CHAPTER-I

INTRODUCTION

1.1. INTRODUCTION

The innovations and new techniques have been made in the modern scientific world giving a better way to live with all modern equipments which has made life easier and enjoyable to live who have been gifted with riches of wealth which enables them to lead a peaceful and enjoyable life giving them opportunities to afford whatever they require at their will. The have and have-not’s are the facets of the same coin the former having their own means to enjoy and the latter having their own sufferings and have to lead the life at the mercy of others and almighty God. India being a country which is rich with full of unutilized resources and the majority of the people are poor, illiterates and live with starvation due to unemployment and great dependence on daily wages and agriculture. Most of the people live in villages without much facility of road, communication, pure drinking water, shortage of electric power and lack of awareness as to the health and hygiene. This has led to the conditions that no appropriate means are available for them to even consult a doctor nearby even if they do so is with the registered medical practitioner (RMP) who is not so well versed in medical science. This has caused untimely death of poor people to worsen their life’s causing another blow to their struggled living. It has been observed that many poor people are afraid of consulting a doctor for the purpose of diagnosis and prevention of the disease the only reason to such an attitude is the heavy cost involved in the process of diagnosis such as tests, CT scan, etc. There is also negligence on the part of the rural community not taking proper care towards their health. No proper care is taken for pregnant women and their child’s growth due to lack of awareness and medical facilities many new born children suffer with ill heath and ailment due to malnutrition, poor quality of food, water and living conditions in additions to the building pressures on the growing population with rapid pace.

At the same time the modern technologies have made the world smaller in terms of space, time, distance and communications in urban areas by means of internet, mobiles, satellites, transport etc., which has led to globalization and liberalization of trade. India being a growing and developing country cannot restrain
itself from being a member to the GATT/WTO which gave acceptance to the agreements to keep it with pace to other nations to facilitate trade, investments, transfer of technology etc. Hence, it was obligatory to the member nations to follow the norms of the agreements as a condition of membership in World Trade Organization (WTO) and the members not accepting the plurilateral Agreements are not entitled to any of the rights emanating there from these rights. One of the important agreements of GATT/WTO was on protection of intellectual property rights (IPRs) namely the Trade Related Aspects of Intellectual Property (TRIPs) Agreement is the major concerns for the developing and under developed nations as there are harmful consequences in terms of certain issues such as patents, utilization of biodiversity, protection of the poor farmers and rural community. This was done by the developed countries under the threat of sanctions against the opposing country.

The central importance was given to the economic development by means of contributing knowledge to the process of production by adopting modern technology sideling the interests of the developing countries. The management of knowledge in IPR has become a very crucial issue, as to its adaptability and applications to the needs and requirements both at the national and international level satisfying the national interest and complying the WTO agreement was a difficult task. The TRIPs agreement facilitated trade by the mechanism of creating multilateral agreements on IPR which includes patents, trademarks, copyrights, geographical indications, industrial designs, layout designs and integrated circuits, trade secrets, breeder’s right and utility models.

The industrialized nations choose to reward innovators by giving exclusive right to use and market the product for a particular period in terms of patent rights, including the recognition of product patents to encourage further innovations in the field of science. Since the inception of TRIPs Agreement many developing countries have accepted the agreement and have brought the IPR laws to suit their own needs and all the developing countries were given transitional period to bring their laws at par with TRIPs agreement by bringing suitable amendments at the exit of the said

---

transitional period. The last decade has witnessed a virtual revolution in protecting and enforcing of IPR laws in this part of the world. Almost all developing countries and underdeveloped countries have either replaced or substantially changed their IPR laws.

Hence, India also in consonance with TRIPs has made amendments to its IPR laws especially the Patents Law in the year 1999, 2002 and 2005.

Under the obligations of the TRIPs agreement which provides for patenting of inventions relating to pharmaceutical drugs including process and product patents a decision required for the countries to grant product patent for pharmaceutical innovations as a condition of membership in the WTO was very contentious. Almost 50 developing countries were not granting patent monopolies for drugs during the transition period when the Uruguay Round of GATT was being debated these countries fiercely resisted the inclusion of this requirement claiming that drug prices would be higher which are associated with such patents. On the other side business interest in the west urged them to consider the beneficial effects of protecting innovations in pharmaceuticals would bring great fruits in Foreign Direct Investments (FDIs) in local research on Tropical diseases. Hence patents on pharmaceutical products and processes provide drug companies with monopolies over the production and marketing of the medicines, allowing them to fix prices at high rates to maximize profits. The TRIPs Agreement under the WTO has come under criticism for facilitating the extension of these patent rights around the world.

The obligation under TRIPs to implement high standards of IPR protection in recognizing product and process patent will effectively eliminate competition from generic pharmaceutical producers and allow for increased prices of medicines beyond the reach of more patients in the developing countries.

Although developing countries succeeded in getting the WTO Ministerial Conference to issue a landmark declaration by stating that public health should take

---

3 Transition Period of the TRIPs Agreement adopted by amending the Indian Patents Act, 1970 in 1999 for filing application under exclusive marketing rights and process patents from the year 1995 up to 2005.
4 Amendments to the Indian Patents Act 2005, recognized for the first time the Product Patents in the field of Pharmaceutical Products, Drugs, Medicines and Food products including Chemicals - Universal’s Bare Act on Patents.
6 Cecilia oh, TRIPs, Patents and Access to Medicines, With Third World, Briefing Paper, June 2001, discussed at a meeting hosted by the Indonesian Mission, P.1
7 Ibid.
precedence over WTO patent rules.\(^8\) The so called Doha Declaration re-affirmed the
duty of governments to use WTO public-health safeguards and other measures to
gain access to the cheapest possible medicines without the threat of sanctions. The
TRIPs agreement is not a uniform law, it sets forth minimum standards to be
provided for any WTO member may grant a broader protection than that required
under the agreement, but it cannot be obliged to do so as Article 7 of the agreement
establishes a general framework for the interpretation of its provisions. The aim is
to balance the interests of innovators and users of technology in the protection of
IPR, in a manner that enhances “Social and Economic Welfare”. The practical
achievement to balance this is not an easy task.

