CHAPTER-1

INTRODUCTION:

In this competitive world Creativity and innovation are in the forefront, driving economy, development, growth and progress in all the knowledge based economies. Intellectual property rights are tools for economic development that should contribute to the enrichment of society.

Intellectual property rights are legal and institutional devices to protect creations of the mind, such as inventions, works of art and literature and designs. They protect products by differentiating them from similar ones sold by competitors through the use of distinguishing marks over the years, the rather elastic concept of IPR’s has been stretched to include not only patents, copyright, industrial designs and trademarks but also trade secrets, plant breeders rights, geographical indications and rights to layout designs of integrated circuits.

System of intellectual property protection has two fold objectives. The first is to promote investments in knowledge creation and business innovation by establishing exclusive rights to use and sell newly developed technologies, goods and services. The second goal is to promote widespread dissemination of new knowledge by encouraging holders of rights to place their invention and ideas in the market.

With the harmonization of intellectual property rights and opportunities, to secure stronger protection for these rights, new statutes were added at international level. As the global protection for intellectual property rights jurisprudence was strengthened by effective implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), concluded under auspices of the World Trade Organization, numerous questions arise about impacts on prospects for economic growth. This has expanded the
definition of trade. It's no longer just buying and selling of goods. Now, the
definition of trade encompasses a whole range of issues from services to
intellectual property rights.

After the TRIPs developing counties no longer have the policy options and
flexibilities, which developed countries, had. This led to the process of
expanding inter nation IPR subject matter, creating new forms of rights and
progressive standardization of the basic features of IPR. With the growth of
international trade and the establishment of world trade organization’s
agreement on trade related aspects of intellectual property rights (TRIPs
Agreement) nations have been obliged to focus in increasing attention on the
role of patents in economic development as an economic driver.

A patent is a legally enforceable right granted by a country driving their rights
from the inventor, for a limited number of years. The first patent grant can be
traced as far back as 500 B.C. This grant was for the promotion of culinary art.
For it conferred exclusive rights of sale to any individual who first invented a
delicious dish? This practice was extended to other Greek cities and to other
crafts and commodities.

Evidences of grant to private individuals by kings and rules of exclusive
property rights to inventors’ dates back to the 14th Century, but their purpose
had varied throughout the history. In England during the 16th and 17th Century
the inventor’s patent of monopoly had become of great national importance.
With a motive to protect the British, during the 18th century it was first
attempted to legislate in India.

In India after independence two committees had reported on the revision of
the patent, then the law relating to Patents is contained in the Patents Act,
1970, which has been amended by the Patents (Amendment) Act, 2002. The
provisions of the present Act were incorporated keeping in view of past
experiences, where the Trans National Corporations patent monopoly created
many problems to the indigenous firms. It also took into consideration the National Plans that have been formulated for the economic up-liftment of the country, rising of the standard of living of its people basing the needs of the community, constitutional goals and objectives.

Prior to Independence only India has entered into Pharmaceutical Industry but even then the pharmaceutical industry was in the control of Trans National Corporations. The Indian pharmaceutical Industry was unable to compete to Trans National Corporations. To control the competition, the Parliament of India during 1957 took a decision to establish Public Pharmaceutical Industries and also introduced regulatory mechanisms to regulate prices of medicines in India. Due to the measures taken by government of India and new patent act of 1970, pharmaceuticals industries attained self-sustainment.

Further, as India stepped towards self-sustainability. By this time the Indian Government has appointed the Hatti Committee. The Hatti Committee has studied the Indian Pharmaceutical Industry scientifically and suggested to reform the Industry. This Report was also containing the UNO Resolution on Essential Pharmaceuticals and further suggested to control the grip of Trans National Corporations over Indian Pharmaceutical Industry The further Reforms to Indian Pharmaceutical Industry was felt in the wake of public interest i.e. the enactment of Public Drug Act. But the same was not implemented; this patent rights help in stimulating sustainable economic growth. Still, there is ample scope for discussion on how to maximize the effectiveness of patents. In any country without appropriate legislation international treaties or agreements entered into by that country would not have the force of municipal law. In India there are innumerable provisions in the constitution of India that outline Indian obligations vis-a-vis the international comity of nations with regard to international treaties are in fact, distributed between the executive and legislature. However, there is a specific article in part IV of the Indian constitution, Art.51 in the directive principles of state policy deals with international treaties.
Art 51 embodies the object of India in the international sphere.\textsuperscript{1} Article 51 reads, the state shall endeavour to, promote international peace and security, maintain just and honourable relations between nations, foster respect for international law and treaty obligations in the dealings of organised people with one another, and encourage settlement of international disputes by arbitration.

