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PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

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ABSTRACT

Patent is an intellectual property right relating to inventions and is a grant of exclusive right, for limited period, provided by the Government to the patentee, in exchange of full disclosure of this invention, for excluding others, from making, using, selling, importing the patented product or process producing that product for those purposes. The purpose of this system is to encourage inventions by promoting their protection and utilization so as to contribute to the development of industries, which in-turn contribute to the promotion of technological innovation and to the transfer and dissemination of technology. Under the system, Patents ensure property rights for the invention for which patent have been granted, which may extremely valuable to an individual or a Company. Patent right is territorial in nature and a patent obtained in one country is not enforceable to other country. The inventors/ assignees are required to file separate patent applications in different countries for obtaining patent in those countries.

KEY WORDS

Patent laws, pharmaceutical industry, Impact.

Origin of the Patent Regime

The roots of the modern patent regime can be traced in the Venetian System, the British and the American System. In India in 1856, the first patent system was introduced. In 1859 special privilege exclusively for the inventor was established which conferred the sole use and selling of his/her invention for 14 years. This act was replaced by Invention & Design Act, 1911. In 1930 there were some major amendments in the similar act. In 1948, the government of India appointed patents enquiry committee under Dr Tek Chand, the committee submitted its report in 1953 but this bill lapsed due to dissolution of Lok Sabha.

The patent system in India is governed by the Patents Act, 1970[1] (No. 39 of 1970) as amended by the Patents (Amendment) Act, 2005 effective from 01-01-2005 and the Patents Rules, 2003 as amended by the Patents (Amendment) Rules, 2006 effective from 05-05-2006. The Patent Office, under the Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, performs the statutory duties in connection with the grant of patent for new inventions and registration of industrial designs. Patent Offices are located at Kolkata, Mumbai, Chennai and Delhi to deal with the applications for patents originating within their respective territorial jurisdictions. PIS located at Nagpur maintains a comprehensive and provides technological information contained in patent or patent related literature, on a worldwide basis and provides technological information contained in a patent or patent related literature through search services and patent document supply services. IPTI located at

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

Nagpur provides training to the officials of IP offices and other users of the system who are working in the field of Intellectual Property Rights.

India is a member-State of WIPO, an International Organisation, responsible for the promotion of the protection of intellectual property throughout the world. India is a member of the following International Organisation and Treaties in respect of Patents:

- WTO with effect from 1-1-1995.
- Convection establishing WIPO.
- Paris Convection for the protection of Industrial Property with effect from 7-12-1998.
- PCT with effect from 17-12-1998.

Types of Patent Applications

Ordinary Application

Application for patent of Addiction (granted for improvement of Modification of the already patented invention, for an unexpired term of the main patent).

- Divisional Application (in case of plurality of invention disclosed in the main application).
- Convention application, claiming priority date on the basis of filing in Convention Countries.
- National Phase Application under PCT.

History of Indian Patent System

- **1856:** The Act 6 of 1856 on protection of inventions based on the British Patent Law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years.
- **1859:** The Act modifies as Act 15; Patent Monopolies called exclusive privileges (making, selling and using inventions in India and authorizing others to do so far 14 years from date of filing specification).
- **1872:** The Patents and Design Protection Act
- **1883:** The Protection of Invention Act.
- **1888:** Consolidated as the Invention and Design Act.
- **1911:** The Indian Patents and Design Act.
- **1972**: The Patent Act (Act 39 of 1970) came in to force on 20-04-1 972.
- **1999:** The Patents (Amendment) Act, 1999 came in to force from 01-01-1995.
- **2002:** The Patents (Amendment) Act, 2002 came in to force from 20-05-2003.
- **2005**: The Patents (Amendment) Act, 2005 came in to force from 01-01-2005.

Early Patents Act & Indian Pharmaceutical Industry.

In late 50s when political and economic set up was being enhanced the Indian pharmaceutical industry was being dominated by the foreign multinational companies. The prices of the drugs with special mention to life saving drugs were too high. These prices were non affordable by common people in India. The previous acts were not being able to meet needs. After observation such chaos in the pharmaceutical sector, the Indian government in 1957 appointed a committee under the chairmanship of justice Raja Gopal Ayyangar[2]. The committee started its work keeping in mind the changing scenario. The report was inspired by the Indian constitution which ensures social economic justice. Article 21 of constitution which ensures the right health to citizen was the guiding philosophy behind Ayyangar.

List of Amending Acts

- Repealing and Amending Act, 1974 (56 of 1974)
- Delegated Legislation Provisions (Amendment) Act, 1985 (4 of 1986).
- Patents (Amendment) Act, 1999 (17 of 1999)

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

- Patents (Amendment) Act, 2002 (38 of 2002)
- Patents (Amendment) Act, 2005 (15 of 2005)

The Present Scenario

The patent Act (Act 39 of 1970) came into force on 20th April 1972. The Patents act of 1970 was designed perfectly in tune with our then national ideology of planned development. This was the time when there was socialistic planning. Since then India has underwent an absolute economic enhancement. India has taken up the strands of globalization and liberalization. Today the country is gaining momentum ahead of the global economy[3]. This process will not be complete unless the research and development is also integrated with global research and development. Also India has entered into an international framework after being the member of WTO. Thus it is in the legal obligation to fulfill all the statuary norms of the WTO. After signing the TRIPs agreement India is continuously updating its patent regime.

