Chapter-1

Introduction
Chapter 1: Introduction

1.1 INTRODUCTION

The provision of good public health is one of the primary concerns of the government. The signing of WTO and consequent implementation of its provisions under TRIPs are likely to have tremendous impact on policy formulation and governance in all the member countries. In India also, opinions and concerns have been raised regularly on possible impact of the WTO on various sectors of economy as well as on various sections of population and policy making.

In this context, this study is aimed at understanding the impact changes in IPR regime on pharmaceutical business strategy and public health in developing countries with special reference to India.

The pharmaceutical industry views the patent system as essential to its business model. Under the basic concept of the patent system, an inventor is entitled to a limited monopoly (technically, a right to exclude) for a period of time, typically twenty years. Such exclusivity may permit high prices during the patent term; the consequent profit incentives provide the basis for the pharmaceutical industry to invest in very costly development process that is necessary to bring new drugs to market. The first generation of owners of patents (or their employers or insurers or, in some cases, the government) pays in this way for the large research costs involved in developing a new drug. When a patent expires, the price normally falls as generic competitors enter the market.
A number of developing countries, however, viewed patent law quite differently and deliberately decided to deny patent protection to pharmaceutical products and to grant protection only to processes for producing pharmaceuticals. These countries believe that access to pharmaceutical products is so important that the products themselves should not be patented. The products would be developed anyway for the market in developed countries, and the market in developing countries is so small that it would not provide adequate incentive to develop new products.

In its 1970 patent law, for example, India excluded drugs from product patent protection, effectively choosing to provide low-cost drugs for its people at the expense of eliminating incentives to create new products. This law was one of the reasons that the Indian generic drug industry was able to evolve to manufacture and market copies of drugs still on patent in wealthier countries. India has become a major international supplier of drugs to countries where these products can be marketed legally because they have not been patented locally. Also, a number of countries had “compulsory licensing” provisions. These provisions define a legal process under which governments can authorize use of a patented technology even over the patent holder’s objection. In practice, compulsory licenses have rarely been formally granted. Rather, governments have used the threat of granting a compulsory license as a way to negotiate lower prices for the technology or product involved.

Patents constitute an incentive for the development of the private sector pharmaceutical industry. The rationale for granting exclusive rights on patented medicines is that while the development of new drugs is a costly process, it is relatively easy to copy an existing drug. Despite the private industry’s plea for patent protection, a number of developed and developing countries traditionally put restrictions on the patentability of drugs on public policy grounds. The Patents Act, 1970, for instance, introduced restrictions on product
patents for medicines to limit commercialisation in the health sector. The adoption of the 
TRIPS agreement is forcing countries that had patentability restrictions like India to 
fundamentally alter their patent laws if they want to be in compliance with their WTO-related 
legal obligations.

The external environmental factors such as formation of WTO, establishment of TRIPs 
agreement and its minimum standards, Doha declaration, etc. has vastly impacted the Indian 
Pharmaceutical industry, particularly the strategic aspects. It is also a matter of great concern 
for public health, particularly the access to medicine. The basic objectives of this study are 
laid down to understand the impact on the above two issues on Indian Pharmaceutical 
Industry. Hence, due to increasing relevance of these issues for India and the Indian 
Pharmaceutical industry, an attempt has been made for a detailed study.

The first objective of the research is to study the TRIPs provisions related to the 
pharmaceutical industry has made a strategic impact on the business model particularly the 
product patent implementation and other relevant provisions laid down in the agreement. 
Another objective was to study the intellectual property provisions and its enforcement in 
Indian Pharmaceutical industry and how these provisions were affected the strategy 
formulations wherein there was an apparent shift of focus from marketing to intellectual 
property management. Yet another objective was to study the significance of intellectual 
property rights on pharmaceutical business particularly after the enforcement of product 
patent i.e. in the post 2005 era. Another focus of the study was to evaluate the impact of 
intellectual property rights enforcement on drug prices from the perception of medicos. The 
medical fraternity was the major stake holder of the change in regime since they are the 
actual customer of the pharma industry being an influencer. The entire pharma market is in 
fact driven by the number of prescriptions written by the medicos. While writing or
suggesting any drug to a patient, price is an important factor which is considered by the
doctor. Therefore, it is important to understand the perception of medical fraternity about the
impact of new patent regime on the drug prices, particularly access to medicine. Hence, in
another objective of the present research it was studied the awareness level of medicos on
intellectual property rights and its enforcement in India as well as its likely implications on
public health concerns from their perspective.