However, this article is only directive, which state has to follow in its relations with other nations to promote international peace and secure. The attainment of Public Health is the Government’s primary concern. The drugs and medicines play a pivotal role in achieving public health. India is developing in Science and Technology. But the same is it contributing for the improvement of the common men and for the same the political will is also necessary in tune with science and technology.

Patent Amendment Ac 2005 reflects on some of their broader implications. In particular on the introduction of product patents for pharmaceutical inventions and the controversial issue of how this change is likely to impact access to medicines.

Introduction of product patent would disturb the pharmaceutical industry structure and adversely affect consumer welfare through higher drug prices, with adverse consequences for the health and well-being of citizens, the basis of their view is that the countries such as India where health insurance coverage is so rare, almost all medical-expenses are met out of pocket and any change in the demand structure could have significant impact on the poor. The Drugs have become expensive and beyond the reach of the common man due to heavy royalties being charged by the patent holder of such drugs\textsuperscript{2}.

\textsuperscript{1}Durga Das Basu, Shorter Constitution of India( Nagpur: wadhwa 2001) p 51
\textsuperscript{2} Intellectual property global and Indian dimension by J.K Bagchi ( IAS) Retd, Manas Publications
The present position of Pharmaceutical Industries has a robust growth and also has diversified its branches and their business. The Indian pharmaceutical industry has been witnessing a phenomenal growth in recent years, and is estimated to be approx. US $ 126 billion industry. India exports around US $13 billion of pharmaceutical products including vaccines to most countries in the world. Pharmaceutical market in India is ranked third globally in terms of volume, accounting for about 10% of the world’s production by volume.³

The Pharmaceutical patenting makes drugs more expensive and less accessible. The Patenting though encourages and also necessary for innovative, life-saving technologies at the same time patents enable companies to create a monopoly on a product, permitting artificially high pricing. As a result, products such as Drugs are often priced out of reach for many of those who need them.

The patent plays a very significant role with regard to pharmaceuticals. In India much study and debate has been done to show and argue that how and what extent the patent system affected the pharmaceutical industry. The study focused on Production of Drugs by industry, the drug prices, exports of drugs etc. The study also touched on the problems of common man for access to health while granting patent to pharmaceutical industry. India being a member of UNO and all other human rights treaties and conventions, it is bounded duty to protect right to health of all its citizens. Because directive principles of state policy has an obligation to provide human right to all its citizens. Simultaneously, it should also give ample scope for development of nation.

³ FICCI’s, position paper On Enhancing India’s Global Role In Supply Of Generic Medicines( India pharma summit) IN Collaboration with WHO and department of pharmaceuticals, Govt of India , 2013-14, page no 6
1.2 - STATEMENT OF THE PROBLEM

The Agreements on trade-related aspects of intellectual property rights which is popularly known to the world as “TRIPS”. The Agreement is one of the three pillars of the World Trade Organization system. The law on patent in the post TRIPs regime, has grown vertically and horizontally across the globe and have played a vital role in harmonizing the National laws of the member countries. The global protection regime strengthens to implementation TRIPS, concluded under the auspices of the World Trade Organization, numerous questions arise about impacts on prospects for economic growth.4

The Trade related Aspects of Intellectual Property Rights is a trade agreement boxed in an exclusive category of its own, it is due to the emergence of commercial importance of intellectual properties for Multi-National Companies in post-industrial world economy and in trade. It is that Prior to the agreement to TRIPs the issues pertaining to Intellectual Properties and its protection was subjected to the National domain i.e., a National Government had complete discretion to determine the nature and extent of protection according to the prevailing socio economic conditions of the country.

