CHAPTER-I
INTRODUCTION

International patent movement, built around multinational corporations (MNCs) and some governments of the developed world, with the assistance of some International Treaties such as Trade Related Aspects of Intellectual Property Rights (TRIPs), the Patent Co-operation Treaty, the substantive patent treaty and the like, seems to establish an inflexible patent system where patents of 20 years run time have to be given for any invention in the field of technology. This being part of ongoing process of globalization wherein rules of international law are assuming importance and national laws are becoming increasingly subordinate to them.\(^1\)

The degree to which treaties and international law intrude on national decision making seem to support attempts made by some states to even prevent others from taking actions to protect their legitimate interest. In this connection World Trade Organisation (WTO) provisions, perhaps those in the intellectual property agreement, which requires governments to fulfill certain standards regarding domestic law and court system, are particularly important.\(^2\) It is often said that full implementation of the TRIPs agreement would impede growth and economic development in the third world countries,\(^3\) often such international rule constraining the governments to act in certain ways are justified on the ground of influence of global market process and in matters of intellectual property was to stop piracy.\(^4\) Some industrialized countries would take undue advantage of international rules such as TRIPs because those rules facilitate, even with the aid of trade sanctions, “what is in the main a payment by the poor countries (which consume intellectual property) to the rich countries (which produce it) in the form of royalties”.\(^5\)

The process of globalization has adversely affected national governments’ monetary and fiscal decisions. It is claimed that economic globalization is the number

\(^{4}\) Article 41, Part I of GATT.
one threat to the survival of the natural world. The global transfer of economic and political power from national governments to multinational corporations is a disaster for human rights, the environment, social welfare, agriculture, food safety, worker’s right, national sovereignty and democracy.\textsuperscript{6}

However, harmonization of patent laws appears to be necessary to promote international trade, particularly in respect of technology transfer. The developed countries are in an advantageous level in economy and technology. Most of the developing countries are certainly economically and technologically at lower level. So, the provisions of formal and substantive laws have to be harmonized to some extent which will suit the interest of both developing and developed countries.

The term ‘harmonization’ could be interpreted by different people to have different meanings. On one extreme, it could mean that the laws and their enforcement would be common to all countries opting for harmonization. In other words, the uniqueness of laws of individual country would merge into a common framework. To some, it may mean only working out of common procedures and administrative practices. To others, it could mean stipulation of common minimum standards to be followed as domestic laws. Harmonization is just a journey towards minimization of such differences existing in the patent systems of different countries.\textsuperscript{7}

1.1 The Problem

Intellectual Property is already a big component of global trade, consequently, the number of cross border disputes, multiple infringement suits related to patents is also increasing. Their resolution is complicated because the scope and coverage of patent protection differs from country to country.

National patent laws of most countries embody principles and concepts that were shaped by the Industrial Revolution. They are ill-suited for our information driven age. Our age deals with inventions that springs from such exotic technologies such as nanotechnology, information technology, biotechnology and robotics. The new developments plus the necessity to mitigate frictions generated by the territorial nature of

patent protection in global trade has created an acute need for harmonization of patent laws and their enforcement.\(^8\)

Over the years, with the intensification of globalised trade, harmonization of patent law worldwide has become an important goal of intellectual property and trade negotiations. Most of these IPR-Trade negotiations are pursued under the auspices of the World Intellectual Property Organization (WIPO).

Developed countries and MNCs have been lobbying aggressively for harmonization of the major substantive aspects of patent law such as grace period, prior art, novelty and inventive step at the global level. Substantive Patent Law Treaty (SPLT) proposed at the WIPO is meant to address the issues and concerns raised by developed country IP holders.\(^9\)

In order to speed up the harmonization process efforts have already begun in WIPO. Dismantling the Standing Committee on Information Technologies (SCIT), which was established by the General Assembly in 1998 to serve as a forum to discuss issues, facilitate coordination and provide guidance concerning the implementation of the WIPO global information network (WIPONET) and it was replaced by Committee on WIPO Standards (CWS), and a Committee on Global IP Infrastructure (CGI).

These efforts are oriented towards setting up a system for aggressive harmonization of patent administration networks. The harmonization agenda designed by the developed countries and MNCs has to be seen with a lot of caution. These efforts had been strongly opposed by developing countries.\(^10\)

The Trilateral Cooperation which was negotiated by Japanese Patent Office (JPO), European Patent office (EPO) and United States Patent Office (USPTO) had the objective that

‘Through harmonization and development of industrial property administration and protection of industrial property rights, the Trilateral Offices strive to contribute to an increasingly efficient worldwide patent system in the 21st century’.


