CHAPTER-I

INTRODUCTION
CHAPTER-I
INTRODUCTION

Worldwide 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 Law 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 any field of technology. This development being part of on going process of globalisation has produced some undesirable results, at least in some states or regions of the world. It has created difficulties in promoting health and safety of products moving across borders such as food stuffs pharmaceuticals, machinery and appliances, and also increased the power of non-governmental organisations and their capacity to operate on a global economy while ignoring particularly of a national governmental regulatory protection.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.² In this connection World Trade Organisation (WTO) provisions, perhaps those in the intellectual

property agreement, which requires governments to fulfil certain standards regarding domestic law and court system, are particularly important. It is often said that full implementation of the TRIPs Agreement would impede growth and economic development in the third world countries. Often such international rule constraining the governments to act in certain ways are justified on the ground of influence of global market forces and in matters of intellectual property was to stop piracy.

However, some industrialised 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”. The TRIPs also allowed the private enterprises, especially MNCs to extract royalty payments through WTO.

The process of globalisation has adversely affected national government’s monetary and fiscal decisions. It is claimed that economic globalisation is the number one threat to the survival of the natural world. The Global transfer of economic and political power from national governments to multinational

---

3 Supra note 1, p.3.
5 Article 41 part I of GATT- “Members shall ensure that enforcement procedures as specified in this part are available under the national laws…”
corporations is a disaster for human rights, the environment, social welfare, agriculture, food safety, worker's right, national sovereignty and democracy.\(^8\)

It would allow a few MNCs of technologically rich states to control access to food medicine and drugs. When Thai companies made AIDS drugs available at a cost well below that of United States drug companies, the United States on behalf of the drug companies threatened WTO and TRIPs challenge for patent infringement. Thailand, which depends on United States for 25% of its exports, was effectively blackmailed into stopping the manufacturer of cheaper AIDS drugs.\(^9\)

It has been claimed that intellectual property rights are well protected by the WTO at the expense of human beings as WTO rules reflect an agenda that serves only to promote dominant corporate interest that already monopolised the arena of international trade.\(^10\) According to UNICEF, in Guatemala 1.5 million infants die every year, primarily from fatal infant diarrhoea caused by the supplementing of breast-feeding with artificial formula. Gerber Food, a US based multinational claimed on its packages that its infant formula would ensure healthy babies, and bolstered the claim with photographs of fat healthy babies. Guatemala enacted a law, modelled after the World Health Organisation Code of Marketing of Breast Milk substitutes, intended to protect infant health. The law required that

\(^8\) Ibid.
\(^9\) Id., at p.436.
formula producers clearly state the superiority of breast-feeding on their labels. All of Guatemala’s domestic and foreign suppliers of formula changed their packaging to comply. The country’s infant mortality rates dropped dramatically. Gerber, however, induced the United States State Department to threaten a WTO challenge based on company’s intellectual property claim to its labelling. In response Guatemala amended its law to exempt imported baby food products.  

When the South African Government sought to enact the Medicines and Related Substances Control Bill, the US government accused it of failing to adequately protect American drug patents. The US objection was divested at provisions in the law, which would allow for compulsory licences and parallel importing. Despite the considerable pressure exerted on the government and the Parliament of South Africa, the Bill was passed in 1997. The pharmaceutical industry in South Africa, backed by the MNCs and the pharmaceutical lobby in the US filed a legal challenge to the new law. The US government taking its cue from its Pharmaceutical lobby began a process of negotiations and threats to get the South African Government to change its stake. It was only after intense campaign by AIDS and health activists that the US retreated from its position and eventually reached resolution of the matter.

11 Supra note 7, at pp 436-437.
13 Ibid.
India is not an exception to this development. The US had taken India to the WTO dispute settlement panel to enforce patent monopolies in pharmaceuticals. Besides India and Brazil, the Dominican Republic, Argentina, Vietnam and Thailand have all been threatened by the US under its special 301 laws. Challenging the might of WTO, the US government and pharmaceutical giants, CIPLA an Indian drug company, announced that it would sell AIDS therapy for $350 a year or less to Medicines Sans Frontiers (MSF) which will distribute it in Africa free of cost. In 2000 Glaxo welcome threatened to sue CIPLA when it tried to sell a generic version of GLAXO anti-Aids drug combination in Ghana. The African Regional Patent Authority ruled against Glaxo, but CIPLA stopped selling the generic drugs.

It is quite clear from all this that developing countries have confronted and continue to confront, significant pressures from industrial countries. The choices for developing countries have narrowed; either they increase protection for intellectual property in general or at least, in particular, extend patent protection for pharmaceutical drugs, or otherwise experience actual or threatened retaliatory actions by Industrial countries.

---

14 Section 301 of the Trade Act of 1974 was strengthened by the 1988 Omnibus Trade Act and has been used to threaten and retaliate against countries, which do not agree with US policies regarding Patent Protection for pharmaceuticals.