Immediately after the end of World War II, the Western Allies had set up international
organizations and regulations that would form the basis for an international economic order
based on economic liberalism and trade cooperation. Thus, the 1944 Bretton Woods
agreements created the International Monetary Fund and the World Bank. Thereafter, the
General Agreement on Tariffs and Trade (GATT) was signed in 1947 and was succeeded by
the World Trade Organization (WTO) in 1995. The liberalization of trade flows was
undertaken rapidly after the war and world trade increased faster than world GDP. Indeed,
trade in merchandise rose to 6.2 trillion dollars in 2000 from 58 billion dollars in 1948, which
corresponds to a multiplication of nearly 22 times in the volume of trade (an average annual
increase of 6 percent)\(^1\). Over the same period, world GDP in real terms was multiplied by 7,
or an average annual increase of 4 percent\(^1\). The nature of trade also changed profoundly.

Progress in dismantling barriers to trade was achieved through negotiations between the
contracting parties of the GATT. The GATT had evolved into an increasingly lengthy
process over the years due to both the increasing number of member countries and issues
discussed. Until the Kennedy Round (1986-1994), negotiations had essentially focused on
lowering tariff barriers on manufactured goods\(^2\). Beginning with the Tokyo Round (1973-
1979), the scope of negotiations was widened to non-tariff barriers on manufactured
products, and agricultural issues began to be raised\(^2\).
However, it was during the long negotiations of the Uruguay Round, 1986 to 1993, closing with the 1994 Marrakech Agreement, as the decisive steps were taken. Indeed, until this round, the industrialized countries the US and Europe - had been the main actors in the liberalization process, which concerned almost exclusively the lowering of tariff and non-tariff barriers on manufactured goods. Over the course of the Uruguay Round, agriculture once again became a major issue, when prior to the Uruguay Round, agriculture had for the most part been the subject of exemptions. The same held true for textiles.

However, the Uruguay Round participants decided to bring textiles back within the scope of WTO rules by gradually dismantling the Multifibre Agreement of 1974. This agreement had limited imports into countries whose national production sectors could be weakened by a flood of foreign products. The Uruguay Round allowed for a decrease in tariff duties of 36 percent, which, including all countries fell from 9.9 percent to 6.5 percent. In addition, the number of products subject to high import duties was reduced.

Moreover, the goal of regulatory integration was added to the effort on tariff integration. The new and extremely ambitious issues of services, investments and intellectual property were also brought forward during this round. Taking into account the legal and regulatory impact on the national level for each of the member countries, these new themes are especially sensitive for developing countries. Despite their sometimes-diverging interests, in these negotiations they began coalescing into a genuine force capable of making proposals.

The Trade Related Intellectual Property Rights (TRIPS) Agreement came into existence as a part of the WTO did, as a result of the Uruguay Round of negotiations for GATT. Intellectual Property Rights (IPRs) are the limited rights legally granted to someone who
creates a new product to be the sole producer of the product for a definite period of time. IPR are very important for researchers who invest significant time and money into developing a new product, be it a new way of making the pulp for paper, a faster computer chip, a new genetically engineered type of banana, or a new pharmaceutical drug. While research costs are high, once the new idea or method comes about, it is usually very easy to reproduce. Thus without IPR protection, there would be little incentive for anyone to invest in innovation.

At the Doha World Trade Organization (WTO) Ministerial Conference (9-14 November 2001), the WTO Members decided to adopt a special declaration on issues related to the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and Public Health. Discussion on this declaration was one of the outstanding issues at the Conference, which launched a new round of trade negotiations on a broad range of issues. This was the first outcome of a process that started in early 2001 when, upon the request of the African Group, the Council for TRIPS agreed to deal specifically with the relationship between the TRIPS Agreement and Public Health.