The agreement leaves considerable room in certain areas to legislate at the
national level to adopt measures that may mitigate eventual negative effects of the
introduction of pharmaceutical product patents as such Article 8.1 in particular,
provides that “members may, in formulating their national laws and regulation,
adopt measures necessary to protect public health and nutrition and to promote the
public interest in sectors of vital importance to their socio-economic and
technological development, provided that such measures are consistent with the
provisions of this agreement.” The agreement specifically permits under Article
27.3(a) exclude from patentability “diagnostic, therapeutic and surgical methods for
the treatment of humans.” In addition Article 27.2 states that “members may
exclude from patentability inventions, the prevention within their territory of the
commercial exploitation of which is necessary to protect public order or morality,
including to protect human, animal or plant life or health or to avoid serious
prejudice to the environment, provided that such exclusion is not made merely
because the exploitation is prohibited by domestic law.”

Many developing countries are confused about the contradictions in the TRIPs
agreement on the one hand having to implement stricter IPR protection and on the
other hand protecting public health policy satisfying the interests of patent holders by
motivating them to improve their research and development in finding new medicines
and investments and at the same time meeting the needs of the common man’s
requirement of providing accessibility to life saving drug at an affordable price.

\(^8\) Declaration on TRIPs Agreement and Public Health Ministerial Conference, 4\(^{th}\) Session, Doha,
14\(^{th}\) November, 2001. WTO,http://www.WTO.org/English the/WTO.e/minist.e/minol.e/min-
dcl/ftrip epdf
Even though the TRIPs Agreement provides for flexibilities, a member country cannot utilize them fluently as there are a number of difficulties and conditions that are put forth subject to which these flexibilities come to the rescue of the general public. The developed countries have a different view as to the protection of IPR more specifically the patent rights in the field of pharmaceutical products they contend that it is not the patent rights which has posed threat to the access of life saving medicines but it is the member State’s inability to protect its subject i.e., to say the government is not framing the required public health policies with the need of the hour. Many of the underdeveloped and developing countries are lagging behind in appropriation of funds towards the public health sectors. When we make a comparison of the budgets of each member countries many of them allocate funds towards the import of oils and oil products, defense equipments and other such activities. Many of the governments have agreed to this fact and have expressed their concern that it was the financial constraint that has forced them to neglect health sectors.

As a counter reaction the developing nations have a say that “extending patent rights to every field of technology including product patents to pharmaceutical products is something harsh i.e., to say the granting of patents to medicines which are essentially life saving drugs have become costlier which forces the poorer sections of the people from getting access to drugs and medicines. They also contend that patent creates monopoly and allows the manufacturers to fix an exorbitant price on the patented medicines it generally means that patent is a tool of exploitation and not an encouragement to the manufacturers and patent holders. This breeds a platform for setting up innovations and innovative ideas for further development of technology and makes Government strive hard to work for the welfare of the general public. But, the fact is innovations takes place to enrich one as it can be clearly made out that the patented medicines are priced highly. The ineffective pricing mechanisms and regulatory bodies have contributed to the difficulties of the poor patients as price control is probably a difficult task to be managed under patent regime. It is an unjust enrichment of corporate sectors at the expense of the poor general public.

In Indian scenario it is the duty of the State to protect its citizens from any difficulty especially to the downtrodden poor people. India does not recognize the
“right to die” or euthanasia for the people who are suffering from life threatening
disease so that they can end their life from all types of sufferings nor recognizes the
right to life in full fleges. “Right to Life” includes ‘Right to Health’ so the
government should make efficient health policies to protect the poor patients by
providing them health care facilities.

Is the Right to health an enforceable right a question has to be posed to
oneself are we speaking practically when it comes to the matter of Right to Health
as we see many instances in different cases that this right is not properly enforced
as is done in any other rights envisaged under the constitution of India, when it
comes to enforceability of Right to Health, even though the courts recognizes and
gives a favorable order the government takes an excuse that it has no binding to
provide health facilities as it is covered under the Directive Principles of the State
Policy as such an individual cannot enforce right to health as a matter of right. It
is the states discretion whether to provide health facilities or not. This is where the
conflict begins between patent protection and health policy of the government.

1.2. STATEMENT OF THE PROBLEM

Since the signing of the WTO agreement till date diverse contentions have
emerged on the issue of “impact of TRIPs on patent laws and on developing
countries”. There is wide consensus that domestic laws needs to make full use of
‘flexibilities’ available in the TRIPs agreement. This was reiterated by the WTO
Doha Declaration on TRIPs Agreement and Public Health which commented that
countries have sovereign right to enact laws to safeguard domestic interest. This
recognizes the public health problems in developing countries and provided for
member countries to protect public health and to promote access to medicines for all.

An attempt should be made to understand and analyze the provisions to give
priority to health policy and at the same time meet the TRIPs norms without
harming public interest in such a manner that India does not compromise the
interest of the country both in terms of its ability to safeguard the health of its
people and interest in promoting a self-reliant indigenous pharmaceutical industry.
Taking into account the decisions and developments in the field of stricter
implementation of IPR regime and protection of health, control of prices etc., which
are conflicting issues and find out a way how best India can utilize flexibilities to
protect public health. An assessment of how India can deal with these both the
protection of health and IPR implementation a critical evaluation is required. In the light of this preliminary analysis the topic for the research is selected. The main problems and issues of the research are identified as follows:

1. How TRIPs agreement affected IPR regimes on product patents?
2. Whether there is any impact of product patents on prices of medicines in India?
3. Whether there are any conflicting issues on health and affordability of medicines and rise in prices and protection of the products through product patents?
4. Whether certain measures are taken to utilize flexibilities within TRIPs subject to conditions to protect public health?
5. Whether it needs analysis of situations concerning the health policies before and after implementation of process and product patent regime in compliance to TRIPs agreement on public health?