The Patents Act, 1970 (39 of 1970)

An Act to amend and consolidate the law relating to patents.

Enacted by Parliament in the Twenty-first year of the Republic of India as follows:-

Statement of Objects and Reasons—The existing Indian Patents and Designs Act was enacted in 1911 and since then there have been substantial changes in the political and economic conditions of the country. The need for comprehensive law so as to ensure more effectively the 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 committee submitted its final report in 1950. The patents bill, 1953, based largely on the United Kingdom Patents Act, 1949 and incorporating some of the recommendations of the committee was introduced in the Lok Sabha on 7th December, 1953. The bill, however, lapsed on the dissolution of the first Lok Sabha.

In 1957, the government of India appointed Shri Justice N. Rajagopala Ayyangar to examine a fresh and review the patents law in India and advise the government on changes necessary. The judge submitted a comprehensive report on Patent laws revisions in September, 1959. The Patents Bill, 1965, based mainly on the recommendations contained in his detailed report and incorporating a few more changes in the light of further examination made particularly with reference to Patents for Food, Drug and Medicines, was introduced in the Lok Sabha on 21st September, 1965. The bill was referred on 25 th November, 1965 to joint committee of parliament. The joint committee, after a careful consideration of the matter, adopted a number of amendments to the bill. The report of the joint committee with the amended bill was presented to the Lok Sabha on 1st November, 1966. The Patents bill 1965 as reported by the join committee was formally moved in the Lok Sabha on 5th December, 1966, but could not be proceeded with for want of time and eventually lapsed with the dissolution of the third Lok Sabha on 3rd March 1967. The present bill contains comprehensive provisions to amend and consolidate the existing law and also contains amendments recommended by the joint committee referred to above. The notes on clauses explain the provision of the bill wherever necessary.

Amendment Act 38 of 2002

Statement of Objects and Reasons The law relating to patents is contained in the Patents Act, 1970 which

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

came into force on the 20th April, 1972. The Act was last amended in March, 1999 to meet India's obligations under the Agreement on TRIPs which forms part of the Agreement establishing the WTO. Apart from the aforesaid amendment, the Act has not undergone any change so far. Since 1972, there has been a considerable technological innovation and development of knowledge and the concept of intellectual property as a resource for knowledge-based industries has become well recognized the world over. Development of technological capability in India, coupled with the need for integrating the intellectual property system with international practices and intellectual property regimes, requires that the Act be modified into a modern, harmonized and user-friendly legislation to adequately protect national and public interests while simultaneously meeting India's international obligations under the TRIPS Agreement which are to be fulfilled by 31st December, 1999.

Given the importance of the issues, the Government engaged itself in broad-based and extensive consultations involving different interest groups on aspects critical to the changes which may be necessary in the Patents Act, 1970. While considering amendment to the Act, efforts have been made to make the law not only TRIPs complaint but also to provide therein necessary and adequate safeguards for protection of public interest, national security, bio-diversity, traditional knowledge, etc Opportunity is also proposed to be availed of for harmonizing the procedure for grant of patents in accordance with international practices and to make the system more user friendly.

The salient features of the Bill are

- To define the term "invention" in consonance with international practices and consistent with TRIPS Agreement,
- To modify section 3 of the present Act to include exclusions permitted by TRIPs Agreement and also subject-matters like discovery of any living or non-living substances occurring in nature in the list of exclusions which in general do not constitute patentable invention;
- To align rights of patentee as per article 28 of the TRIPs Agreement;
- To add provision for reversal of burden of proof in case of infringement suit on process patent in accordance with article 34 of the TRIPs Agreement;
- To provide a uniform term of patent protection of twenty years for all categories of invention as per article 33 of the TRIPs Agreement;
- To align the provisions relating to CL and to omit provisions relating to licensing of rights;
- To provide provisions relating to parallel import of patented products;
- To make a provision for enabling persons other than patent holder to obtain marketing approval from the appropriate regulatory authorities within three years before the expiration of the term of the patent;
- To incorporate measures for protection of bio-diversities and traditional knowledge;
- To provide an Appellate Board for speedy disposal of appeals and rectification of register of patent which at present lie before High Court;
- To amend the provisions relating to national security;
- To amend several provisions of the Act with a view to simplifying and rationalizing the procedures aimed at benefiting users.

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

Amendment Act 15 of 2005

Statement of Objects and Reasons- The law relating to patents is contained in the Patents Act, 1970 (39 of 1970) which came into force on the 20th April, 1972. This Act was amended in March, 1999 and June, 2002 to meet India's obligations under the Agreement on TRIPS, which forms part of the agreement establishing the WTO. The amendments primarily focused on the obligations which came into force from 1st January, 1995 (in respect of amendments made in March, 1999) and obligations which came into force from 1st January, 2000 (in respect of amendments notified in June, 2002). The first amendment to the Patents Act introduced a transitional facility ("mail box") from January 01, 1995 to receive and hold product patent applications in the fields of pharmaceuticals and agricultural chemicals till January 01, 2005 and also for grant of EMRs for a period of 5 years or till the product patent is granted or patent application is rejected, whichever is earlier. Before making the latter amendment, a Joint Committee of both the Houses of Parliament examined all aspects and recommended various provisions in order to provide necessary and adequate safeguards for protection of public interest, national security, biodiversity and traditional knowledge, including effective flexibilities to enable appropriate and timely response to national and public interest concerns, especially those relating to public health and nutrition. These were included in the second amendment.

