.

(e) **The guiding tests:** To decide whether an alleged invention involves novelty and an inventive step, certain broad criteria can be indicated. Firstly if the "manner of manufacture" patented, was publicly known, used or practiced in the country before or at the date of the patent, it will negative novelty or subject matter. Prior public knowledge of the alleged invention can be by word of mouth or by publication through books or other media. Secondly, the alleged discovery must not be the obvious or natural suggestion of what was previously known.

In short the invention must involve an inventive step and the same must be capable of industrial application. It must be supplemented by the concept of non-obviousness.

OBJECTS OF PATENT LAW IN INDIA

The existing Patents and designs act was enacted in 1911 and since then there have been substantial changes in the political and economic condition of the country. The need for a comprehensive law so as to ensure more effectively that patent rights are not worked to the detriment of the consumer or to the prejudice of trade or the industrial development of the country was felt as early as 1948 and in that year the government appointed the patents enquiry committee to review the working of the patents law in India. The present bill contains comprehensive provisions to amend and consolidate the existing law and also contains amendments/recommendation by the Joint Committee referred to above. The notes on clauses explain the provisions of Bill, whenever necessary."

This Act was mainly based on the principles laid down in English Law merchant. The main object of this Act was to do away with the inconsistencies existing prior to its enforcement especially with regard to applicability of law of Patent to persons belonging to different communities.

ADMINISTRATION OF PATENT IN INDIA

In 1957, Government of India appointed Justice N. Rajagopala Ayyangar examines and review the Patent law in India who submitted his report September 1959 recommending the retention of Patent System despite shortcomings. The Patent Bill, 1965 based mainly on his recommendations incorporating a few changes, in particular relating to Patents for food, drug, medicines, was introduced in the lower house of Parliament on 21st September, 1965. The bill was passed by the Parliament and the Patents Act 1970 came into force on 20th April 1972 along with Patent Rules 1972. This law was suited changed political situation and economic needs for providing impetus technological development by promoting inventive activities in the country.

Uruguay round of GAYP negotiations paved the way for WTO. Therefore India was put under the contractual obligation to amend its patents act in compliance with the provisions of TRIPS. India had to meet the first set of requirements on 01-01-1995. This was to give a pipeline protection till the country starts giving product patent. It came to force on 26th March 1999 retrospective from 01-01-1995. It lays down the provisions for filing of application for product

patent in the field of drugs or medicines with effect from 01.01.1995 and grant of Exclusive Marketing Rights on those products.

India amended its Patents Act again in 2002 to meet with the second set of obligations (Term of Patent etc.), which had to be effected from 1-1-2000. This amendment, which provides for 20 years term for the patent, Reversal of burden of proof etc. came into force on 20th May, 2003. The Third Amendment of the Patents Act 1970, by way of the Patents (Amendment) Ordinance 2004 came into force on 1st of January, 2005 incorporating the provisions for granting product patent in all fields of Technology including chemicals, food, drugs & agrochemicals and this Ordinance is replaced by the Patents (Amendment) Act 2005 which is in force now having effect from 01-01-2005. Patent system in India is administered under the superintendence of the Controller General of Patents, Designs, Trademarks and Geographical Indications.

The Office of the Controller General functions under the Department of Industrial Policy and Promotion, Ministry of Commerce and Industry. There are four patent offices in India, The Head Office is located at Kolkata and other Patent Offices are located at Delhi, Mumbai and Chennai. The Controller General delegates his powers to Sr. Joint Controller, Joint Controllers, Deputy Controllers and Assistant Controllers. Examiners of patents in each office discharge their duties according to the direction of the Controllers.

PATENT LAW IN TODAY'S CONTEXT

The sensitive issues such as product patents for drugs, all agricultural chemical product, and exclusive marketing rights are still to be addressed as far as Indian law on patent stands today. Therefore a separate legislation in this regard will be necessary before 01.01.2005 WTO deadline. This span of time has to be harmonized the patent granting procedures with international practices and to make the system user friendly. The implications will not be evident overnight. The new amendments still do not provide for Patent protection to drugs.