1.3. OBJECTIVES OF THE STUDY

Taking into account the problems or issues of the research the study is aims to conduct research with the following objectives:

1. To appraise whether product patent regime in the field of medicines is a boon or a bane to the developing countries.
2. To assess what are the impacts and implications of product patenting on pharmaceutical industries and their products.
3. To examine to what extent the prices on medicines are affected and its affordability being denied.
4. To evaluate whether the pricing policy of the patent holder has a negative impact on public health policies and effect human rights as it restricts the purchasing power of a poor when there is already recession like, conditions and inflation on prices have gone beyond control and harmed the standard of living conditions.
5. To examine to what extent government has been able to control the prices of the drugs under patent regime keeping in mind the public interest.
6. To examine to what extent the government can undertake measures to control prices of the medicines and drugs.
7. To suggest for prioritizing for implementation of public health policy for the poor living in poor economic conditions.
8. To evaluate the extent of monopolistic nature of business in pharmaceutical products affecting public health.

9. To evaluate what alternative measures the Government can take to compensate the Research and Development (R&D) expenditures incurred by the patent holder by taking measures such as licensing, tax holiday, royalties etc., and take advantage of flexibilities available to curb price rise of pharmaceutical products to shoulder the burden of the needy people.

10. To suggest appropriate amendments in national and international laws and policies to control unlawful monopoly in the field of pharmaceutical products to enable the poor people to access the essential medicines.

1.4. REVIEW OF LITERATURE

IPRs protected by TRIPs agreement at international level is a new area to this part of the world and research has not been undertaken as much as has been expected in this area. Since the effect of TRIPs Agreement can be made out only after it is practically dealt with at so an early stage of its infancy to the adoption of product patent regimes. Legal instruments at the international level touching upon the problem of the study such as the TRIPs Agreement, Paris Convention and decisions and documents of the WTO Ministerial conferences are reviewed and analyzed.

Legal instruments on the topic of research in India such as the Patents Act, 1970, as amended from time to time, the Union Government drug policies and orders are reviewed and analyzed. Enormous literature is available in the form of books, articles; comments on the topic are reviewed and analyzed.

1.5. SCOPE OF THE STUDY

The topic of research necessarily requires the study of international instruments such as the TRIPs Agreement of GATT/WTO and Paris Convention for the Protection of Industrial Property. The TRIPs Agreement and Paris Convention covers in their ambit the Copyrights and related rights, Trademarks, Patents, Designs, Integrated circuits, Geographical indications, Trade secrets etc. However, the study is restricted to critically analyze the impact of product patent regimes in the field of medicines on Indian product patent policy.
The TRIPs Agreement under the WTO is an international instrument ratified by more than 158 countries. However, the study is being conducted with special reference to Indian patent regime governing product patent in the field of medicines.

1.6. SOURCES OF DATA

The primary sources of data includes instruments covering the topic such as TRIPs Agreement under WTO and Paris Convention for the Protection of Industrial Property at international level and Patents Act 1970, as amended up to date and Drug policy of Government of India.

The secondary sources of data includes books, articles, comments, news items, proceedings of seminar and conferences available in the form of hard and soft copies are utilized to carry out the research.

1.7. METHODOLOGY

The methodology adopted for the research is doctrinal method. It is basically descriptive and analytical type of study, wherein the topic is critically evaluated touching the problem of the research by making use of primary as well as secondary sources of data collected by various techniques.

1.8. HYPOTHESES OF THE STUDY

The following are the hypotheses formulated based on aims and objectives of the study:

1. There is conflict between product patent protection and protection of public health.

2. The product patent regime in the field of medicines and drugs has a negative impact on public health policy.

3. The product patent regime in the field of medicines and drugs has increased the non-affordability of the life saving drugs for common man due to high tendency of monopoly.

4. Priority to the health is not given in Indian Patents Act in utilizing the flexibilities to regulate the effect of prices of product patents in the field of medicines and drugs after its amendments in 1999, 2002, and 2005.
5. Disease sufferers’ right to have access to medicines and drugs is inefficiently addressed under the existing laws such as Indian Patents Act and Drug Price Control Policy (DPCP) of Government of India.

6. There is a need to amend the existing national and international laws and policies to extend the fundamental right to health on par with the fundamental right to education.

1.9. CONCEPTUAL FRAMEWORK

The conceptual framework of the study has been formulated by conceptualizing various aspects of the problem that has been raised by the experts in the fields of legal, scientific, technical and pharmaceuticals manufacturers on the various types of literature available in the field of study.

1.9.1 Access (to medicines)

In health services, the opportunity to obtain health care or medicines. Barriers to access includes cost, non-availability at point of service, and cultural factors.

1.9.2 Sui generis

A term meaning a specialized regime of intellectual property rights, separate from copyright, patents and other forms of intellectual property rights. *Sui generis* is a legal expression (Latin) meaning “of its own kind”. For example, it has been proposed to develop sui generis legislation for the protection of traditional medicine, since it is difficult to protect traditional medicine under intellectual property rights.

1.9.3 Working

The use of an invention in a commercial context, such as manufacturing of a patented product, use of a patented process and commercialization of a protected product in some cases, also the importation of a patented product is included. “Local working” and “national working” are synonymous. Both terms refer to the requirement that the patentee must manufacture the patented product, or apply the patented process, within the patent granting country. By requiring local or national working, the patent granting country forces the patentee to transfer the patented technology, or the technology needed to produce the patented product, into the country.

---

10 ibid
1.9.4 Orphan drug

An orphan drug is one that addresses a tiny patient population that’s normally ignored by researchers and manufacturers as it doesn’t make commercial sense for them.

1.9.5 EMR

If a product that has been the subject of such a patent application obtains marketing approval before the decision on the grant of the patent is taken, there is an obligation under Article 70.9 to grant exclusive marketing rights (EMRs) to tide over the gap. EMRs must be granted for five years, or until a decision on product patent is taken, whichever is shorter.

1.9.6 “Parallel importation”

It is based on the legal idea of exhaustion, which allows a rights holder to get remuneration by selling a product, but only for the first time. After this, the buyer has the right to use the product and even resell it. Economically, this ability provides additional local competition for the holder and helps to drive down costs … therefore, a company can charge drastically different rates for residents of different countries, but TRIPS does not prohibit a competing company from buying the goods in the cheaper markets and then exporting it to the countries facing higher prices”.