The earlier amendments had provided for the modalities for a ten-year transition facility (which India had negotiated at the time of its accession to the WTO), commencing from the 1st January, 1995. As a consequence, the law was required to be amended further in respect of India's obligations under the TRIPs Agreement, due from 1st January, 2005.

Given the importance of the issues, the Government undertook broad-based and extensive consultations involving different interest groups on aspects critical to the changes which were necessary in the Patents Act, 1970. These included country-wide interactive sessions with various interest groups, including scientists, academicians, economists, representatives of various industry sectors (such as pharmaceutical, biotech and software), chamber of commerce, private and public sector units, journalists, non-governmental organizations, representatives of State Governments, lawyers and attorneys and other interest groups and extensive inter-Ministerial consultations.

The time-frame for this set of amendments was most crucial as any slippage in meeting the January 01, 2005 deadline had the potential of inviting retaliatory action under the WTO disputes mechanism. Having availed of the entire ten-year transition period provided under the TRIPs Agreement, India had no legal basis to defend its default on the deadline. The past record of delayed implementation would also not have helped the Indian case. 7:15 default would also have created a legal vacuum for the "mailbox" applications, as there would not be any mechanism to deal with them from January 01, 2005. This would have amounted to a specific default on the international commitment to examine and dispose of these cases, and might have again provided an opportunity to WTO member countries to raise a dispute against India in the WTO. There would also have been a legal vacuum in respect of fresh applications after January 01, 2005, as the law was salient on whether the “mailbox" provision would subsist or whether it would have ceased. Finally, there would have been an erosion of India's credibility in the international field. In the circumstances it was considered necessary to bring in the required amendments in time and as Parliament was not in session, the President promulgated the Patents

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

(Amendment) Ordinance, 2005 (Ord. 7 of 2004) on the 26th December, 2004.

While considering the third set of amendments to the Act, efforts have been made not only to fulfill our final obligation under the TRIPs Agreement, but also to simplify and rationalize the procedure governing grant of patents so as to make the system more efficient and user-friendly.

The salient features of the amendments are

To introduce product patent protection in all fields of technology (that is drugs, food and chemicals since product patent protection already exists for all other fields), as per Article 27 of the TRIPs Agreement;

- To modify the provisions relating to EMRs since these were part of the transitional arrangements;
- To modify and clarify the provisions relating to patenting of software related inventions when they have technical application to industry or in combination with hardware;
- To modify the provisions relating to opposition procedure with a view to streamline the system by having both pre-grant and post-grant opposition in the Patent Office;
- To introduce a provision for enabling grant of compulsory license for export of medicines to countries which have insufficient or no manufacturing capacity, to meet urgent public health situations (permissible under paragraph 6 of the Doha Declaration on TRIPs and Public Health);
- To amend and strengthen the provisions relating to national security to guard against patenting abroad of dual use technologies;
- To amend the provisions relating to the Intellectual Property Appellate Board with a view to extending its jurisdiction to revocation of patents also;
- To amend certain provisions with a view to harmonizing them with the Patent Co-operation Treaty to which India is a signatory;
- To rationalize the provisions relating to time-lines with a view to reducing the processing time for patent applications, and to simplify the procedure.

Patent Laws and Pharmaceutical Industry

Protection of intellectual property rights in India continues to be strengthened further. The year 1999 witnessed the consideration and passage of major legislation with regard to protection of intellectual property rights in harmony with international practices and in compliance with India's obligations under TRIPS. The Government of India has taken several measures to streamline and strengthen the intellectual property administration system in the country. Projects relating to the modernization of patent information services and trademarks registry have been implemented with help from WIPO. The Government of India is implementing a project for modernization of patent offices at a cost of Rs.756 million incorporating several components such as human resource development, recruiting additional examiners, infrastructure support and strengthening by way of computerization and re-engineering work practices, and elimination of backlog of patent applications. An amendment to the Patent Rules was notified on June 2, 1999 to simplify the procedural aspects.

The Trade Marks Registry is also proposed to be further strengthened and modernized. A project for modernization was earlier implemented during 1993-96. Further strengthening of the Registry is being taken up at a cost of Rs.86 million. The main thrust now is to strengthen the infrastructure of the Trade Marks Registry and the early removal of backlog of pending applications, transfer of records to CD-

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

ROM's, re-engineering of work processes, appointment of additional examiners, etc.

As regards the aspect enforcement, Indian enforcement agencies are now working very effectively and there has been a notable decline in the levels of piracy in India. In addition to intensifying raids against copyright infringers, the Government has taken a number of measures to strengthen the enforcement of copyright law. Special cells for copyright enforcement have been set up in 23 States and Union Territories. In addition, for collective administration of copyright, copyright societies have been set up for different classes of works.

Concerns expressed over IPR protection & India's response

It has been alleged that there is absence of effective patent protection in the pharmaceutical sector. India does provide for patents in the pharmaceutical sector. However, in terms of Section 5 of the Patents Act, the patents are presently restricted to the methods or process of manufacture and not extended to the substances/products themselves. In terms of the TRIPS Agreement, India has time till January 1, 2005 to extend patent protection to this area. The ten year transition period available for providing product patents to pharmaceutical products is within WTO rules.