India is required to provide such protection only by 2005 and the minister for commerce has indicated that a subsequent amendment shall provide for this. When this happen Indian companies will lose the opportunity to develop processes for patent protected drugs in the

country. India will become dependent on MNCs for technology to produce new drugs. Votaries of the new Patents Act argue that old drugs will not be affected by this Act, While this is true, it must be understood that the rate of obsolescence of old drugs are extremely fast today.

Further, technological dependence on MNCs is the proverbial "thin edge" which will be used by the MNCs to establish their dominance over the Indian drug market once again (a position they had lost after the mid-seventies). They will then again start charging exorbitant prices for drugs in the Indian market. Since the early eighties, the categories of drugs which show the maximum rise in sales are categories which include overwhelming majority of drugs still under Product Patent or whose Product patents have expired recently. In other words if we had a. product patent regime today, the drugs showing fastest growth would have been priced way beyond the capacity of the average consumer.

PATENT LAW AND ITS EFFECT IN INDIA

Introduction Modern world is marked by Globalization and Liberalization. Hence economic reforms have been introduced by many countries like India which has to compete with other countries in the world market. Patent law plays a very significant role in the development of a country. More so because of the advent of the World Trade Organization in which India has to compete with developed countries like U.S.A. The Paris convention for the protection of industrial property, 1883 was the first convention for the protection of Intellectual Property. It is said the nationals of the signatory country would have equivalent rights and status in all other signatory countries.

Though India was not a member of Paris convention, but having signed the TRIPS agreement, India is now obliged to recognize and implement the provision of "national treatment to nationals of other members" as has been incorporated in the TRIPS agreement. The law of patents has also become an important discipline of international trade and commerce due to great advancement in science and technology, revolutionary changes in computer software development and with the shift from process to product patent, the patent law has been striving to keep pace with the changes in technology.

A patent is not a right to practice or use the invention. Rather, a patent provides the right to exclude others from making, using, selling, offering for sale, or importing the patented invention for the term of the patent, which is usually 20 years from the filing date subject to the payment of maintenance fees. A patent is, in effect, a limited property right that the Government offers to inventors in exchange for their agreement to share the details of their inventions with the public. Like any other property right, it may be sold, licensed, mortgaged, assigned or transferred, given away, or simply abandoned.

The rights conveyed by a patent vary country-by-country. For example, in the United States, a patent covers research, except "purely philosophical" inquiry. A U.S. patent is infringed by any "making" of the invention, even a making that goes toward development of a new invention which may itself become subject of a patent.

A patent being an exclusionary right does not, however, necessarily give the owner of the patent the right to exploit the patent. For example, many inventions are an improvement of prior inventions that may still be covered by someone else's patent. If an inventor takes an existing, patented mouse trap design, adds a new feature to make an improved mouse trap, and obtains a patent on the improvement, he or she can only legally build his or her improved mouse trap with permission from the patent holder of the original mouse trap, assuming the original patent is still in force. On the other hand, the owner of the improved mouse trap can exclude the original patent owner from using the improvement.

Some countries have "working provisions" that require the invention be exploited in the jurisdiction it covers. Consequences of not working an invention vary from one country to another, ranging from revocation of the patent rights to the awarding of a compulsory license awarded by the courts to a party wishing to exploit a patented invention, The patentee has the opportunity to challenge the revocation or license, but is usually required to provide evidence that the reasonable requirements of the public have been met by the working of invention.

The patent law recognizes the exclusive right of a patentee to gain commercial advantage out of his invention. This is to encourage the investors to invest their creative faculties, knowing that their invention would be protected by law and no one else would be able to copy their inventions for certain period during which the respective investors would have exclusive rights.