1.9.7 Exhaustion of rights

The principle whereby the right holders’ intellectual property rights in respect of a product are considered exhausted (i.e. he or she can no longer exercise any rights) when that product has been put on the market by the right holder, or by an authorized party.

1.9.8 Pharmaceutical product

It means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Doha Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.

---

1.9.9. **Flexible**\(^{12}\) means “easily led, manageable, adaptable, versatile, supple, complacent”. The meaning of the word “flexibility” as used in the Preamble is explained by Article 66.1, which reads: “In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of...”

The famous meaning construed in context of TRIPs Agreement is defined as flexibilities as a range of rights, safeguards and options that WTO Members can exploit in their implementation of the TRIPS Agreement; Flexibilities (or safeguards) relevant to access to medicines include compulsory licensing, parallel importation, limits on data protection, use of broad research and other exceptions to patentability.

**1.9.10 Generic Drug**

A drug that is chemically identical to a brand name drug and which is allowed to be produced after the innovator drug’s patent has expired, or, exceptionally, under TRIPs provisions before patent expiry. It is also called a “generic equivalent”.

**1.9.11 Differential Pricing**

The practice of setting different prices for different markets (typically higher prices in richer markets and lower prices in poorer markets). It entails charging different prices in different markets based on “Ramsey pricing” such that prices are inversely related to the elasticity of demand. Price differentials could be such that prices in high income countries exceed the cost of production and distribution to cover joint costs of RandD and prices in low income countries cover their marginal costs.

**1.9.12 Tiered Pricing**

Equitable allocation of costs can be achieved by “tiered pricing”, also called “equitable pricing,” under which patients in developed, high-income nations pay higher prices than patients in developing, low-income nations.

\(^{12}\) Concise Oxford Dictionary, p. 373
1.9.13 Priority Foreign Country

Countries failing to provide adequate intellectual protection has been designated “priority foreign country”.

1.9.14 Essential Drugs

“Those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage form. The WHO Model List of Essential Drugs is intended to be flexible and adaptable to many different situations; exactly which drugs are regarded as essential remains a national responsibility”\(^{13}\)

1.9.15 Me too drugs

This phenomena is exacerbated by the market flooding of ‘me too’ drugs which are much less valuable, modified imitations of existing medications sold with a new or extended patent. Drugs, which are very similar, are not completely identical to one another.

1.9.16 Compulsory Licensing

“Compulsory licensing” refers to granting a license to an entity other than the patent holder to manufacture a patented product without the patent holder’s permission. Compulsory licensing refers to the practice of governments to compel the transfer, from a patent holder to a third party, of some or all of the patent holder’s right to produce a patented product, or use a patented process.

1.9.17 Intellectual Property Rights

Rights awarded by governments to individuals or organizations over inventions, literary and artistic works, symbols, names, images, and designs used in commerce. They give the titleholder the right to prevent others from making unauthorized use of their property for a limited period. Ideas, including literary and artistic works, are protected by copyright; inventions are protected by patents; and signs for distinguishing goods of an enterprise are protected by trademarks. IPR aims to strike a balance between the long-term benefits and short-term costs to society. Society benefits in the long term when the IPR system encourages creation and innovation, but the short-term effect is increased costs.

---

1.9.18 Patent

A patent is an “intellectual property right” in an invention. Intellectual property rights (IPRs) are rights given to a person or a corporation over mental creations, such as: an author’s copyright in their book or the rights of musicians in their recordings; a company’s distinctive trademark on its products; or a patent on a technological invention.

A patent gives its owner (the "patentee") the right to prevent others from making, using, importing, or selling an invention. In other words, patenting an invention gives the patent owner a monopoly over the invention. A patent is usually granted for a limited time, such as 20 years.

1.9.19 Invention

Section 2(1)(j) of the Patent Act, 2005 "invention" as a new product or as process involving an inventive step and capable of industrial application.

New invention means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.

1.9.20 Data Exclusivity

A legal provision that data collected for the purpose of obtaining marketing approval (e.g. the results of clinical trials) may not be used for a specified period by the regulatory authorities to grant approval to a generic equivalent (Note: not to be confused with data protection). TRIPs provided for protection of the data submitted to governments in order to obtain approval of pharmaceutical and agrochemical products. This is known as the “Data exclusivity”. Article 31.9.3 of the TRIPs Agreement is interpreted to mean that such tests and data must be protected against unauthorized disclosure and unfair commercial use.

1.9.21 Data Protection

An obligation imposed on third parties to protect test data (e.g. the results of clinical trials)—usually collected in order to comply with government regulations on the safety, efficacy and quality of a broad range of products (e.g. drugs,
pesticides, medical devices). For example, TRIPs provides for the protection of such data against unfair commercial use.

1.9.22 Essential Drugs/Medicines

Essential medicines are those that satisfy the priority health care needs of the population. Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. WHO maintains a Model Essential Medicines List and countries are encouraged to develop national essential medicines lists adapted from the WHO model according to the national situation.

1.9.23 Neglected Diseases

Diseases for which prevention and cures have received inadequate attention from global public health and research institutions and from private industry these diseases almost exclusively affect impoverished people living in rural areas or poor urban slums of low-income countries.

1.9.24 Type of Diseases

a. Type I Disease

Diseases that is incident in both rich and poor countries, with large numbers of vulnerable population in each. Examples of communicable diseases in this category include measles, hepatitis B, and haemophilus influenza type b (Hib), and examples of non-communicable diseases are diabetes, cardiovascular diseases and tobacco related illnesses.

b. Type II Disease

Diseases that occur in both rich and poor countries, but with a majority of cases in poor countries Type II diseases are often termed neglected diseases. HIV/AIDS is an example.

c. Type III Disease

Diseases that overwhelmingly or exclusively occur in the developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis). Type III diseases are often termed much neglected diseases’.

1.9.25 Health

World Health Organization (WHO), whose preamble defines Health as “a state of complete physical, mental and social well-being and not merely the absence
of disease or infirmity”. The preamble further states that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.”

1.10. RESEARCH DESIGN

The Chapters are designed suitably to cover all the aims and objectives of the research so that a conclusion can be made out definitely with regard to the testing of the hypothesis. The pattern of arrangement of the chapters is done in a manner to justify the research work and understand the theme at a glance.