1.2 INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL BUSINESS

Patents and copyright inherently confer both costs and benefits to individuals and companies, and to society at large. They provide an incentive for invention or creation that may benefit society, as well as the rights holder, but they also impose costs on the users of protected works.

In some countries, the patent system was fully implemented only well into the 20th century. The East Asian countries, the most successful recent examples of development, have grown and developed their scientific and technical capabilities in the context of weak IP regimes.
Now, under TRIPS and growing pressures for harmonisation, most developing nations are restricted in how they can apply the IP system. They may not discriminate among fields of technology, or by nationality, and the use of various tools of IP policy that were used historically are circumscribed under TRIPS.

The fundamental facet of IPR is to provide rational legal framework to create and establish ownership or propriety domains of knowledge. Such a protection would enable fair sharing of knowledge with due recognition and reasonable benefits to the creator/owner of that knowledge. Reasonable legal framework that would discourage misuse of IPR, unfair and anti-social monopolistic practices should compliment a strong IPR regime. Only then would society provide an ethical climate that promotes innovation, spur productivity, and investment via fair “knowledge prospecting” and contribute to the establishment of a competitive, non-monopolistic and balanced humane world. Intellectual Property Rights is a system that allows for legal protection of the “added knowledge” in the existing knowledge pool provided certain conditions are met.

IPRs are patents, copyrights and related rights, trademarks, geographical indications, industrial designs, layout designs of integrated circuits and trade secrets. IPRs are crucial sources of competitive advantage in industries where patents are central, such as chemicals, drugs, plastics, engines, turbines, electronics, industrial control and scientific equipment; or where marketing relies on brand names and product recognition, such as food and beverages; where copyright is key, such as publishing, software, music and film; and in design intensive industries like clothing and automobiles.

Intellectual Property can mean the difference between success and failure in business today. Companies need to be aware of the legal implications at each stage of the Intellectual
Property life cycle. The evolving nature of Intellectual Property laws and the growing need for companies to have IP management programs and policies are elucidated.

In today's dynamic and competitive business environment, Intellectual Property (IP) rights are key elements needed to maintain a competitive edge in the market. Intellectual property is a business asset, an integral part of the business process. Effective acquisition, management, and protection of intellectual property can mean the difference between success and failure in businesses today.

Impact of Intellectual Property Rights enforcement is significantly high on the knowledge base industry. Pharmaceutical industry being a knowledge driven industry is highly affected by the Intellectual Property Rights enforcement which has changed the fundamentals of business strategy.

1.3 INTELLECTUAL PROPERTY RIGHTS AND PUBLIC HEALTH

By including access to medicines among its Millennium Development Goals (MDGs), the international community has rightly recognized the central importance of drug access for human development and anti-poverty efforts. Ill health is one of the most formidable factors trapping people in poverty, while poverty itself is in turn a significant determinant of illness. Though simply doling out more pills will not solve this complex problem, quality-assured therapeutic drugs remain a powerful, cost-effective means of combating sickness. Their absence can constitute an insuperable barrier to the achievement of health goals. Strengthening disadvantaged communities' capacity to obtain safe, effective medicines (including but not limited to the biomedical pharmacopeia) is one component of an integrated effort to address poverty and disease.
Another concern is about public health in less developed countries like India. Prior to TRIPS, developing countries like Brazil, India and Egypt had refused to recognise many patents for pharmaceutical formulations that are essential to public health. They encouraged local firms to manufacture generic substitutes for branded medicines at a fraction of the cost. With TRIPS, these countries are now being required to change their laws to recognise the patents held by pharmaceutical firms. There is some room to maneuver, because TRIPS allows compulsory licensing of patents that are essential for public health and nutrition. Compulsory licensing allows a government to authorise the use of a patent for these purposes under certain conditions, including the payment of reasonable compensation. However, the difficulties of using the TRIPS Agreement for this purpose are shown by the experience of South Africa when it tried to access cheap anti-AIDS medications.