It has been further alleged that India has failed to meet its current obligations required under Articles 70.8 and 70.9 of the TRIPS Agreement by implementing appropriate, conforming mailbox and exclusive marketing rights procedures. However, the Government of India has taken the following steps to meet its obligations under Articles 70.8 and 70.9:

- On December 31, 1994, Government of India promulgated an Ordinance to provide a means to receive product patent applications in the fields of pharmaceutical and agricultural chemical products and also for grant of exclusive marketing rights. Pursuant to this measure the Indian Patent Office has been receiving product patent applications in those fields.
- India has established a mail box system through administrative instructions. Numerous applications have already been filed in this mail box system, and many of them have been filed by US companies;
- India has also made changes to its Patents Act to put in place machinery for implementation of Articles 70.8 and 70.9 by providing for establishment of a mail box system to file patents and according exclusive marketing rights for 5 years. This provision was made in the Patents (Amendment) Act of 1999.

Concern has also been expressed over the CL provision in the Patents (Amendment) Act, 1999. It may be noted that as per the provisions of Section 84 of Patents Act, 1970 and Clause 35 of Patents (Second Amendment) Bill, 1999, a compulsory license may be granted in case the patented invention has not met the reasonable requirement of the public at a reasonable price. This provision is intended to provide for necessary and adequate safeguard for the protection of public interest taking in to account the specific needs of a developing country like India.

Furthermore, the CL system has been in place since the inception of the Patents Act, 1970 in India. It is noteworthy that not a single case of misuse of this provision has been observed during the last 30 years. An application for compulsory license may be granted only after the applicant has approached the patentee prior to the application with an offer to grant license on reasonable terms and conditions (as per Clause 36 of Patents (Second Amendment) Bill, 1999). In

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

determining whether or not to grant a compulsory license, the Controller of Patents is required to take in to account, the nature of the invention, the time that has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention (Section 85 of Patents Act, 1970). In settling terms of a compulsory license, the Controller of Patents is required to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights (Section 97(1) (ii)). These provisions substantiate the extent of a non-discriminatory administration of compulsory licenses.

In addition, the Patents (Second Amendment) Bill, 1999 has provided for an appeals process, before an Appellate Board, on any decisions by the Controller of Patents including a grant of compulsory license (Clause 54) before approaching the Indian Courts. The Patents Law provides for compulsory license to avoid misuse of an Exclusive Marketing Right by the right holder. This provision meets a larger public interest, keeping in mind the specific Indian conditions and is in compliance with Article 31 of TRIPS.

The Indian Patent laws are neutral in their application to domestic or foreign inventions. Any disqualification, CL, and exclusion from patentability, are provided for only in the larger interest to provide therein necessary and adequate safeguards for the protection of public interest, national security, bio-diversity, traditional knowledge, etc. These provisions are within the sphere allowed under Article 27, 30 and 31 of TRIPS. It is to be noted that 1999 has been a year of great coherence of political will, resulting in the passage of major IPR laws and work toward the establishment of an effective administration mechanism.

The implications of TRIPS for the pharmaceutical sector are that: patents will be granted both for products and processes for all the inventions in all fields of technology; the patent term will be twenty years from the date of the application (compared to seven years under the 1970 Act), which is applicable to all the member to all member countries and thus rules out all the differences in the protection terms prevailed in different countries.

Product Patents and Prices of Medicines

The debate on impact of product patents on the pharmaceutical industry in India[4] has centered on the issues of price of the patented product and their accessibility. The positive association is observed between stronger protection and prices of the drugs, also the prices declined with the expiry of patent. The adoption of process patents along with the domestic regulations that restricted the role of Pharmaceutical Industry of India has reached a position of near self sufficiency in formulations. After long experience of having a negative balance of trade in pharmaceutical products, India started enjoying positive balance of trade from the late 1980s. In production volume India accounts for 8% of world's pharmaceutical production and is the fifth largest in the world.

Irrespective of the competition, because of the socio-welfare implication of the pharmaceutical prices, all over the world other than US, the prices of medicines are subject to government regulations. In some counties the government meets the part of bill. Most of the governments list the drugs, which qualify for reimbursement and the extent to which they do so. In absence of such health security schemes and with the very low purchasing power of the people in India, the government of India has brought certain essential

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

drugs under the price control. The price control along with the amendment of patent laws in early 1970s resulted in a declining impact on prices. In India three factors have contributed to the lower cost of production: 1) the process development capacity of the units; 2) severe competition among the firms and 3) relatively lower cost of production. The comparison of patented drugs introduced elsewhere in the world shows that prices of the drugs had increased manifold after the protection. In the other side, developing countries may not be affected by the increase in the price of the drug due to low participation of patented drugs, because dynamic domestic players in India have managed to introduce substitutes of the patented products within four or five years after their appearance in the world market.

Impact of Weak Protection Regime

One of the major advantages of the universal system is that, it would facilitate access to new medical products. While welfare loss due to possible price increase in the post WTO regime is high lightened in the most of the studies, the welfare loss due non introduction of new patented drugs in India due to the weak protection regime is not discussed adequately. In this context, one of the advantages of the product patents is that the stronger patents will provide access to the latest inventions in the drugs, which the developed world will not shy away from introducing in India.

