CHAPTER-VIII

CONCLUSIONS AND SUGGESTIONS
8.1 Conclusions

Worldwide patent movement, influenced by the current trends in globalisation, appears to have produced some undesired result in the developing countries including India. The study undertaken to ascertain the impact of patent regime on pharmaceutical sector and public health is able to establish to a great extent the fact that the patent regime contemplated under TRIPs agreement is not able to promote the economic development and consequent welfare of all as claimed by the promoters of WTO even though the regime has some positive aspects as well.

Patents as statutory rights granted by the state for a limited period in respect of a new and useful inventions, have played a dominant role in economic development of a state. Patent rights having originated as an exception to the rule that all monopolies are illegal,\(^1\) have been statutorily regulated by every state to promote general welfare of the citizens on the ground that patents are the tools of public policy that should be used to attain higher level of public interest than to promote only the individual interest of inventors or the owners.\(^2\)

National laws provide for patentability of inventions and generally inventions satisfying the three criteria, namely, novelty, inventive step and

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\(^1\) Supra, p.16.
\(^2\) Supra, p.75.
industrial application qualify for patent grant. States also exclude certain inventions from patentability on the ground of public order and morality. The scope and ambit of patentable subject matter vary from time to time and place to place. National laws determine the procedure for the grant of patents and every state has a system of patent administration. The procedures are provided to ascertain the patentability of inventions and also to prevent piracy of patents. For this reason Indian law provides for both pre-grant and post-grant opposition procedures.

Patent once granted, confer upon its owner a limited monopoly irrespect of commercial exploitation of the invention. The distinction between ownership of material objects and the ownership of patents required elaborate rules determining the rights of the owners, assignees and licensees. It is often said that failure to perceive the distinction properly has created some inconsistencies in the law.

The expansion in international trade, growing commercial significance of patents, inability of national patent laws to protect legitimate interests of patent holders against counterfeiting and piracy, difficulties in obtaining patents in more than one state, fear of loss of novelty and growing demand for harmonisation of patent laws paved the way for international recognition of patents and conclusion of the Paris Convention for the Protection of Industrial Property, 1883. The Convention, for the purpose of protecting the interests of inventors and patent

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3 Supra, p. 58.
4 Supra, p. 66.
5 Supra, p. 17.
holders and to promote technology transfer and economic development, introduced principles of national treatment, right of priority and rules regulating patent holder’s monopoly through compulsory licences. However, the Convention leaves substantive issues such as patentability of inventions, fixing the term of patent and patent claim interpretation and enforcement to be determined by each member country. Further the Convention requires that an applicant has to file separate applications in different countries. The failure of the Convention to harmonise patent law and the opposition by developed countries led to the adoption of the Patent Co-operation Treaty (PCT) by the members of the Paris Union.

The PCT is an agreement for international co-operation in the field of patents and it was primarily concerned with filing of international applications, international publication and examination. But PCT does not grant “International Patents” and granting patents remains exclusively in the hands of the patent office of the respective countries where patent is sought. The limitation of the Paris Convention and the PCT, significance of IPR in international trade, increased piracy of IPR in developing countries and the need to provide substantive international legal standards led to the adoption of TRIPs agreement.

The policy behind introduction of IPR issues into the WTO was to use the threat of trade embargoes to force developing countries to follow the dictates of developed countries on whole range of economic and industrial policies on the one
hand and on the other to use these new issues to create barriers against developing countries wishing to access the domestic markets of developed countries.\textsuperscript{6}

The TRIPs requires all state parties to comply with its provisions before 1.1.2005 barring least developed countries and it insists state parties to suitably modify their laws and institutions. Firstly, it lays down standards concerning the availability, scope and use of IPRs. Article 27 of the Agreement provides that patents shall be available for both products and processes in all field of technology. It also stipulates certain exceptions on the ground of public order, morality and health. Secondly, it confers upon patented products exclusive rights, which include right to prevent third parties from making, offering for sale, selling or importing them. Thirdly, it insists that any use of patent by third parties except by way of compulsory licences must be prohibited. Lastly, it tries to harmonise patent laws of different countries and infact attempts to establish competition between unequals. This appears to be one of the most controversial aspects of the agreement.

The underlying principle of Indian patent law prior to 2002 was that patent grant is not only to encourage innovation but also that inventions are worked to the advantage of the society. Accordingly, the Indian Patent Act 1970, provided for the following; first, an invention in order to be patentable must relate to a new and useful manner of manufacture, which includes not only a process of manufacture but also a manufactured product. Second, grant of monopolies in respect of a

\textsuperscript{6} \textit{Supra}, p. 248.
discovery of a scientific principle or an invention injurious to public health, or a method of agriculture or horticulture or a process of treatment of human beings, animals or plants is prohibited in public interest. Third, patent monopoly being purely a creation of the statute, the Act can impose any condition for its grant. Thus, in respect of food medicine and drugs patent can be granted only for the process of manufacture of the substance and not on the substance itself. Further the term of a patent for an invention relating to food, medicine and drugs, has been reduced substantially with a view to mitigate the evil effects of monopoly.