COMPULSORY LICENSING

The procedure for granting patent, the requirements placed on the patentee and the extent of exclusive rights vary between countries according to the national laws and international agreements. Typically, however a patent application must include one or more claims defining the invention which must be Novel, Inventive and Useful. In many countries certain subject areas are excluded from patents such as business methods and mental acts. A patent is a negative right which grants exclusive rights to a patentee to prevent or exclude others from making, using, selling, offering to sell or importing the invention.

In the thirty years of the working of India's patents system, Compulsory Licensing provisions were never invoked. However, today it is the most widely debated topic in India. The Government of India and a number of other stakeholders consider Compulsory License as a statutory tool to effectively protect 'public interest' from possible abuse of monopoly. One step ahead, many consider that Compulsory License will ensure a level playing ground between the owners of Intellectual Property Rights and their competitors.

The Patents (Second Amendment) Bill, 1999 (which later became the Patents (Amendment) Act, 2002 brought in substantial amendments in the provisions concerning Compulsory Licenses. The Patents Act, 1970 originally contained a Chapter titled 'Working of Patents, Compulsory Licenses, Licenses of Right and Revocation'. The legislative intent behind the inclusion of Compulsory Licensing provisions was evident from Section 83 of the 1970 Act. The Section contained the general principles applicable to the working of a patent aimed at curbing the potential abuse of monopoly by the patentee.

The local working of inventions to the fullest extend and on commercial scales and preventing the patentee from creating import monopolies were the two fundamental principles recognized in the original Act. The recent amendment added clauses (c) through to (g) to the original set of principles. The new principles are addressed at striking a balance of interests between the technology owners and technology users, promoting socio-economic progress by technological development, protection of public health and the Government of India's rights in that regard prevention of unfair trade practices by abuse of monopoly rights by the patentee and the availability of the patented invention at affordable prices to the public.

The Act originally contained two important grounds for invocation of Compulsory Licenses. Any interested person could approach the Controller of Patents seeking a Compulsory License on grounds that (a) the reasonable requirements of the public with respect to the patented inventions have not been satisfied, and (b) patented invention is not available to the public at reasonable prices.

The amended provision contained in Section 84 of the Act has included a third ground of 'local working' for seeking Compulsory Licenses. If the patented invention is not worked within the territory of India, it can be a ground to seek Compulsory License by any interested person. While explaining the meaning of ‘reasonable requirements of the public’, the law as it originally stood did contain a provision that the reasonable requirements of the public is deemed not to have been met, if for reason of the default of the patentee to manufacture in India the patented study, or not to give a license for the manufacture of the patented study the interests of the existing trade or industry is adversely affected.

In addition to the above, under Section 92(1) the Central Government can issue notification for the grant of compulsory licenses, at any time after the sealing of patent, in the case of ‘national emergency’ or ‘extreme urgency’ or ‘public non-commercial use’. The Controller of Patent is required to endeavour to ensure that the patented invention is available at the lowest price consistent with the patentees deriving reasonable advantage from their patent rights.

Further, subsection (3) of the same Section provides that in circumstances of ‘national emergency’, ‘extreme urgency’ or ‘public non-commercial use’ including health crisis relating to AIDS, HIV, tuberculosis, malaria or other epidemic, the controller is not required to afford an opportunity of opposition to the patentee. Difficulties may arise in the interpretation of the meaning and extent of the grounds on which Compulsory Licenses can be sought. The expressions ‘National Emergency’ and ‘Extreme Urgency’ are nowhere defined though it can be safely inferred that these terms refer to situations of grave magnitude.

National emergency can take the form of ‘perceived terrorist attack using biological warfare’. For instance, in the year 2001 Canada overrode Bayer Corporation’s patent over Ciprofloxacin and ordered production of a million tablets of generic version from a Canadian company. Ciprofloxacin was stockpiled as an antidote for any attack on the nation using the deadly Anthrax.

The amended provisions have in general broadened up the grounds for seeking Compulsory Licenses. Also the amendments have re-emphasized some of the basic principles behind the inclusion of Compulsory Licenses. The amendments are, therefore, a combination of policy statements and a set of substantive augmentation of the earlier provisions respecting Compulsory Licenses.