Consequently, this trilateral co-operation led the way to the formation of Patent Prosecution Highways (PPH). The harmonization of patent office administration in developed countries are realized through the MoUs for administrative collaboration between patent offices. Initiatives such as Patent Prosecution Highways (PPH) initiated by the USPTO and JPO one of the best examples. According to the provisions of PPH, search and examination work of the office of first filing can be used while processing the same application in the office of second filing.

Patent examination is one of the substantive aspects of patenting. If it is done judiciously, it can facilitate better industrial development and better access to medicines. For instance, Tamiflu, that is used extensively for the treatment of H1N1 flu (Swine flu) across the world is an off-patented drug in India. Hence it is cheaper in the Indian market. On the contrary, in most of the developed countries, tamiflu is a patented medicine and is exorbitantly priced. Similarly, the Indian patent office has rejected many foreign patent applications of pharmaceutical substances that are used in medicines such as tenofovir, darunavir (HIV/AIDS) and imatinib mesylate/Glivec (leukaemia) on the ground that the applications did not satisfy novelty as required by the Section 3 (d) of the Indian Patent Act. Generic industry in India has benefitted enormously from these off patented drugs. An important fact to be noted is that it has also ensured better accessibility to comparatively cheaper drugs in India and other developing countries.\(^{11}\)

Depending upon the provisions available in the domestic laws, the scope and coverage of patent protection differs from country to country. It should be noted that provisions of the Patent Act is a reflection of the ground realities of that country. For example, both India and Thailand have inserted more pre-grant safeguards in their patent laws to protect the public health needs viz., provisions to curb “evergreening” of patents, higher inventive step/utility criterion, pre & post grant opposition at patent offices are some of the important safeguards. It should also be noted that TRIPS and the Doha Declaration allow countries some leeway in moulding their patent system according to their domestic needs, present state of development, and to address public health needs.

From the past experience, it is a well documented fact that weak examination standards of developed countries, especially in the US, have resulted in mushrooming of

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\(^{11}\) *Ibid.*
frivolous patents. This has contributed to manifold increase in the number of patent filings and patent litigations. Transaction cost is skyrocketing to unsustainable levels. The question before us is that is this the model we want to replicate in India?\(^\text{12}\)

The harmonization of patent law will have serious implications for the industry, agriculture as well as public health. It will impede local innovation and technological development in developing countries by restricting access to patented knowledge held by the foreign IP creators. Increasing number of patenting of innovators from US, Japan and EU through PCT filing is an example of this. In the guise of capacity building of HR in developing countries, the flawed model of IP culture is being instilled among the patent examiners of the developing countries by the developed countries. The despicable fact is that this is done in connivance with the local industrial organizations and the government officials.

The present law built on TRIPs is believed to ignore certain legitimate interests of the developing countries and may create certain problems for them including India.

Firstly, some critiques warned that there were serious problem with the quality of patents in developed countries, and if the SPLT is based on that system, it would “export a dysfunctional system to the rest of the world”.\(^\text{13}\)

Secondly, generally developing countries which have shown the fastest economic growth are those that retained relatively protected markets until they reached a position of strength. Regrettably, harmonization is a way for those who have already arrived at a prosperous situation to pull up the ladder and stop others joining them.

Thirdly, given the imperfections of the patent system, harmonization should not be the first thing to think of and indeed may do more harm than good. The diversities of national law and practice are needed to make the system bearable particularly with regard to less and least developed countries.

Fourthly, flexibilities provided for by the TRIPs agreement are good on paper but difficult to apply.

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Fifthly, what objectives should developing countries pursue in responding to the harmonization demands of developed countries?

Sixthly, how feasible and practical do these proposals have to be in order to gain support from other stakeholders and to be successfully carried forward in international fora?

Seventhly, which could be the areas of the respective reform processes where coalitions could be built between developing and developed partners?

Eighthly, product patenting, conferring property rights would allow a few MNCs of technologically rich states to control access to food, medicines and other resources essential to the health and welfare of billions.

Ninthly, new patent monopolies in India will dramatically drive up the cost of medicines.

Tenth, enforcement of TRIPs provisions through trade sanctions may lead to economic imperialism of the west and there are enumerable instances where U.S.A. used WTO provisions to protect its MNCs.