**Effect of TRIPs on Indian Patent Law**

The patent law in India has undergone drastic changes to incorporate TRIPs provisions. There was some resistance to the amendments to the Patent Act 1970 both inside and outside the Parliament on the ground that the agreement was an attempt by the industrialised countries to strengthen their monopoly over technology regardless of the fact that such an approach is protectionist anticompetitive and antiliberalisation.\(^7\) The Indian Patent Act was amended three times to comply with TRIPs mandates. The first two amendments were concerned with exclusive marketing rights and extension of patent term to 20 years. The third amendment in 2005 introduced product patenting.

The 1999 Patent Amendment Act actually gives exclusive marketing rights (EMRs) merely on the basis of foreign patents obtained after 1995 without

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\(^7\) *Supra*, p. 295.
scrutiny of the consequences of EMRs on public health, morality and public interest.

The 2002 amendment, introduced after Doha Declaration, incorporated major provisions of the TRIPs except those relating to product patenting of food, drugs and pharmaceuticals. The amendment also introduced certain general principles intended to regulate excessive monopoly associated with patenting. Those two aspects of the amendment were subject to sever criticisms by the developed countries and they put pressure upon the Indian government to further amend patent Act so as to make it TRIPs complaint this led to 2005 amendment.

The major change that 2005 amendment made was the recognition of product patents in respect of food, drug and pharmaceuticals. Thus the effect of TRIPs on Indian patent law may be summarised as follows. Firstly, the amendments established product patenting by defining invention as a new product or process involving inventive step and capable of industrial application. Secondly, the amendments excludes from patenting inventions the primary and intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to the human, animal or plant life or health or to the environment. Thirdly, the amendments further excludes from patenting living organisms, plants and animals including seeds, plant and animal varieties except microorganisms. Fourthly, an important aspect of the Indian Patent law is that an invention which in effect is a traditional knowledge or which is an aggregation or duplication of known properties of traditionally known
components is not patentable. This provision is extended to conserve biological diversity against bioprospecting and bio-piracy. Fifthly, a uniform term of 20 years from the date of patent has been incorporated by replacing earlier provision providing for shorter term for inventions relating to food, medicine and drugs.

Lastly, for the purpose of regulating excessive monopoly associated with patents and in consonance with TRIPs provisions relating to anti-competitive measures, section 83 of the Act incorporates certain general principles. They are (i) the patents are granted to encourage inventions and they should be worked in India on a commercial scale; (ii) patents are not to be granted merely to enable patentees to enjoy a monopoly for the importation of the patented article; (iii) the patents granted do not impede protection of public health and nutrition; (iv) patent granted in any way do not prohibit central government in taking measures to protect public health; (v) patent rights are not normally abused by patentees; and (vi) patents are granted to make the benefit of patented invention available to the public. On the basis of these principle patenting of drugs and pharmaceuticals and its effect on public health are discussed in the study.

**Impact of TRIPs compliant Patent law on drugs and pharmaceuticals**

Novel compounds, which have a pharmaceutical utility, are patentable *per se* in all countries, which have implemented TRIPs. There are now very few countries of any importance which totally forbid the patenting of pharmaceutical inventions. The patenting of drugs and pharmaceuticals must take into consideration difficulty in distinguishing chemical compounds from
pharmaceuticals and medical treatment exception to patenting. The novel pharmaceutical compounds are of three types combination preparations comprising two or more pharmaceutically active ingredients, new drug delivery systems or genetic forms and compositions comprising a compound not previously used as a drug together with any conventional pharmaceutical carrier or excipient.\textsuperscript{8}

However, earlier patent systems have provided separate standards for pharmaceuticals and restricted patents only to those drugs and pharmaceuticals produced through new technological process. Recognition of product patents in the field of pharmaceuticals has to take in to account the fact that many substances used in the manufacture of drugs and pharmaceuticals are not chemical compounds but naturally occurring plants, animals and living organisms. It is often said that naturally occurring products are not patentable but a claim to a newly discovered natural product may be valid if it is framed in such way as to distinguish the claimed product from the product as found in the nature. In many countries, there have been many such patents and that many antibiotics are natural products. This has led to the use of biological diversity for production of drugs and this process is called bio-prospecting. Now, sophisticated biotechnological processes are used to transform plant and animal derived substances into commercial products.\textsuperscript{9} It is asserted here that confirm of patents to those products run counter to the principle that natural products are not patentable and

\textsuperscript{8} Supra, pp.84 & 96.