The drug prices in India were brought under control based on recommendations of Hathi Committee, which observed that since the drugs industry has a social responsibility, it should operate much above the principles of trade for profit. However due to repeated plea of the industry that the drug production was becoming unprofitable, in 1986, government reduced the number of drugs under control from 347 and 166. Yet in spite of the price reduction in India, over a period of 15 years from 1980, there has been a general rising trend in the prices especially of essential life saving drugs recently, where as the finance ministry under which DPCO is monitored has announced the decision to reduce the number of drug under price control.

The pharmaceutical policy 2002 indicated a drastic reduction in number of drugs under price control. According to the industry sources, the new DPCO would cover about 34 bulk drugs and their formulations under control. Despite the price controls, monitoring and enforcing such prices has been very poor in India where, significant differences persisted between the prices charged by different manufactures for the same formulation.

Product Patents and Research and Development

One of the advantages of the universal patent regime is that private venture capital firms become willing to invest in technology based start-up companies; technical knowledge flows more rapidly from university laboratories to the market place and local firms become willing to devote substantial resources to internet search. The higher cost of the R&D proves to be an effective entry barrier for new firms and hence only firms with large flow of funds become responsible for industrial inventive activity. In developing countries, only few firms have sophisticated R&D facilities and other benefit mainly from the spillovers of the resultant R&D. But in order to move on to the higher echelon, firms need to invest in R&D. For instance, cost of developing one new drug in the US increased from $54 million in 1970 to $231 million in 1990. Recent studies indicate that 1 out of 5000 compounds synthesized during applied research eventually reaches the market. Though global investment in the R & D has been increasing rapidly, R &D efforts need not necessary result in new products and innovations. Because of these reasons

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

and due to the protected policy regime, the R & D investment in India has been very low and started picking up only in the early 1990s. Rising R & D costs imply that only giant corporations with formidable R & D, marketing and financial capabilities will be able to afford extensive new drug developments and commercialization. Since it is difficult for each unit to invest in R & D, economize on scare R & D resources and to avoid the probable duplication, pooling of R & D resources and mergers of firms have been identified as possible solutions. The number of patents filed and granted also indicates the level of inventive activity and the R & D capabilities of the country.

Patents, Foreign Direct Investment and Technology Transfer

In India total FDI flow has been stagnating, due to various forms of regulatory framework and the government control over production that was prevalent for a long time. These regulations have been relaxed as part of the liberalization measures and currently 100% foreign equity is allowed in the pharmaceutical industry. Vast differences are observed between the amount approved and the actual inflow, which suggests that a large number of proposed investments to not materialize and perhaps wither away due to the bottlenecks encountered at the time of implementation. In pharmaceutical industry till 1999 it has been less than 0.5%. However, with the measures towards adopting stronger patents and increasing the FDI limit in the pharmaceutical industry from 74%-100% should attract more FDI over a period of time.

Future Scenario of the Indian Pharmaceutical Industry

The impact of IPR will largely depend on the developmental status of the economy such as the availability of technical manpower and infrastructure; capacity of domestic industry. A country with strong domestic industry such as India is in a relatively advantageous position than country where domestic industry does not have much presence and depends on multinationals. It is true that the impending WTO regime has stimulated the R & D investment in India. Some of the big units have started strengthening their R & D and have also filed number of application for patents. Some evidence regarding the mergers and amalgamations to pool the human and financial resources to strengthen the R & D in new product development. Some of the R & D and manufacturing facilities set up in these firms meet the international standard, and they have already been approached by multinationals for conducting research and undertaking manufacturing on their behalf. Besides the R & D investment in traditional chemical based screening, some of the R & D firms are looking for breakthrough in biotechnology research.

Pharmaceutical outsourcing is increasing world over and it is expected to increase still more with the vertical disintegration of activities by the multinationals as they review their core competencies. Henceforth, R & D could take place in one country, manufacturing in another and marketing rights could be given to totally different country.

In order to increase the global prospects of pharmaceutical industry in the post 2005 period, the central government has fixed the deadline of December 2003, to comply with Good Manufacturing Practices. Set by World Health organization. Since this is mandatory for all the units, it means incurring expenditures that could range from Rs. 15 lakhs to 1 crore per unit. The strength of the Indian Pharmaceutical industry is in reverse engineering. Such units by utilizing the provisions under CL, exceptions to exclusive rights and the Bolar exception should aim at producing the generic version of patented product and those that are near patent expiry.

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

Such firms are also be engaged in research leading to new drug delivery mechanisms and in identifying new uses of existing drugs. In this context, it is also essential to protect the innovations that have been introduced by the technology spillovers.

As far as India's pharmaceutical industry is concerned, various options are possible in the WTO regime. These are to: (a) manufacture of patented generic drugs, (b) produce patented drugs under CL, (c) invest in R & D to engage in new product development, (d) produce patented and other drugs on contract basis, (e) explore the possibilities of new drug delivery mechanisms and alternative use of existing drugs, and (f) collaborate with multinationals to engage in R & D, clinical trials, product development, or marketing the patented product on a contract basis and so on. Besides these strategies, India's strength lays in process development skills. This expertise utilized within the WTO framework with emphasis on quality standards will provide India a competitive advantage over other Asian countries.