In 2005, November's WTO Ministerial Meeting at Doha, pressure from the developing countries resulted in the Doha declaration on TRIPS and Public Health. This significantly clarified the right of members to grant compulsory licenses on the grounds of national emergency. The problem for small developing countries like those in the Caribbean (which has the highest incidence of AIDS in the world after sub-Saharan Africa) is that most of them lack a domestic pharmaceutical industry with the capability to use compulsory licensing. They would need to engage on so-called "parallel importing", making special arrangements with countries like India and Cuba. And the provisions for parallel importing are not spelt out in the Declaration. So developing countries still have to do a great deal of technical work and hard political bargaining within the TRIPS Council in order to make use of the Declaration.

Currently, there is a plethora of possible remedies for the TRIPS and public health problem. Some remedies aim at engineering systemic changes into the TRIPS agreement while others
focus on measures to mitigate the most negative and often deadly impact of lack of access to affordable medicines. All these have been discussed in the study in the subsequent chapters and suggestive measures have also been narrated in the final chapter.

1.4 RATIONALE FOR STUDY

With the advent of WTO and TRIPs, the entire scenario has changed. Specially from 1st January, 1995, when India was obliged to comply with its obligations under WTO and TRIPs. Being a developing country with no product patent protection, India was eligible for 10 years (5 + 5) in transition for full TRIPs compliance. According to this India has to enforce product patent from 1st January 2005, which primarily excludes other then innovator from making selling, or distributing the patented product in India. During the transaction period i.e. between 1st January 1995 to 1st January 2005, India has adopted mechanism of exclusive marketing rights from.

Prior to TRIPS, most developing countries and some developed countries excluded medicines from being patented even if they met the criteria of being new and inventive. Today, almost all these countries are members of the WTO and have to implement TRIPS, thus allowing for the filing of patents for new pharmaceutical inventions at least from 1995 and the grant of product patents or similar exclusive marketing rights on them, where eligible.

WTO, TRIPS and pressure of enforcement of Intellectual Property enforcement as affected almost all the industries but the impact is most significant as far as Pharmaceutical Business is concerned. It has changed the entire equation of Pharmaceutical Industry. Today it is one
of the knowledge driven industry where the main focus of business is to increase the Intellectual Wealth of the company by increasing the Intellectual Property of the company. In the current scenario all the major pharmaceutical companies are focusing more on strengthening their research and development activities and aligning their corporate strategies keeping in mind their research activities and future developments in research.

Intellectual Property has not only added the new dimension in pharmaceutical industry but it has also changed the strategic perception where only effective marketing strategy is not the contributing factor in the company’s growth. But it is equally important how a pharmaceutical company successfully protects and increases its Intellectual Property.

The purpose of this study is to understand the significance of Intellectual Property regime on Pharmaceutical business. This study attempts to analyze the impact of Intellectual Property regime on pharmaceutical business. It discuss the current environment and impact of enforcement of Intellectual property regime in Pharmaceutical business and its dynamism in India.

Further it attempts to study the impact of Intellectual Property Rights regime on public health and related policy. Creation of own Intellectual Property sometimes results in monopoly over that medicine for some period of time and this will results in increase in of price of essential medicine. This situation gives rise to public health concern. Sometimes Intellectual Property drives pharmaceutical companies to research in only those areas which have good business potential.
The impact is even more significant when we analyze the environment and social imperatives of India. Access to medicine is an important issue that not only affects the poor of the society but it has an impact on overall health standard of the country.

The study aims to suggest how to minimize the anticipated adverse impact on public health without compromising the importance and incentive to innovation by means of enforcing intellectual property rights.
1.5 OBJECTIVES OF STUDY

For the purpose of present research study several objectives have been specifically identified after a comprehensive review of literature and present states of Indian Pharmaceutical industry.

The following objectives have been framed to study the “Intellectual Property Rights – unfolding its strategic impact on pharmaceutical business and public health in India.”