1.10.1 Introduction

1.10.2 The Indian Patents Act - An Overview

1.10.3 The TRIPs Agreement and other International Agreements

1.10.4 The Indian Patents Act on Drugs and Medicines

1.10.5 The Impact of Product Patent Regime on Prices of Drugs and their accessibility

1.10.6 The Role of Government in Framing and Protecting the Public Health Policy

1.10.7 Conclusions and Suggestions.

1.10.1. Introduction

The first chapter deals with the preliminary aspect of the research by introducing the topic in a brief manner. This chapter covers methodological aspect of the research covering the statement of the problem, broad objectives of the study, review of the literature available in the field of research, scope of the study indicating limitations of the research and further scope of the study, sources of data touching upon the topic of the study, the methodology adopted for the conduct of the study, formulation of hypothesis and to be tested during the study, design of the research in the form of chapterisation of the whole work and conceptual frame work defining the terms and expressions used in the research work.

1.10.2. The Indian Patents Act - An Overview

The second chapter focuses upon the historical overview of the Indian Patents Act, 1970 including the changes and reforms made in it from time to time as India has been opposing the patents act being extended to all the fields of technology. The then Prime Minister Mrs. Indira Gandhi declared India’s policy
when she said, "idea of a better world is one in which medical discoveries would be free from patent and there will be no profiteering from life and death ". What happened to this policy? How did India - a champion of the world’s poor and a major supplier of cheap medicine - miss the wood for the trees?

The Government of India initiated to amend the Patents Act 1970 to introduce product patent protection to drug, medicine and food as required under the TRIPs Agreement. In this direction India tried its best by initiating amendments to the Patents Act, 1970 for several times but it was failed. Ultimately in 1999 the Act was amended to facilitate the receiving of applications for product patents keeping them in mail box and extending Exclusive Marketing Rights (EMRs) for the products of drugs and medicines until grant of product patents by suitable further amendments to the Patents Act, 1970. The second amendment initiated by the Patents (Amendment) Act, 2002 which made 64 amendments to the Patents Act, 1970 to extend the term of patents from 14 to 20 years, exceptions to exclusive rights, compulsory licensing and so on. A third Amendment was necessary for meeting the deadline of transition period by the end of 2004 to replace the EMR system and to introduce product patent protection in the field of drugs, medicines, chemicals and food. The Government of India in a hurried manner adopted the path of introducing ordinance. The President of India promulgated an ordinance entitled the Patents (Amendment) Ordinance, 2004. The ordinance has received vehement opposition from across the country. Keeping in mind the opposition and mandatory requirement of the TRIPs, the Government of India introduced a bill entitled the Patents (Amendment) Bill, 2005 extending product patents to all fields of technology including food, drugs, chemicals and micro-organisms and introduced a provision for enabling grant of compulsory license for export of medicines to countries which have insufficient or no manufacturing capacity to meet emergent public health situations.

India equipped itself to show the international bodies its adaptability by amending the Patents Act, 1970 in 1999, 2002 and 2005 to meet the aspirations of the people of the country and to fulfill the obligations that have been necessitated under international instruments pertaining to the protection of patents especially the Paris Convention for the Protection of Industrial Property and TRIPs Agreement of the GATT/WTO.
1.10.3. The TRIPs Agreement and other International Agreements

The third chapter focuses upon the evolution of IPR laws generally and patents laws at international level. It was felt necessary to establish international trade organization (ITO) to facilitate international trade and commerce. It was materialized in the Brettonwoods Conference by taking decision in it to establish three international agencies such as World Bank, International Monetary Fund (IMF) and International Trade Organization (ITO) with a purpose to bring uniformity, certainty and transparency in world trading system by restraining the members from invoking arbitrary and unilateral trade policy measures. However, former two agencies had been established and the latter the ITO is not taken place but in its place a temporary negotiating body by name the General Agreement on Trade and Tariff (GATT) came into existence. Since its inception in 1944 the GATT conducted and concluded eight rounds of negotiations until 1986. There was no any plan to bring the IPR into GATT negotiations up to seven rounds of GATT talks. It was only at the last round i.e., eighth round of GATT negotiations the IPR had been brought to discuss and include in the Uruguay round. The reasons advanced for the inclusion of IPR within the GATT rounds talk was that WIPO which had been established in 1970 is useless agency and toothless body to protect the IPRs effectively argued by the developed countries especially the USA. The developed countries alleged that their intellectual properties are pirating by the developing countries in a widespread manner and the WIPO is not having sanctioning power against the countries which are involved in pirating the IPRs. The developed nations have become successful in bringing the IPR within the purview of the GATT and discussed extensively and resolve to arrive at an agreement namely the Trade Related Aspects of Intellectual Property Rights (TRIPs). The TRIPs Agreement including agreement establishing World Trade Organization (WTO) and many agreements associated with GATT/WTO came into existence from 1995.

The Preamble of the WTO Agreement states its objectives as “raising the standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for optimal use of the world’s resources in accordance with the objective of sustainable development, seeking both to
protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development”. Among the several agreements under GATT/WTO are plurilateral or multilateral agreements such as the Agreement on Agriculture, Textiles and Clothing, Agreements on Technical Barriers to Trade, Agreements on Trade Related Investment Measures (TRIMs), Industrial Products, Subsidies, Anti-dumping Rules, Government Procurement, Balance of Payments Provisions, Safeguard Action and Coherence in Global Policy Making, General Agreement on Trade in Services (GATS) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

The TRIPs Agreement includes General Provisions and Basic Principles of IPR and types of IPR such as Copyrights, Trademarks, Patents, Geographical Indications, Trade Secrets, Industrial Designs and Layout Designs of Integrated Circuits. All agreements were backed by a hidden agenda of commercial exploitation and profit maximization. In the backdrop of this, analysis of TRIPs agreement and its provisions with special reference to patent is made. It is believed that the TRIPs Agreement provides a balance between long term benefits to the society and industry through knowledge creation and placing the same in public domain short term benefit to IP creator through market exclusivity.