V. K Shrivastava[5] has written about Parent Law and Indian Pharmaceutical Industry. According to him the law relating to patents is contained in the patents Act 1970, which came into force on April 20th, 1972. This Act was amended twice in 1999 and 2002 before the latest amendment in 2005. The amendments were carried out to meet India's obligations under the Agreement on TRIPs, which forms a part of the agreement establishing the WTO. The first set of amendments 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 are fulfilled. While the second amendment which was introduced in 2002 aimed at bringing the Patents Act in conformity with all the relevant provisions included in the TRIPs Agreement, barring a solitary exception of extending the product patent regime in the field of pharmaceuticals, agro-chemicals and food.

B.C. Nirmal[6] has written about Indian Pharmaceutical Industry and The New Patent Regime. According to him the pharmaceutical industry is well developed and capable to produce and sell practically all the drugs required in the country. Indian companies supply a large number of generic bulk drugs and their formulation to the global market. According to a study, 67 percent of the medicines produced in India are exported to developing countries. The leading companies in India have acquired over 20 companies aboard and the Indian industry has now become global in certain segments. The largest Indian companies have sales turnovers of $ 50 million to $1.2 billion. Although this size of sales turnover is relatively small as compared to annual sales of the leading MNCs of US, Europe and Japan which are in the range of $ 5 billion to $ 50 billion, the position of the Indian industry as a global player is widely acknowledge and Indian companies have adequate capabilities to create riche position in the global market in the days to come.

Global Status of Indian Pharmaceutical Industry

The media giants like the New York Times coming out with misguiding editorials[7], possibly aimed at stifling India's strength and powers in science and technology. It is important yet to analyze threadbare whether the new Patent Act is a sell-out or a well-planned game plan to isolate India at the WTO. Without reforms, India would not have reached such dizzy heights. It yet does not select Indian companies to seek extra protection on their home turf. Ironically, these pharma majors are also filing patents abroad and are doing roaring business in the very countries where patent laws are strictly in force. It also demeans the

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

well-established strength of the Indian intellect that is headed for the destination 2020.

There is a concerted move to crush India's science and technology skills. The well-known British think-tank Chatham House ran a seminar entitled, "Can Indian research changes the paradigm of the global pharmaceutical industry?" After the conference many Indian companies showcased their research. Consequently, streams of foreign R&D heads have been arriving in India to seek partnerships with Indian companies across the whole pharma supply chain including clinical, discovery, herbal research and manufacturing.

Robert Blackwill, former Dean of Harvard University and Ambassador to India said, "There has been a sea change in attitude by the people of India towards patents as they reap the benefits of the knowledge economy. The science and technology prowess of India is cutting edge and she must take her rightful place, along with China at the head of developed economies."

Similarly, in the 229th meeting of the American Chemical Society, the policy makers noted that scientists from India would soon be able to have the most innovative products outclassing the Americans. While a new drug development costs touch $1.5 billion overseas, it is an established fact that India can produce state-of-the-art drugs at a fraction of that amount leveraging on low cost, high quality, speed and large patient profile.

Together with the presence of largest number of US FDA approved plants outside[8] the USA, producing high quality drugs at lowest cost, India is in an enviable position to take on the best in the world. It is this reality that is causing worries for the policy makers in the West.

The Patent Act, 2005 can in no way influence cost of drugs. The government has taken care that drugs patented before 1995 are not covered by the patents. These include the drugs in the WHO essential list. With over 20,000 competitors, market forces will keep the prices under control. Rise in prices, if at all, would be more due to illogical policies of the finance ministry and rising duties and taxes than the patent law. In India, 97 per cent of drugs are off patent and are manufactured by a vast number of companies. Besides, physicians will always have the alternative of using older, cheaper but equally effective molecules to treat patients.

The new Patent Act Ordinance, introducing the long awaited product patents. The Ordinance includes several provisions aimed at rationalizing timelines, allowing flexibility and reducing processing time for patent applications. The new Act will boost R&D and will help to bring in foreign direct investment in the industry and contribute to improved healthcare. There are three areas where India will continue to lag behind in ushering in World Class IPR standards. The first is that India should join other leading countries and progressive nations in moving away from pre-grant opposition. The Ordinance as announced will provide representation by third parties and lengthen time for grant of Patent. The second area of concern for the Industry are the existing CL provisions that go much beyond national emergency and extreme urgent situations, public health crises and anti-trust situations. Broadening the scope of CL can lead to unfair commercial gains to favored companies. The third area of concern for the research based manufacturers is that a new provision has been added in the Ordinance that treats patent holders in respect of mailbox applications on a discriminatory footing in so far as them being denied the rights and privileges from the date of publication retrospectively.

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

The Patent Amendment opens up vast opportunities for the Indian pharmaceutical firms. Large companies like Ranbaxy, Nicholas Piramal, Dr Reddy's, Wockhardt, Lupin etc, are investing heavily in R&D and in a few years should be able to launch their own patented molecules all over the world. We also have the largest number of US FDA approved manufacturing facilities outside USA. Therefore, India is poised to emerge as a significant player in the area of generics. There is an apprehension that medicine prices are going to go through the roof in the product patent regime. This is a myth propagated by some sections of the industry. Over 97% of the drugs in the WHO list of essential drugs are already out of patent, and will continue to be available at current prices. And there are several therapeutic equivalents available for the rest. The NPPA will keep on monitoring medicine prices. As such, medicines contribute to only about 15% of healthcare expenditure. The bulk of the expenditure (85%) comes from diagnostic tests, hospitalization, doctor's consultation fees etc. Therefore, this obsession with medicine prices in India is not warranted.