\textsuperscript{9} Supra, pp. 91-92.
patent claim should be restricted to processes only. The impact of product patenting of drugs and pharmaceuticals have far reaching consequences on pharmaceutical policy and public health systems in developing countries and the following conclusions emerges from the study.

(1) The product patenting, conferring property rights would allow a few MNCs of technologically rich states to control access to food, medical and other resources essential to the health and welfare of the billions of people. The patent system would have a grave impact on pharmaceutical sector and posed the danger that indigenous drug industry would be “gobbled up by the foreign multinationals”. However, proponents of product patenting have constantly maintained that to attract foreign investment and technological development such a patent regime is necessary. But the study indicates the opposite\(^\text{10}\) and the product patents have further enhanced MNC’s monopoly. The developments in microbiology and Biotechnology made them to claim monopoly over the drugs and pharmaceuticals derived from natural products and it is asserted that in such cases only process patent is desirable. The argument advanced by MNCs in respect of product patenting was to recoup investment in R & D and development of a new drug involves investment above one Billion Dollars. It is established that investment in R & D in many cases is less than what they spend for marketing and publicity.\(^\text{11}\)

\(^{10}\) *Supra*, pp. 296-97.

\(^{11}\) *Supra*, p. 298.
(2) There is some truth in the assertion that the patent system built on TRIPs would strengthen western monopoly over technology and 20 years term would discourage research and development in India even though there is an assumption that the patent system would assist technology transfer. The study has indicated that the patent system instead of encouraging domestic pharmaceutical sector would allow MNCs to market their products resulting in closure of large number of small and medium scale units and public sector units. By mergers and acquisitions MNCs will capture and take control of Indian companies to dominate the Indian market.

(3) The TRIPs agreement is likely to inhibit reverse engineering, the process by which research-based industry products are copied and adapted for developing country usage. Even developed countries also have applied the method of reverse engineering. This has the grave impact on generic production of drugs and pharmaceuticals. One effect of the patent law would be that generic players either have to discontinue production or continue by paying heavy royalty as the section 11A failed to define properly the phrase “reasonable royalty”.

(4) The patent regime, which treat importation as working of the patent would further impair technology transfer and thereby defeat the governmental initiative to modernise Indian pharmaceutical and drug industry. This justifies

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12 Supra, p.332-35.
13 Supra, p.338.
14 Supra, pp. 279-90.
the claim that some industrialised countries would take undue advantage of international rules such as TRIPs because such rules facilitate them even with the aid of trade sanctions to extract royalty payments.

(5) By putting TRIPs into WTO, a self-standing treaty was incorporated into international trading system. This would necessarily commercialise certain aspects of social life that should belong to non-commercial sectors. For the purpose of preventing over commercialisation of food supply and healthcare the Indian patent Act contain general principles of working of patents. But there are doubts as to the efficacy of these principles to effectively regulate monopolistic behaviour of economically powerful patent holders.

(6) The studies from the developing countries argue that as the TRIPs agreement comes into effect, massive drug price escalation will ensue and it is established that medicine prices are directly related to patent system prevailing in a country.\(^\text{15}\) The increase in prices of the essential drugs in third world countries can be attributed to product patenting, exclusive marketing rights and disappearance of generic production.

(7) UN Human Rights bodies have rightly pointed out that there is a conflict between IPR regime contemplated in the TRIPs and International Human Rights law and reminded all states of the primacy of human rights obligations over economic policies and trade agreements. It is asserted here that high cost of patented medicine will prevent the governments of poor countries to take

\(^{15}\) Supra, p. 285.
effective steps to control the spread of diseases like HIV/AIDS, TB and malaria. The health care systems in developing countries will be badly affected, despite the fact that there are provisions in the TRIPs relating to emergency.

(8) It is claimed that TRIPs compliant patent law reduce individual’s access to medicine and health care and the worst affected are the poor. Lack of access to health care impairs productivity and economic development while low productivity keeps citizens too poor to afford appropriate health care.

(9) To mitigate the evil effects of patents and to promote public health, the Government of India, under its pharmaceutical policy, provides for legal regulation of prices of essential drugs and pharmaceuticals. Curiously patented drugs are exempted from price control and companies determine the prices. Where as in Canada and in some other countries retail prices of drugs are determined through consultation with the government agency and the manufacturers. It is also asserted that after introduction of product patenting, Government control over production, distribution and sale of essential medicines are decreasing.