While some implications of the Compulsory Licensing provisions are direct and predictable, some others are indirect, and far less apparent. The law says that Compulsory License can be granted to any interested person if the patentee does not make the invention 'available to the public' at 'reasonable prices'. What would be the nature and extent of 'making the invention available to public' for purposes of invoking Compulsory Licenses may lead to a contentious issue. These indirect and less apparent issues are likely to surface once the TRIPS compliant product patent regime comes into existence. Here again, the Courts of Law may play a decisive role in explaining the pith and substance of the textual law.

CONCLUSION

The Indian patent legislations has a relatively short period, as compared to western countries, particularly England, of legislative protection to inventions that are novel, involve inventive step and capable of industrial application, dating back hardly to over one hundred and fifty years with the judiciary playing a vigorous supportive role. The tradition has been kept alive with the Indian patent Act, 1970; modernized in keeping with the global trends and updated to meet the complex contemporary needs and demands from time to time.

The Act provides, inter alia, with the basic fundamentals as regards conferment of patent rights, their commercial exploitation, infringement and consequential remedies leaving the rest as a matter of detail interpretation and construction of those funds at the hand of judiciary whenever uncounted with patent infringement litigation. These fundamentals are substantially full of merits satisfying to a greater extent the hypothetical question of protecting and reflecting the bond or relation between the inventor/patentee and the invention patented, yet a few of them have their own pros and cons, demerits and negative points that.

While the discussion in this study is confined to the above three issues that the Indian pharmaceutical companies face in the anvil of the new TRIPS compliant regime, the transition from a limited term process patent regime to the product patent regime can have several other far reaching implications. The impact of this transition will become evident in the years to come. In the meantime, the Indian pharmaceutical industry must gear up to face the challenges. Creation of a level playing ground is possible the moment the domain knowledge of patents is even among all the players in the Indian market place. To begin with, the efforts to achieve parity in knowing the rules of the game can be confined to India.

There are some suggestions which can bring the new patent law more practical and able to meet the TRIPS obligations better. They may be describes as follows:

1. The new Act should also provide for transparent guidelines for the examination of patents with regard to software so that software patents do not get restricted only to embedded software.
2. Section 47 (3) makes provisions for the experimental use of a patented invention However it states that the grant of a patent under the Act shall be subject to the condition that "any machine, apparatus or other article in respect of which the patent is granted, or any article made by the use of the process in respect of which a patent is granted, may be made or used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils".
3. India is now moving to a new product patent regime and Indian patent examiners will need time to gain experience in examining product patents.
4. Product patent procedures and practices should be simplified and transparent to attract more companies to produce quality drugs at reasonable prices.
5. Network between the drugs controller General of India (DCGI) and the patent office must be a balanced one so that the position regarding issue, renewal and registration of patent can be known earlier.

Hence the overall Indian has to transform its drug industry and other sector into a world class manufacture of quality products on a sustainable scale of operation. The essence of future growth lies in its ability to innovate and introduce new products. If the Indian pharmaceutical and other industry have to emerge as a global competitor, the manufacturing and marketing

innovation is the focus. Cost reduction opportunities in manufacturing and marketing innovation through quality and promotion will have to be concentrated. Companies that prepare for the future keeping the present in perspective will emerge as the survivors in the long-term.

These changes would ensure India's compliance with TRIPS and also protect national interests in a balanced and equitable manner. The domestic market will be attractive due to the growing awareness of industrial and medical care, changing profile of diseases, rising per capita income and improving health infrastructure. Hence it is clear that the competition will only rise and the profit margins will be thin but the growth is guaranteed.

ENDNOTES

[i] Member Information: India and the WTO.
[ii] Details about WTO agreements are available at Understanding the WTO: The Agreements, Overview: A National Guide, WORLD TRADE ORG.,