One area where the threat to human rights was perceived is pharmaceutical sector. The worst impact of TRIPs that the pharmaceutical industry of developing countries foresees would be the end of generic drugs. It is feared that the product patent regime mandated by TRIPs might lead to the destruction of a strong indigenous industry that produces generic substitutes for drugs discovered elsewhere and supply these generics both domestically and to other developing countries at a fraction of the cost of branded originals. It is also feared that in the post TRIPs era large number of units in the industry may be compel to close down and only a few hundreds may survive.  

A Parliamentary Committee in its Report asserted that TRIPs would adversely affect India's interest and would impair its obligations towards health and welfare of millions of citizens. The patent law in its present form would erect barriers against fulfilment of states, obligations towards its citizens arising out of constitutional mandates and even obligations arising out of international law also.

India being a social welfare state, the Indian Patent Act was framed in a manner that ensured the predominance of public interest over the interests of inventor. Patent law in India has always strived to strike a balance between the individual interests of patentee and the interest of the society at large. Therefore, Indian Patent Act 1970 did not grant patent protection for food and pharmaceutical 

products. It was an effort to keep the prices of necessary medicines at an affordable level by placing public health considerations above property right concerns. It was successful in its endeavour to a certain extent. The Indian pharmaceutical industry flourished in the absence of product patents for pharmaceuticals. The competitive generic market resulted in production of generic versions of block bluster drugs at very low prices. But the signing of WTO TRIPs Agreements has brought about major changes in the existing legal regime of patents. Amendments to the Indian Patent Act 1970 in the year 1999, 2002 and finally in 2005 generated heated debate on the issue of public health. The option available to the nations to have a process patent regime in the areas of national importance has been completely taken away by the TRIPs agreement. There was some resistance to the amendment both inside and outside the Parliament on the ground that TRIPs agreement is an attempt by the industrialised countries to strengthen their monopoly over technology regardless of the fact that such an approach is protectionist, anti-competitive and anti-liberalisation.\footnote{\textit{Supra} note 4.}

1.1 The Problem

The proponents of product patenting have always insisted that for the purpose of economic development, to improve technology and to recoup the investment made in Research and Development (R & D) product patenting is a must. However, those concerned with welfare of the poor and the oppressed have vehemently argued against product patents taking into account the possible impact
of product patenting on health, safety and welfare of the people. 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 have asserted that it would strengthen western monopoly over technology and the 20-year term would discourage research and development in third world countries.

Secondly, the TRIPs agreement, which treats importation, as working of the patent would further impair technology transfer and there by defeat the government’s initiative to modernise Indian pharmaceutical and drug industry.

Thirdly, it would have grave impact on the drug prices and posed the danger that the indigenous drug industry would be “gobbled up by the foreign multinationals”.

Fourthly, 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.

Fifthly, 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.

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

Seventhly, implementation of TRIPs agreement will, result in violation of human rights such as right to life and right to good health.
Lastly, there is the question of how far Indian patent system would effectively regulate the behaviours of large MNCs that dictate prices of food, drugs and medicines.

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 object of the study is to investigate into the problems posed and issues raised by the compliance of TRIPs agreement in India and its possible impact on pharmaceutical industry, public health, safety and welfare of the people.

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 and India, which is essential for evaluating recent trends.

iii) An attempt is made to evaluate the provisions relating to patentability of pharmaceutical inventions.

iv) For the purpose of analysis of possible impact of law on pharmaceutical industry, attempt is made to analyse structure of pharmaceutical industry, its role and policies regulating it.

v) The study tries to ascertain whether Indian patent law has gone beyond the requirement of TRIPs agreement.
vi) An attempt is made to investigate whether the compliance with TRIPs would escalate drug prices and make them inaccessible to the poor and needy.

vii) The study makes an attempt to ascertain that whether generic drug industry will disappear from the pharmaceutical sector.

viii) Through critical analysis of the provisions of Patent (Amendment) Act 2005 an attempt has been made to ascertain whether India has made adequate provision for compulsory licensing, parallel importation and others to ensure fair competition and to promote availability of essential drugs.

ix) The study investigates whether transfer of technology and foreign direct investment in developing countries will increase under the new patent regime.

The primary hypothesis to be tested in the course of study is that introduction of TRIPs compliant patent regime is inimical to the interests of health, safety and welfare of the citizens of India.

1.3 Importance of the study

It is believed that the study is going to be useful not only to academicians but also to administrators, policy makers, legislators, social activists and lawyers who intend to practice in this highly specialised and technical field of intellectual property law. The study is useful to patent attorneys and business people concerned with pharmaceutical industry. It is also believed that the study will
provide certain policy choices to find solutions to pressing problems concerning accessibility to essential drugs and those relating to public health. The study in general makes an attempt to contribute something original to enrich the discipline of law.

1.4 Methodology adopted

The study has been primarily doctrinal and not empirical. But empirical data have been used to critically evaluate the concepts. Various Statutes, International Treaties, Books, Journals, Articles have been referred and various websites are visited to get accurate information about the problem.