❖ To study TRIPS provisions related to pharmaceutical industry.
❖ To study Intellectual Property Rights provisions and enforcement in Indian Pharmaceutical Industry presently.
❖ To study the changing business strategy in Pharmaceutical Industry.
❖ To study the significance of Intellectual Property Rights on Pharmaceutical business.
❖ To study the impact of Intellectual Property Rights enforcement on post 2005 era.
❖ To study the impact of Intellectual Property Rights on access to medicine.
❖ To study the impact of Intellectual Property Rights on drug prices.
❖ To study the government’s role in enforcing the Intellectual Property Rights, encouraging the research and development and public health concern.
❖ To suggest possible strategy to pharmaceutical industry in India in post 2005 era.
❖ To study likely implications on public health concerns and related policy in India.
❖ To study the awareness level of Medicos on Intellectual Property Rights.

The above objectives have been attempted in this study by testing the following hypothesis.
1.6 HYPOTHESIS
In order to study the abovementioned objectives, several hypothesis have been framed and subjected to test for whether the hypothesis is correct or not. Following is the list of hypotheses which are tested for the purpose of this study:

1. There will be a significant impact of Intellectual Property Rights enforcement on Indian Pharmaceutical Industry.
2. The business strategy of the Indian Pharmaceutical Industry has changed in dimension by giving due importance to Intellectual Property.
3. Intellectual Property Rights enforcement in line with TRIPs agreement will have a significant impact on public health and Indian Pharmaceutical business.
4. Intellectual Property rights enforcement will have a negative impact on public health.

After reviewing the literature, analyzing the comprehensive primary and secondary data gathered, these hypotheses is being tested to arrive at conclusions and suggestive measures which are elaborated in the subsequent chapters.

1.7 SCOPE OF THE STUDY
The scope of the study have been restricted to India for the purpose of study the access to medicine from medicos perceptive and regarding Indian Pharmaceutical Industry for the purpose of studying the strategic impact of changing IPR regime on pharmaceutical business. The study aims to cover Industry professional, doctors and general public. Industry professionals include the professionals who are working in Intellectual property related fields.
1.8 RESEARCH METHODOLOGY

1.8.1 RESEARCH DESIGN

The study has been based on primary and secondary data. Primary data have been collected through structured questionnaire and personal interview with Pharmaceutical Industry personal and Doctors. The sample size of pharmaceutical Industry professional have been 100 from all over India. The sample size of Doctors have been 100 from all over India.

The primary data of the study is a survey of approximately 90 leading Indian firms, complemented with insights from case study interviews conducted to supplement information gathered in the survey. The scope of this study is limited to analyzing emerging firm strategies of Indian firms as a response to a gradual transition to product patent protection, and not to predict or to assess India’s present legal situation and issues therein related to the full implementation of its product patent protection regime. Therefore, data collected in the survey was mostly for a time period of 2000 to 2006, in order to be able to assess emerging firm strategies.

In addition, a variety of other data sources were employed, including secondary sources and case studies that rely considerably on scientific expertise perception of scientists. Secondary research consisted of a detailed review of existing literature including general documents on access to medicines and international developments related to the TRIPS Agreement and policy documents and papers on the impact of product patent protection on the Indian pharmaceutical industry.

A range of semi-structured interviews with experts in the area of pharmaceutical innovation and intellectual property rights were conducted as the second step in order to firstly, help clarify the structure and content of the study framework and secondly, to refine and provide
content validation to the survey questionnaire. Based on the secondary research and semi-structured interviews, a structured questionnaire was completed. A background report on the Indian pharmaceutical industry and emerging prospects and strategies from 2005 onwards was prepared to assist in identifying the main issues. About 90 leading pharma firms that participated in the survey were chosen using a purposive probability sampling technique from a list of companies’ generated for purposes of this study using major Indian databases like the India Info line and Pharmabiz, IMS Health, ORG data...etc.