It is the mandatory of the TRIPs under WTO that all the nations including developing nations to fully abide by their IP laws and enforcement practices with the Agreement on TRIPs by no later than 1st January 2005. It lays down minimum standards for protection and enforcement of intellectual property rights in member countries which are required to promote effective and adequate protection of IPRs with a view to reducing distortions and impediments to international trade. For the least-developed countries (LDCs) the transition period will remain in force for pharmaceutical patents and data protection at least until 2021 under Article 66.1 of TRIPs under paragraph 7 of the Doha Declaration.

TRIPs Agreement provides an effective mechanism for the resolution of IP related disputes among state members in a systematic manner. The most contentious aspect of the TRIPs Agreement is the protection of pharmaceutical products. Article 27 relates to patentable subject matter and patents rights are enjoyable without discrimination to the place of invention, field of technology and
also whether products are produced locally or are imported. Patent owners opine that Article 27 of TRIPs Agreement forbids the state to give rights to generic players to make patented drug and offer the same to the poor at reasonable rates. The TRIPs Agreement member countries are bound to provide such protection, yet certain compensatory measures and schemes are taken in the hands to avoid the negative impact of monopolization of product patents especially in health and pharmaceutical sectors. Such measures as per the TRIPs are as follows:

1) Transition periods  
2) Compulsory licenses  
3) Public, non-commercial use of patents  
4) Parallel imports  
5) Exceptions to patent rights  
6) Exceptions from patentability and  
7) Limits on data protection

This chapter also highlights the role of international agencies in protecting the IPRs and patents such as WIPO and WTO. A detail study of patents especially with reference to Article 27 on Patentable Subject Matter: Exclusive right to owners against third party for using subject matter including process patent, without his consent (Art. 28); Conditions on Patent Applicants (Art. 29); Exceptions to Rights Conferred (Art.30); Other Use without Authorization of the Right Holder (Art. 31); Revocation/forfeiture is subject to judicial review (Art. 32). The term of protection shall be at least 20 years from the date of application (Art. 33). Reversal of the burden of proof in civil proceedings relating to infringement of process patents is to be established in certain cases (Art. 34). The TRIPs Agreement is analyzed with special reference to utilization of flexibilities such as compulsory licenses, parallel imports, and government use with stipulations.

1.10.4. The Indian Patents Act on Drugs and Medicines

The fourth chapter deals with the Indian Patents Act highlighting the protection of patents pertaining to drugs and medicines. There is a shifting change that has been brought in Indian Patents Act in the matter of patents on drugs and medicines from time to time. The Patents Act, 1911 which was a British legislation modeled on English law introduced product patents in the field of drugs and
medicines. The Patents Act of 1970 specifically prohibited product patents on “substances intended for use, or capable of being used as food or as medicine or drug” or “relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds)”, while allowing the processes for the making of such substances to be patentable for a short period of between 5 to 7 years. The terms of all other types of patents (for e.g., mechanical devices) were 14 years from the date of the patent. In shaping its first indigenous patents regime, India made a deliberate choice to stimulate domestic manufacturing and reduce the prices of products deemed “essential”, such as food and medicines.

India led the opposition to the inclusion of patent and intellectual property rights in a GATT accord. India and other developing countries viewed the GATT framework as a tool by which wealthy nations would impose strong IPRs as the cost of much needed access for the developing world to western markets. Members may, of course, choose to give effect to the rules of the TRIPs Agreement by the adoption of national legislation or administrative rules that specifically implement its provisions. However, not all legal systems require that the rules of treaties (or international agreements) be transformed into national law by the adoption of specific legislation. In some national legal systems, the constitution provides that treaties may be given “direct effect” by the regulatory authorities and courts by 1989; India had reversed its anti-TRIPs stance and agreed to serious negotiations over patent protection, while arguing for special provisions to be made within the framework of TRIPs for developing countries. Upon it’s signing the Uruguay Agreement along with 116 other countries in 1994; India became a member of the WTO from January 1, 1995 and became obligated to amend its domestic IP laws. India was given ten years to implement its new laws.

TRIPs Agreement provided some transitional arrangements to developing country Members. Though the provisions of the Agreements are expected to be in force by 1st January 1996, developing countries which had process patent regimes were given time, if they wanted, to extend the period for further four years, i.e., till 1st January 2000. However, the Agreement required these Members to make provisions for receiving patent applications under Art 70.8 for developing countries which are obliged to extend product patent protection to areas of technology not so
protectable in its territory on the general date of application of the Agreement, i.e., 1\textsuperscript{st} January 1996, could delay the application of the provisions for an additional period of five years, i.e., till 1\textsuperscript{st} January 2005. India was having process patent regime in pharmaceuticals and agro-chemicals and had the time till 1\textsuperscript{st} January 2005 to extend product patent rights in pharmaceuticals and agro-chemical products, though in other areas it had to meet its obligations by 1\textsuperscript{st} January 2000.

India complied with its obligations under the TRIPs Agreement in three steps. The first step was the Patents (Amendment) Act of 1999, which provided for receiving of patent applications (mail-box applications) and for exclusive marketing rights. The Patents (Amendment) Act 2002 introduced comprehensive amendments to bring together various provisions of the Patents Act, 1970 into conformity with the TRIPs Agreement. The Patents (Amendment) Act, 2005 brought full-fledged compliance of the TRIPs Agreement by introducing product patent regime for the fields of food, medicines and chemicals.

Making Patent law with compliance to TRIPs Agreement had its own short comings hence Analysis of the amendment made with respect to third amendment granting patents on pharmaceutical products and types of components and compound that can be patented under different drugs and medicines are made. The important concern related to the introduction of product patent protection is the patenting of known substances. Various aspects of how often pharmaceutical companies misuse the patent protection to seek patents on known substances claiming incremental modifications as inventions the third amendment also introduced two more definitions, with an objective of limiting the scope of patent protection with special reference to Section 3 of the Patents Act which excludes 16 categories of inventions from patent protection, because they are not considered inventions within the definition of invention.