1.5 Scheme of the study and its presentation

The investigation into the problem pertaining to TRIPs compliant patent law and its impact on the pharmaceutical sector and public health 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, “Basic principles of Patent Law”, for the proper understanding of the impact of patent law on the pharmaceutical sector and public health makes a brief analysis of evolution of patent law. The chapter also covers the nature and scope of patents, the procedure for the grant of patents, and patentability of inventions. It also focuses on the evolution of patent law in
different countries such as U.K. and U.S.A., and deals with history of patent legislations in India.

The Third Chapter, “Patents for Pharmaceutical Inventions” makes an analysis of patenting of pharmaceutical products. Pharmaceutical products were patented under certain circumstances, and in India until recently process patent was granted for pharmaceutical inventions. This chapter discusses the need for protecting pharmaceutical inventions, patentability of chemical inventions and patentability of methods of medical treatment. The chapter also traces the recent developments relating to expansion of patent protection for pharmaceuticals and drugs and the effect of such expansions.

The Fourth Chapter, “Internationalisation of Patent System” examines internationalisation of patent law. It highlights the need for internationalisation and its impact on domestic patent law. It also examines the implications of international rules relating to patent on domestic patent law. For this purpose a brief analysis of International Conventions such as Paris Convention, Patent Co-operation Treaty and TRIPs agreement are undertaken.

For the purpose of proper understanding of the impact of law there is a need to analyse various facets of pharmaceutical policy in India. The chapter examines basic elements of pharmaceutical policies in India promulgated by the government from time to time. The policy in general concerned with the growth of pharmaceutical industry, licensing, price regulation and availability of drugs. The attempt is made in the Fifth Chapter, entitled “pharmaceutical industry in India
and the patent system”, to establish that the recent policy changes may adversely affect the interest of the industry, consumers and the general public.

The TRIPs agreement introduced global minimum standards for protecting and enforcing nearly all forms of intellectual property rights. TRIPs agreement requires all member countries to grant patents for products and process including pharmaceuticals for a period of twenty years. TRIPs has not been universally welcomed, particularly in countries where there was no protection or weak protection for pharmaceuticals. Whether or not TRIPs agreement benefits the developing countries is a matter for debate. The arguments in favour of TRIPs agreement are that protection for pharmaceuticals is essential for promoting research and development (R & D) as well as stimulating innovation. It also encourages multinationals to invest and supports innovation by the existing producers within the country. People who argue against it say that it is expected to have the great impact on the pharmaceutical sector and thereby on the system of health care. It will raise the prices of drugs and eliminate all hope of providing affordable treatment of the millions affected with HIV/AIDS and other life threatening diseases in India and other parts of the world. Therefore, in the Sixth Chapter, entitled, “impact of TRIPs agreement on Indian pharmaceutical sector and public health”, an attempt is made to examine impact of TRIPs on generic production, drug prices, access to medicines. The chapter also examines its impact on Indian economy and on human rights. The policy options available to the
government and the future scenario of pharmaceutical industry have also been discussed.

The opposition to TRIPs by the developing countries led WTO members to adopt a special Ministerial Declaration at the Ministerial Conference in Doha to clarify ambiguities between the need for governments to apply the principle of public health and the terms of the agreement. In particular, concerns had been growing that patent rules might restrict access to affordable drugs for populations in developing countries, and adversely affect their effort to control diseases of public health importance, including HIV, Tuberculosis and Malaria. The Doha Declaration responds to the concerns of developing countries about the obstacles they faced when seeking to implement measures to promote access to affordable medicines in the interest of public health in general, without limitation to certain diseases. While acknowledging the role of intellectual property protection for the development of new medicines, the declaration specifically recognises concerns about its effects on prices. The Doha Declaration affirms that, "the TRIPs agreement does not and should not prevent member countries from taking measures to protect public health". In this regard Doha Declaration enshrines the principles that World Health Organisation (WHO) has publicly advocated and advanced over the years, namely, re-affirmation of the right of WTO members to make full use of the safeguard provisions of the TRIPs agreement in order to protect public health and enhance access to medicines in poor countries. The Doha Declaration refers to several aspects of TRIPs, including right to grant
compulsory licences and the freedom to determine grounds upon which licences are granted and the exhaustion of intellectual property rights. Therefore Seventh Chapter, entitled “Doha Declaration on TRIPs and Public Health” discusses the background to Doha Declaration and other events, which are responsible for the signing of the Declaration. This chapter also examines various provisions of the Declaration and developments that took place till today. Finally an attempt has been made to show whether the Doha Declaration has successfully promoted the interests of developing countries with respect to access to medication.

The Last Chapter, “conclusion and suggestions”, examines the impact of TRIPs in the light of the analysis and discussion made in the earlier chapters. An attempt is also made to draw conclusions and to establish the thesis that TRIPs agreement has both positive and negative effects. The effect of Doha Declaration is also evaluated to show that it was able to mitigate to a certain extent, hardships caused to the developing countries but it cannot provide solutions to other genuine problems relating to promotion of public health since WTO is based on ‘free trade’ but the people want ‘fair trade’.