Big pharma companies may enter India, not just to set up their own facilities but also to actively partner with Indian scientists, academic institutions and hospitals. Kerala, Maharashtra and Gujarat are already leading in clinical trials and work done there is accepted even by the foreign regulatory agencies, where quality requirements are most stringent. India, by not reneging on its commitment, will now be part of the global knowledge economy. This, in turn, would increase manifold cross border research, alliances, outsourcing, contract manufacturing, clinical research and in-licensing/out-licensing of products and services. Consequently, this would also bring in a paradigm shift in the pharma industry worldwide, enabling India to take rightful place at the head of the table among the developed nations. This would also mean that Indian drugs would move up the value chain.

The opportunity for the MNC pharma is improving their growth by launching patented new products. However, just having the Patent Law on paper will not be enough inducement to launch patented products. Once the TRIPS compliant law is in place the MNC's will monitor its implementation and if they find that it is being done in a transparent and fair manner only then they will launch their products. MNC's are also requesting the government to provide data protection to the safety and efficacy data developed by them through costly and time consuming clinical trials. All over the world in countries such as USA, Europe, China, Korea, Singapore etc, data protection is in force. We have recommended to the government that at least 5-year of data protection is granted from the time of marketing approval. It is necessary for the government to provide an environment of IPR protection that fosters innovation and stimulates launch of patented molecules, which will result in better healthcare for all. Another opportunity for MNC's is to enter into alliances with domestic companies for generic drugs sourcing for use by their overseas formulations plants. Again the local manufacturing units of MNC's can be utilised to manufacture bulk drugs and formulations for global supply to other affiliates.

The global pharmaceutical industry is under tremendous pressure to reduce costs. While the drug discovery cost has ballooned to a reportedly US $ 1 billion per NCE the R&D productivity is continuously declining. The global industry, therefore, is looking for cost containment through outsourcing and India offers tremendous opportunity in the area of contract R&D, manufacturing, clinical trials, bio-informatics, custom synthesis, technical services etc.

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

India will emerge as a leading country in the world pharmaceutical market. Many Indian companies like Ranbaxy, Dr Reddy's, Wockhardt etc, have begun international operations which will make a significant contribution to their turnover. Exports will be the major thrust of the industry, in the Post Product Patent Era. Also, the manufacturing costs for formulations would be half of what it is in the developed world due to lower costs of inputs. MNC's may make their Indian manufacturing facilities "centers of excellence" for supplying to other countries. Partnering for developing NCE's by outsourcing to India offers tremendous cost advantage without sacrificing on quality. The biopharmaceuticals market is also evolving very fast and the Indian market is flooded with biogenerics like erythropoietin, filgrastim, tPA, Interferon, human insulin, vaccines, etc. In fact India is likely to emerge as one of the largest producers of vaccines in the world in few years time.

China brought world-class patent act and data protection laws years before it was required to for similar reasons. Although it is behind India in research and development, it seems to be catching up quickly and is pouring billions of dollars in life sciences and biotechnology. Singapore, Thailand and Korea, too, are leaving no stone unturned to be on the forefront in the area of knowledge economy.

IP is a journey and will evolve over time as has happened in cases of telecom, insurance sectors. These sectors, due to new legislations, not only have witnessed steep fall in costs, the quality has also improved manifold. It is not by accident that CSIR[9-11] has filed largest number of patents abroad. It only shows that the Indian intellect is capable of creating its own space given the freedom to spread the wings of its intellect to its full potential. The patent law is a step that would help in opening of knowledge centers in the Indian villages and lead us to be a developed economy in the coming decades.

CONCLUSION

The Indian pharmaceutical industry has achieved remarkable progress in the last three decades or so. It is now a source of low cost drugs to the entire world including the largest and most regulated market of USA. One of the most important factors which made this possible is the abolition of ***product patent protection in pharmaceuticals*** under the Patents Act, 1970. But in line with TRIPs agreement of WTO, India has again introduced product patent protection in pharmaceuticals since 1 January, 2005. This study analyses how the new patent regime will affect:

- The market structure and prices
- The growth of the Indian generic companies, particularly SMEs
- Provides some suggestions for improvements.

In the product patent regime, the prices of the new drugs would depend on:

- What prices the MNC's holding the patents would charge
- What steps can be taken to regulate such prices.
- What prices (and manufacturing decisions) the MNC's will take for the new patented drugs
- What extent they will introduce them in India and other developing countries in the first place, are still not clear.

As and when they introduce new products, if they charge lower prices in developing countries, drugs will become more affordable. But in general the MNC's do not seem to be keen on such differential pricing in pharmaceutical products. Thus it is very important to put in place other mechanisms to control the prices of new patented products. Two important

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

and immediate flexibilities related to intellectual property are exemptions from grant of patents and CL.

Developed countries, for example, USA follow very liberal patent standards. Patents are granted not only for NCE's involved in the new drugs. Secondary patents can also be taken for new formulations, new combinations and new uses of existing NCE's which effectively enhances the life of the patent and hence generic competition.