1.10.5. The Impact of Product Patent Regime on Prices of Drugs and their accessibility

The fifth chapter is the core chapter of the research in which the testing of all the hypotheses is done by utilization of various research tools analyzing various provisions that were included in the three amendments were brought to the Indian Patents Act in compliance to TRIPs Agreement. The various aspects has been made as to the provisions of Article 27 to 31 inclusively so as to how exceptions can be
utilized without infringing the patent rights and various stipulations are gone through so as to reveal whether in reality they work. The patent laws extending to pharmaceutical products have been analyzed taking into account the prices of various products that are currently in the market. The drugs are prescribed and their effect on affordability is made by making comparative tables making it easy to form a conclusion on the price effect and accessibility to life saving drugs.

The government’s ability as to the utilization of various exceptions that are present in the Indian Patents Act to regulate the effect of prices on affordability, various steps have been taken by the government for free supply of medicines to the needy people and how the policy in respect of health is lacking in meeting the needs of the peoples demand is looked into to make a conclusion and bring out the deficiencies these policy suffer and lastly an analysis as to the remedy that are available under the Indian Constitution and relevant laws and policies are analyzed to seek whether the provisions under various laws and policies suffice to meet the needs of the people so as to enforce the “Right to Health” as of right and not as charity. Various provisions are interpreted taking into account the case laws to effectively analyze the current position that India is forced to pose to minimize the harmful consequences of the patent especially in health and pharmaceutical sectors.

1.10.6. The Role of Government in Framing and Protecting the Public Health Policy

The sixth chapter discusses about remedy as a measure to compensate or regulate the effect of patent on common man by going through policies under health sectors and right to health under Indian Constitution. The Preamble and the chapters on the Fundamental Rights and the Directive Principles of State Policy, provides under Constitution of India an useful starting point to situate and analyze the rights to development in the Indian context. As is well-known, the Indian Constitution, as it came into being in 1950, was interpreted to have a clear distinction between a set of fundamental rights (essentially consisting of some basic civil and political rights) vis-à-vis which an individual is guaranteed against coercive or arbitrary state action, and a set of directive principles i.e., a set of economic, social and cultural rights which should be the guiding principles, or the goals and aspirations, for State’s actions in the interest of the citizens’ welfare. From a legal point of view, the sharp distinction between the two sets of rights was that the former i.e., the set of
fundamental rights was justifiable whereas the latter i.e., the set of directive principles was not. Thus in terms of legality, the Directive Principles, which essentially consist of what the contemporary discourse views as preeminent rights to development such as the rights to food, shelter, health, basic education etc., are inferior to the

Fundamental Rights, It was hoped by the framers of Indian Constitution that in spite of Directive Principles being ranked lower than Fundamental Rights, the seriousness of the former would not be undermined.

It is rightly said by Dr. Baba Saheb Ambedkar: “it is the intention of the Assembly that in future both the legislature and the executive should not merely pay lip service to these principles. But, they should be made the basis of all executive and legislative action that may be taken thereafter in the matter of governance of the country.”

Ostensibly, one of the primary reasons for Directive Principles being kept non-justifiable was the financial weakness of the newly independent state.

The other major reason for keeping the Directive Principles non-justifiable was presumably the inherent difficulties in specifying the duties (of the State) in a rigorous and precise manner, vis-à-vis the economic social and cultural rights covered under the Directive Principles.

Both these ostensible reasons for keeping the Directive Principles non-justifiable are contentious and merit closer scrutiny. But before we do that, it may be worth recalling some of the major commitments made internationally by India. In this regard, the first point to note is that the Fundamental Rights and the Directive Principles between them cover almost the entire ground laid out by the Universal Declaration of Human Rights (UDHR). Three years after the United Nations came into being; its General Assembly put into place a most significant instrument in the form of the UDHR, in the hands of the emerging human rights discourse.

The Constitution of India places obligations on the Government to ensure protection and fulfillment of right to health for all, without any discrimination, as a Fundamental Right under Articles 14, 15 and 21 (rights to life, equality and non-discrimination), and also urges the State, under the Directive Principles of State Policy, to eliminate inequalities in status, facilities and opportunities (Article 38); to
strive to provide to everyone certain vital public health conditions such as health of workers, men, women and children (Article 39); right to work, education and public assistance in certain cases (Article 41); just and humane conditions of work and maternity relief (Article 42); raise level of nutrition and the standard of living and improvement of public health (Article 47); and protect and improve environment (Article 48A). The Union of India has also signed various international treaties, agreements and declarations specifically undertaking to provide right to health including but not limited to Universal Declaration of Human Rights (UDHR) under Article 25 (1); International Covenant on Economic, Social and Cultural Rights (ICESCR) under Article 12; Convention on the Rights of the Child (CRC) under Article 24; Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) under Article 12; UN Convention on Rights of Persons with Disabilities (UNCRPD) under Article 25; Declaration of Alma Ata (1978); Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care (1991); Declaration on the Elimination of Violence against Women (1993), Programme for Action of the International Conference on Population and Development, Cairo (1994); Platform of Action for the Fourth World Women’s Conference, Beijing (1995) and the Millennium Development Goals (2000); Declaration of Commitment on HIV/AIDS, ‘Global Crisis-Global Action’ (2001), WTO Doha Declaration on TRIPs Agreement and Public Health (2001), International Health Regulations; 58th World Health Assembly (2005); and several other declarations and conventions on health.

Though the Constitution of India does not directly recognize right to health as a fundamental right but the Supreme Court of India have played and playing proactive role in upholding the health as a fundamental right under Article 21. Article 21 is a very abstract provision but its scope has been expanded by the Supreme Court of India by bringing several components in its ambit such as right education, right good environment and pollution free environment and right to health etc., while deciding time-tested issues in various cases.

The Ministry of Health just leaves the challenges of product patent regime to the patent laws a serious issue only to be handled by the Ministry of Commerce and Industry, which is in charge of administration of patents. The health policy is silent on the concrete measures to be taken in the case of deficiency in access to
medicines due to patent protection. Proposal of reducing the number of drugs under price control was stayed by the Supreme Court. The proposal would have resulted in the reduction of the number of price-controlled drugs from 74 to 34. The Court instructed the government to “consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control”. In fact, price control is one of the flexibilities available under TRIPs to ensure public access to medicines. Nothing in TRIPs prohibits member countries from controlling the prices of patented drugs. In fact, the government should have expanded the price control to include all the life-saving medicines. Instead of that the policy prescription was exactly the opposite.