1.2 Objectives of the study

The study for the purpose of suggesting solutions to the problem stated proceeds with the following objectives.

i) The primary objective of the study is to evaluate the efforts towards harmonization of patent laws by International community, some industrialised countries and India and to evaluate the consequences of such harmonisation on wellbeing of people, in particular poor citizens of India.

ii) The study makes a brief analysis of basic principles of patent law and its evolution in various countries such as U.K., U.S.A., European Countries and India, which is essential for evaluating recent trends.

iii) An attempt is made to elucidate briefly the general principles of patent law of major industrial countries and India highlighting the differences in laws prevailing in those countries.

iv) To examine the need for harmonization of patent laws by looking into the conflicting and contradicting provisions of patent laws prevailing in different countries.
v) To examine the core principles of harmonization of patent laws that are evolved and the success of efforts made by international community of states to ensure uniform patent laws.

vi) To discuss the advantages and disadvantages of harmonization of patent laws and the benefits and burdens of the same on different types of countries namely developed and developing countries.

vii) To analyse and evaluate the factors that are responsible for success or failure of harmonization process including challenges faced by developing countries.

viii) An attempt is made to investigate whether or not the process of harmonization created certain problems to the developing countries by preventing them from promoting the welfare of its poor masses. It is believed that harmonization is responsible for escalation in drug prices and thereby it reduced the poor’s access to vital medicines. It is also alleged that harmonization reduces the poor’s access to quality food and nutrition.

ix) The study is also concerned with the analysis of TRIPs provisions and its impact on the ability of national government to ensure economic development without surrendering its authority to MNCs.

x) Lastly, the study proposes to make certain suggestions that could mitigate the evil effect of harmonization on Indian citizens by balancing the interests of various stakeholders in international trade.

1.3 Importance of the study

Multilateralism and globalization are co-producers of each other. The synergy between the two is so intense that one is today witnessing the development of a new world order. In a borderless economy the competition has become severe and companies, corporations and R&D institutions must search for new solutions to beat problems that may have an adverse and immediate impact on their competitiveness and a long term impact on their survival. These are comparatively new issues being faced by developing countries which are trying to move up the value chain and are breaking off from the closed economy to enjoy the fresh air of open economy. It is now well understood that solutions to problems and challenges emerging out of globalization will be found in
developing innovations in strategies, products, processes, marketing, business methods and so on.

Companies from developing countries have to learn the rules of the new game as they do not have the necessary experience of handling global trade and commerce. It is clear that the new environment has become very dynamic and complex. One of the major challenges faced by them is developing an understanding of the laws of different countries, and also using them correctly to their own advantage. The success of a multilateral system depends heavily on formulation and practicing of common rules.

On one extreme it could mean that the laws and their enforcement would be common to all countries opting for harmonization. In other words the uniqueness of the laws of individual countries would merge into a common framework. To some it may mean only working out of common procedures and administrative practices. To others it could mean stipulation of common minimum standards to be followed in domestic laws. It may be safe to assume that the degree and extent of harmonization would actually decide the success or failure of the harmonization exercise. The process of harmonization of IPR systems started with the Paris Convention and is continuing today. Harmonization of IPR systems among nations cannot be dispensed with by any nation interested in having a share in the global trade. Some countries may have a vision of a truly global patent system, with one central office issuing patents valid in any country in the world. The countries, however, has to work for the task of what should be the extent, scope and degree of harmonization, which would be acceptable to all and not interfere with the sovereignty of nations.

It is believed that the study is going to be useful not only to corporates and industrialists but also to academicians, administrators, policy makers, legislators, social activists and lawyers who intend to practice in this highly specialized and technical field of intellectual property law. The study is useful to patent attorneys and business people concerned with patents. The study in general makes an attempt to contribute something original to enrich the discipline of law.

1.4 Methodology adopted

The methodology adopted for the study is completely doctrinal and not empirical. But empirical data have been used to critically evaluate the concepts. Various Statutes,
International Treaties, Books, Journals, Magazines, Newspapers, reports, Articles and Case laws have been referred and various websites are visited to get the current information about the study.

1.5 Scheme of the study and its presentation

The investigation into the problem pertaining to the harmonization of patent laws and its impact on Indian legal system is presented in eight chapters.

The First Chapter “Introduction” while introducing the study makes an attempt to elucidate the genesis of the problem and its scope. It highlights objectives of the study, its importance and the methodology adopted. An attempt is also made to indicate in brief outlines of the study.