The Patents Amendment Act of 2005 has provided the important qualification that some secondary patents cannot be granted "unless they differ significantly in properties with regards to efficacy". But what is "significant" in terms of efficacy is a matter of interpretation. The patentees can claim even a minor innovation as significant. The generic companies may not be able to afford the time and the resources to fight such cases and hence the MNC's may get an unfair advantage. The way out is to replace the phrase "unless they differ significantly in properties with regards to efficiency" by "unless they are therapeutically different". It is also important to put in place a proper procedure to scrutinize the product patents applications already made and those which will be made in future. The detailed procedure under the Indian Patents Act 1970 has been diluted. Full scale proceedings for opposition to grant of patents can now start only after the patent is granted and unlike as under the Act of 1970, a patent can be granted even when it is not convincingly settled that it can be granted, Since TRIPS does not impose any restriction on what procedures WTO member countries can adopt, there is no need or justification for India to change the procedure of pre-grant scrutiny as provided in the 1970 Act. A properly administered CL system is of vital importance in promoting competition while ensuring that patentees get compensation through royalties.

Article 31 of the TRIPs agreement permitting CL does not place any restriction on the grounds on which CL can be given. Some conditions are required to be followed. But it is not difficult to take care of these conditions. The Amended Patents Act has elaborate provisions of CL, but these have not been operationalised to have a simple and easy to administer CL system. Without violating TRIPs, India can adopt such a system. Price control is not forbidden in any WTO agreement. The government of course is free to fix maximum selling prices of such monopoly products. But if the patentees do not want price control, they can simply threaten to withdraw the patented protected monopoly products from the market, which is such a small market for them. The better option is to have a competitive market structure. This is possible with a proper CL system. Genetic competition can play a much more effective role in regulating prices than official price control measures. So far as new drugs are concerned, the options for the Indian companies in the post 2005 scenario are to:

- Produce these under CL arrangements
- Develop new drugs themselves.
- Collaborate with the MNC's as manufacturing and/or marketing partners for the new drugs developed by the MNC's.

A number of Indian companies are very optimistic about the prospects of increasing marketing and manufacturing alliances with the MNC's. The latter of course may find it profitable to take advantage of India's low costs and infrastructure. Outsourcing by MNC's from Indian companies has started but the present size is modest. India's prospects depend on how important costs would be in deciding on alternate locations and how the opposition to job loss in

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

developed countries is dealt with. So far as the existing generic drugs are concerned, the Indian companies can of course continue to produce these in India and abroad. The Indian companies can also start production of the new drugs after expiry of patents. But in the new product patent regime, Indian companies will no longer be able to produce the new drugs patented abroad. Thus competition will intensify in the existing generic market. The SMEs will be exposed to increasing competition from the larger companies as the latter will have less opportunity to diversify to new patented products. It is anticipated that a number of SMEs will not be able to face such competition and continue independent operation. A significant re-structuring of the pharmaceutical industry is under way.

The relationships between the larger and smaller units in the pharmaceutical industry in India have been competitive and collaborative. While a large number of smaller units in both bulk drugs and formulations manufactured for the larger units, they also competed with them. As competition increases in future, the elements of competition will decrease. In the retail formulations market, the smaller units will find it increasingly difficult to compete with the larger units, which have greater marketing and other resources. Independent small formulators will increasingly be confined to pockets of regional and local markets. The smaller units can play a much bigger role if the institutional markets grow in India.

Because of the weak drug control administration in India, not all the products available in the market are considered to be equal in quality, efficacy or safety. As a result, the doctors' and public confidence appears to be more with the products of the reputed companies. A good quality product of a small formulator may not sell much because it may not have the resources to spend on branding and establishing its reputation.

It is of fundamental importance to improve the drug control administration in the country. If drug control administration improves in the country, if all the products available in the market can be considered to be equally good, then SMEs with the price advantage can muster a much larger market share. Another important step which can be taken not only to enlarge the scope of SMEs but also to make drugs more accessible is to improve public health and health insurance facilities.

Public funded health care and/or subsidized insurance not only can influence prices. It can shift the financial burden from the poor who are unable to afford the cost themselves and hence can improve accessibility. It also provides a greater scope for smaller units which manufacture quality drugs but cannot afford the marketing costs and hence find it difficult to compete in the retail markets.

The Indian pharmaceutical industry is in general quite optimistic about the export prospects. In fact many of them believe that the growth in exports will more than compensate for the declining domestic opportunities in the new product patent regime. But our assessment is that the export prospects in coming years may not be as bright as it is often thought to be Product patent protection in pharmaceuticals in India was abolished in India in 1972. The positive impact of this was not felt immediately. It took almost two decades for the Indian generic companies to take full advantage and establish themselves. Similarly, it will take some time for the negative impact of product patent protection to be felt. It is possible that Indian generic companies are still too much influenced by the past growth and experience and are yet unable to properly assess the negative impact of shrinking domestic opportunities.

PATENT LAWS IN INDIA AND ITS IMPACT ON PHARMACEUTICAL INDUSTRY

If we want the Indian generic companies to have a steady growth in future, then there is no alternative but to devise measures so that they can continue to manufacture and sell the new patented products in the domestic market. This is possible within TRIPs by having a simple and easy to use CL procedure.

The most important recommendation from the point of view of ensuring a competitive market structure and affordable prices and helping the growth of Indian generic companies, it is of fundamental importance to have a proper CL system. The government will take the Ordinance route to bring about amendments to the Patents Act. Sources in the group of ministers, constituted to look into the draft Bill, said there were only "minor issues" to be sorted out.

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