For the last five years, the government has been making efforts to come up with a new pharmaceutical policy. One of the features of the proposed policy is to expand the number of drugs under price control from 74 to 354. However, it was opposed by the pharmaceutical industry. However, this list of 354 drugs does not cover patented drugs. To address the issue of high prices of patented drugs, the government set up a committee to explore the possibility of price negotiations for Patented Drugs and Medical Devices before the granting proposal. The committee is yet to come out with its recommendations. Instead of controlling the prices of patented drugs in the proposed mechanism, negotiations would be carried out with the patent owner. This would give much way to the patent holder to set a high price. Often the price of the patented article is extremely high and there will not be a sufficient price cut through negotiations. Further, it may undermine the compulsory license option. For instance, under the Indian Patents Act, the high price of a patented article constitutes a ground for granting compulsory license. Hence, if the price for the patented article is high then generic companies can approach the authorities for a compulsory license citing the high price of the patented medicine. This option would be undermined through a price negotiation mechanism, wherein a negotiated token price cut would be treated as a legitimate reasonable price.

Similarly in 2008, the Drugs Control General of India (DCGI) attempted to introduce patent linkage. This would have prevented the registration of a generic company from obtaining marketing approval of a patented medicine. This would have made the DCGI’s office to become the de facto authority for the enforcement of patents. Since multiple patents are obtained on single medicine, it is really
impossible for the DCGI’s office to find out the relevant patent and deny marketing approval. It would also prevent generic competition. The most important fact is that patent linkage is a TRIPs plus obligation and reduces the policy space for the TRIPs flexibilities. Thus the policy responses do not address the challenges of product patent regime. Instead, as mentioned above, the SandT Policy and Pharmaceutical Policy not only recognizes patent, but also encourages IP protection rather than coming up with policy tools to face the challenges of product patent regime. Some of the policy initiatives give a confusing signal on the intention of government on using the flexibilities available under the TRIPs Agreement and make the Indian state vulnerable to pharmaceutical MNCs and their host states pressure for implementing law and policy that minimizes the scope of TRIPs flexibility. Further, the lack of clear-cut policy frameworks prevents the generic pharmaceutical industry from developing a viable business model using TRIPs flexibilities.

Drug Policy Formulation in India, Successive Price Control Regimes, Report on Committee on Drugs and Pharmaceutical Industry (Hathi Committee), Drug Policy of 1978, Flaws in 1978 Policy and its Implementation, The Drug Policy of 1986, Drug Policy of 1994, Drug Policy of 2002, National Pharmaceutical Pricing Authority (NPPA) . Drug Prices Equalization Account (DPEA) under DPCO, Pricing Patented drugs, ‘Modifications in Drug Policy, 1986’ announced in September, 1994, which is based on production data of 1990. The Government announced the ‘Pharmaceutical Policy 2002’ in February 2002. However, a public interest litigation filed in the High Court of Karnataka at Bangalore resulted in an Order dated 12-11-2002, which stopped the Government from implementing the price control regime of the Pharmaceutical Policy 2002. This Department filed a Special Leave Petition (SLP) before the Supreme Court of India against the Order of the Karnataka High Court. The Supreme Court vide its order dated 10.3.2003 directed the Government to consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control. Mergers and Acquisitions of foreign companies and Indian companies to take the advantage of tax benefits and pricing the patented product to their benefits are covered wherever necessary to evaluate the price control regimes.

All the aspects are covered taking into consideration, the public health aspects and why still after independence of about 68 years the rural masses have no
access to medicines to life threatening diseases no policy is well established to work efficiently in health sectors. Therefore, it is clear that providing healthcare to all is the duty of the Central and State Governments, ‘health’ being a state-subject under Indian Constitution. Unfortunately, India is far from providing a universal healthcare coverage.

1.10.7. Conclusions and Suggestions

The seventh chapter concludes the research with certain suggestions to be addressed with on the basis of forgoing chapters, we can clearly prove that patent law has no concern whatsoever towards the issue of human right to health as there are no sufficient provisions for addressing this issue except flexibilities, the law is silent as to the disclosure of expenditure on Research and Development including the cost of developing the drug is not made public, on the other hand companies and the patent holder take all the benefits of tax concessions under various sections of Income Tax Act such as creating intangible assets and depreciating in the profit and loss account, charging research and development charges as revenue expenditure or capitalizing them and then amortizing it from companies profits. The price of the patented drug is arbitrarily fixed without taking into account the cost of production. Companies have no obligations such as corporate social responsibility towards the poor sections of the society as no patented medicine is supplied to meet the demands of rural masses due to patent act the life saving medicines prices have shoot up exorbitantly to which access is possible only to rich class persons along with this a surprising fact is that even in district level places many of the patented medicines are not available in the market this is due to the reason that there are no proper cancer hospitals, diabetes specialty clinics, palliative care centers, and some of the tests for diagnosis are sent to metropolitan cities. Some treatments like chemotherapy, radiations are not available at the district centers. Surprisingly many of the government hospitals supply the medicines for communicable diseases and there is inadequate supply of medicines for diabetes. Blood pressure, nephropathy, neuropathy, anti-venom injections for snake bite, hemophilia etc.

From this it can be clearly made out that there is a conflict between patent rights and protection of public health and this has a negative impact on the country’s public health policy. The patent flexibilities that exist within the patent
act are not utilized properly because of the stipulations that are put forth for this purpose.

The sufferers right to have access to life saving drugs under Article 21 of the Indian Constitution which includes Right to health is not properly implemented as was required by a country like India being a welfare country it is expected that it protects the interest of its people upholding the largest democratic interest for the welfare of its people. Because of the reason that Right to Health is not enforced efficiently as a right as it is the discretion on the part of the government to provide health care facilities either at central or state level to protect and provide the facilities for access to medicines in spite of having various Supreme Court judgments, which have upheld the Right to Health but due to government policy this right to health is inefficiently implemented without taking into account the needs of the people.