The Second Chapter, “Evolution of Patent Laws” makes an analysis of evolution of patent laws in different countries such as U.K., U.S.A., European countries and deals with history of patent legislations in India. The chapter traces the development of patent laws in India particularly from the point of view of economic development and general welfare of the people.

The Third Chapter, “Principles of Patent Law” deals with important aspects of present substantive and procedural patent law principles. The chapter also covers scope of patents, conditions for patentability, the procedures for the grant of patents and rights and obligations of patentee. The thrust of the chapter is to highlight the differences in the law prevailing in most important countries and in India.

The Fourth Chapter, “Internationalisation of Patent System” examines internationalization of patent law. It highlights the need for international protection of patents. It also examines the implications of international rules relating to patent on domestic patent law. For this purpose, an analysis of International Conventions such as Paris Convention, Patent Cooperation Treaty, WIPO and TRIPs agreement are undertaken.

Since the 1883 Paris Convention, there have been considerable efforts being made to harmonize patent laws internationally, culminating in the conclusion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) under the auspices of the WTO. However, patent law still remains independently administered and enforced by each country, creating substantial administrative, financial, and legal costs to
multinational corporations operating in technologically sensitive industries. The necessity of harmonization of substantive patent law does not recognize any border, but the patent protection is limited to territory of the state in which it is granted. With the intense globalization of trade due to advancement in transport and communication technology, there is a need to protect the invention in multiple countries. There is as such no global patent granting system. The application has to be processed in all the countries, where protection is required. A basic framework for patent protection is in place due to the Paris convention, PCT and TRIPS agreement. However there are dissimilarities in the formal requirements, substantive requirements and the procedural requirements of the patent laws of different countries.


The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of 1994 is the most notable step taken towards harmonization. It introduced intellectual property law into the international trading system for the first time and nudged signatory countries towards a level of uniformity which most are still struggling to cope with.

The TRIPS Agreement greatly underestimated the technological catch-up abilities of developing countries in terms of social, administrative, infrastructural and other costs due to their uneven stages of technological advancement. This is particularly true for pharmaceutical products in countries lacking local manufacturing ability.

The Sixth Chapter, “Influence of TRIPs on Indian patent law” examines the impact of TRIPs on Indian Patents Act 1970. This chapter analyses the provisions of Patents (Amendment) Act, 1999, 2002 and 2005. In this chapter an attempt is made to
analyse various changes made in the Indian Patent Act 1970, so that Indian patent law moving towards complying with the provisions of TRIPs.

The 1999 Amendment Act with intention of providing stronger patent protection to foreign pharmaceuticals and to create stronger domestic research capabilities, introduced EMR provision for a period of five years.

The 2002 Amendment Act introduced a uniform term of 20 years for patents abolishing the distinction between general patents and patents for food and medicinal inventions.

The 2005 Amendment Act by deleting section 5 of the Indian Patent act, 1970 introduced product patenting in the area of pharmaceuticals and other inventions.

These changes as it appears were necessitated to make the Indian patent law TRIPs compliant, but some have argued that Indian patent law is still not fully TRIPs complaint. But it is argued that even though there may be some divergences are there, still it is TRIPs compliant.

Thus in the Seventh Chapter “Harmonization and its consequences”, an attempt is made to examine the impact of harmonization on the general welfare of citizens of India in general and pharmaceutical sector, public health and agriculture and food in particular. The proponents of harmonization and TRIPs compliance argue that such patent law encourages innovation, promotes technology transfer and economic development. Adversaries have argued that such a patent regime is not helpful for India as it affects generic drug production, escalate drug prices and this reduces individuals’ access to medicines. It is argued that such a patent regime will impose unwarry burden on the State to promote public health and thereby reduce governmental efforts to combat public health problems such as epidemics, infectious diseases and nutritional deficiencies. There is an apprehension that such patent regime may adversely affect the governmental effort to combat diseases such as AIDS etc.

The patenting of food and related products may adversely affect the interests of poor and farmers since the patent regime recognises patenting of living organisms and biological products if these production includes use of some technology. To mitigate the hardship caused to the poor there is the need to evaluate some inventions relating to food
and drug from patenting. It is argued in the thesis that a patent regime fully compliant with TRIPs is counterproductive.

The last Chapter, “conclusions and suggestions” on the basis of the study, an attempt is made to draw certain conclusions directed against mitigating the evil effects of harmonization on Indian patent system, impact of harmonization on general welfare of the people of India. An attempt is made to argue that the present process of harmonization is not conducive to the economic development and general welfare of India. Accordingly, some suggestions are made to minimise adverse impact of harmonization process.