(10) The opposition to the TRIPs by the developing world led to the adoption of Doha Declaration, which enables the states to unilaterally regulate patent rights through compulsory licences. The efficacy of the declaration is yet to be ascertained, even though section 92 of the Indian Patent Act provides a 'special provision' by which Central Government may issue notification
calling applications for issue of compulsory licences in cases of national emergency, in circumstances of extreme urgency or in case of public non-commercial use. The effectiveness of the 'special provision' appears to be diminishing since the licence issued under section 92 is also governed by terms and conditions governing the issue of compulsory licence under section 84 except the procedure prescribed under section 87 of the Act. The non-application of section 87 in cases of public health crisis arising out of epidemics enables the government to take appropriate measures ignoring patent monopoly.

(11) The proponents of TRIPs have claimed that IPRs will stimulate local innovation, attract foreign direct investment and technology transfer. However, the study is unable to establish link between IPRs and innovation, flow of FDI and technology transfer.\textsuperscript{16} It is asserted that profitability appears to be the sole factor and not IPRs that stimulate innovation, FDI and technology transfer.

(12) Despite the debate over adverse impact on pharmaceuticals sector, Indian firms intend to have some kind of alliance with established foreign multinationals at least for the time being. Firstly, the presence of large firms provides expertise and resources necessary for Indian firms.\textsuperscript{17} Secondly, Indian firms may have strategic partnership in respect of drug testing and

\textsuperscript{16} Supra, pp.325-33.
\textsuperscript{17} Supra, pp.336-37.
human trials. Thirdly, enable Indian companies to undertake contract manufacturing. The patent regime may promote strategic alliance, international networking and co-ordination amongst different constituents of the innovation chain comprising of academia, industry, public funded laboratories to promote new drug discovery and to improve pharmaceutical sector.

8.2 Suggestions

It is generally agreed that the TRIPs compliant patent regime may not likely to promote the interests of all and to mitigate its evil effects on public health and general welfare, incorporating following aspects in to the Indian patent system appears to be desirable.

(1) The grant of product patents to inventions relating to drugs and pharmaceuticals shall be restricted to new chemical entities the invention of which involve huge investment in R & D. The patent law should clearly define new chemical entities in such a way that products developed out of modification of natural products through chemical or biological process are not granted product patents. The reason is that what is really invented is the process of modifying the natural products and the product itself is not entirely new as it has natural elements. Accordingly, natural products obtained from plants and animal sources, which have useful pharmacological properties, must be excluded from patenting to prevent monopoly over natural resources. The other reason for exclusion of patent protection to such product is to enable the competitors in business to produce similar products through alternative cheaper and better processes, otherwise they have to wait till the original patent expires.
(2) The proviso to section 11A (7) enables the patent holder to claim royalty in respect of generic products produced by generic manufacturers even in respect of those products produced before the grant of patents and before 1st January 2005. It is suggested that the above provisions be replaced so that the interests of generic producers are protected to that extent and giving retrospective effect is contrary to the well established principles of law.

(3) Compulsory licensing provisions in the Act must spell out clearly the circumstances under which it can be issued by the government. The phrase 'prima facie' case and 'national emergency' have to be defined in such ways that the government can effectively deal with the spread of epidemics such as bird flu, HIV/AIDS, T.B. and the like. The Act must empower the central government to declare emergency if substantial number of people are affected by the communicable diseases and it is desirable that some agencies like the Department of Public Health must be empowered to take such decision by taking in consideration the nature of the diseases, availability of drugs and other relevant factors.

(4) The section 92 enabling the Central Government to grant compulsory licences in cases of national emergency, extreme urgency or non-commercial use are also subject to the same provisions governing issue of compulsory licences under sec.84 appears to be ineffective and therefore it is suggested that the section be suitably modified to empower the Central Government to impose additional terms and conditions to make the special provision to deal with emergencies effectively.
(5) It has been noticed that in the recent past the number of drugs subject to price control are decreasing and pharmaceutical policy has to be modified to include more and more drugs under price control. The three years limit in respect of patented drugs must also be relaxed in cases of national emergency and extreme urgency. A mechanism has to be evolved to fix minimum retail price of essential drugs and its periodic revisions. The mechanism prevailing in Canada appears to be suitable to India.

(6) A professionally constituted National Health Authority must be constituted to advice the Central Government, the controller of patents and other departments and officials concerned with public health administration. The Authority must consist of patent attorneys, representatives of pharmaceutical sector, social workers and public health officials. The functions of the Authority must be related to advice the Controller as to when compulsory licences have to be issued and to determine the terms and conditions of the issue of such licences. Secondly, on the basis of a reference by the Central Government, it shall recommend the government in respect of existence of national emergency and extreme urgency and the like. Thirdly, it shall conduct necessary studies and survey in respect of fixing prices of drugs and pharmaceuticals. Fourthly, to hold negotiations with patent holders and manufacturers in respect of fixing prices and in determining the quantum of royalty in cum of compulsory licensing. Lastly to advice the government in respect of formulation and implementation of public health measures.