The study was initiated in October 2003 and the questionnaire survey and fieldwork for the study was carried out in the months from November 2004 to March 2005. Most of the information presented in this study was collected during fieldwork in India: in addition to the questionnaire survey, interviewees and major organizations in India working with the pharmaceutical industry, such as the Organization of Pharmaceutical Producers of India (OPPI), the Indian Pharmaceutical Alliance (IPA), the Indian Drug Manufacturers Association (IDMA), the Confederation of Indian Industries (CII) and the Federation of Industries and Chamber of Commerce of India (FICCI), all provided documents that have served as inputs in the analysis. Wherever possible, annual reports were collected for over a period of three years from all firms interviewed.

Secondary data was collected regarding what is the current scenario in trade negotiations, current happening in the field of Intellectual Property field, Indian Intellectual property law, and its amendments, various statistical data required for study like how many patents filed by various firms etc.
1.8.2 INSTRUMENTS USED FOR DATA COLLECTION

Well structured questionnaires were used for data collection. Both broad open ended and closed ended questions were used for the purpose of flexibility. The terminology used in the questionnaire was adapted to that of the respondent so as to ensure that the questions were fully understood.

There were two types of questionnaires prepared. One set was designed to collect the primary data from the medicos (Annexure I) and the second set were for Industry professionals (Annexure II). Questionnaire for Industry Professional included all most all the major issues involved in Intellectual Property and its impact on corporate strategy, issues involved in public health and government role in striking the right balance.

Apart from some common questions, the industry professionals questionnaire contained questions related to strategy making and impact of IPR on strategic issues. The doctors questionnaire contained specific questions on access to medicine aspects.

1.8.3 DATA ANALYSIS

The collected data through various sources have been analyzed with the specialize software which was designed using the Microsoft excel. After analyzing the data testing of hypothesis was be done by comparing the conclusion from data analysis and the original hypothesis.

Statistical methods are a mechanical process especially designed to facilitate the condensation and analysis of the large body of quantitative data. The aim of statistical
method is to facilitate better comparison, study relationships between the two phenomena and to interpret the complicated data for the purpose of analysis.

For the purpose of this study simple statistical method used which was developed by using the Microsoft excel by initially feeding the primary data collected using the questionnaire and interview followed by interpretation and analysis of these data in tabular and graphical method.

1.9 LIMITATION OF STUDY

Finding of the study may or may not be generalized for other developing countries but certainly can be used for comparison and common issues can be identified with other developing countries.

1.10 CHAPTER SCHEME

Study has been divided into eight chapters. Present chapter represents the first chapter which mainly deals with introduction of the research topic, study design, the objective which have been studied and hypothesis which have been tested. Second chapter covers review of literature to identify gap in existing research work and the need for the present study. The third chapter is devoted to explain the WTO it evolution and the agreements. It narrates the most important TRIPs agreements which has impacted the most to pharmaceutical industry. In fourth chapter, study of the structure of Indian Pharmaceutical Business and the status of Indian Pharmaceutical Industry before and after the product patent regime has been done. Chapter five is a review of amendments in Indian patent act in complying with TRIPs provisions. Chapter six and seven are contains in depth study of impact of intellectual
property regime on pharmaceutical business and impact on access to medicine from the perception of medicos in relation to the objectives set for study respectively. Chapter eight contains conclusions of the study. This chapter elaborates the overall finding of the study and correlates the same with the predefined objective and hypothesis. Based on the conclusion from hypothesis testing recommendations have been made and lastly likely area of future researches have been suggested.

In summary, the study has been divided into the following Chapter scheme to explain the objectives and outcome of the research study.

Chapter 1 - Introduction
Chapter 2 - Review of Literature
Chapter 3 - WTO-TRIPs and Public Health
Chapter 4 - Indian Pharmaceutical Industry: An Overview
Chapter 5 - A review of Amendments in Indian Patent Act in complying TRIPs and its Implications
Chapter 6 - Strategic Impact of changing Indian IPR regime on Indian pharmaceutical business
Chapter 7 - Impact of changing Indian IPR regime on Access to medicine from the Medics perspective
Chapter 8 - Conclusion

Next chapter explains the review of literature to identify gap in existing research work and the need for the present study.