The Various International treaties were executed to ensure the protection of the Intellectual Properties at International level. TRIPs advocates harmonization of the Intellectual Property protection systems and laid down

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the universal Intellectual Property protection standards, stringent than those existing in most of the developing countries.

The agreement requires all World Trade Organization Member - States to grant patents for Pharmaceutical products for inventions for a minimum of twenty years. India being a member of WTO has to implement the TRIPs agreement in totality. This requires that Indian Intellectual property laws have to be amended to bring them in conformity with the provisions of the TRIPs agreement. While the laws on Trade Marks, Copy Rights, and Designs are almost in conformity with the provisions of the TRIPs agreement, Patent laws are the ones which was cause of concern in the minds of both the Indian and International communities.

The major shift for countries, such as India was that the TRIPS agreement forces upon member countries a patent regime that recognizes product patents for chemicals and pharmaceuticals. India being a social welfare state, the Indian Patent Act of 1970 was framed in a manner that ensured, the patent rights relating to pharmaceuticals could be regulated by the government. The original Patents Act, 1970 was a balanced Act which helped the growth of industry and also adequately covered the public interest angle. The pharmaceutical industry produces high quality products of almost all therapeutic groups and exports the generic produce to the developing and developed countries at most competitive prices.

The developing countries are now apprehending difficulties in importing pharmaceuticals from India because of the tight provisions with regard to the compulsory licenses for effective role of the domestic enterprises in the patented products. And in the context of Indian pharmaceutical industry, the industries have performed well since the beginning of the TRIPs regime and

\footnote{B.K.kealya, “Amended Patents Act: A Critique”, combat law, vol.4,issue2}
also in terms of growth in the domestic and export markets but also financially.

The Indian Patent Act ensures that, the reasonable requirements of the public with respect to availability and affordability are taken care of. The Public interest, particularly public health and nutrition is protected and effectively balances intellectual property protection with public health concerns and national security. The patent Act has undergone various amendments in 1999, 2002, 2003 and 2005. New concepts and provisions were added to the Patent Act 1970, to incorporate the guidelines given by the TRIPs Agreement.

The TRIPs have always been highlighted as the trade agreement prioritizing the economic concerns over the social one. The “Product Patent Regime” in particular has been accused for ignoring the state’s legal obligations for protection of its citizen’s right to Self Determination, food, housing, work, health and education as promised in the International Covenant on Economic, Social and Cultural Rights. The same has been observed by UN Sub-Commission on the Promotion and Protection of the Human Rights in August 2001 and the Sub-Commission adopted a resolution on “Intellectual Property Rights and Human Rights”. The resolution stressed that the promotion and protection of Human Rights in conformity with the charter of the UN, is the first responsibility of governments. The resolution also advised the WTO in general and council on TRIPs, in particular to take fully in to account the state’s obligations under the international human rights instruments. The Resolution also has advised the government to integrate in to their national and local legislations and policies, provisions, in accordance with international human rights obligations and the principles, hence to protect the social foundation of intellectual property.
Traditionally, the Indian pharmaceutical industry has not concentrated much on research and development in the area of pharmaceutical drugs and related issues in the era of global development and of the human rights..., it is the result of increasing export orientation of Indian pharmaceutical companies and diversification to the regulated markets at the global level. Development of new chemical entities is not yet a significant part of the research and development activities of Indian companies.

The Member countries were entitled for incorporation in their national patents legislation. The Doha declaration is an important land mark for the developing the public health problems has been recognized, especially several issues that those of resulting from HIV/AIDS, tuberculosis malaria and other epidemics. The Declaration inter-alia clarified that the TRIPs agreement did not and should not prevent members from taking measures to protect public health. The declaration also reaffirmed the right of the members to use the full provision in the TRIPs agreement which provides flexibilities for this purpose. It also stated that members were free to determine the grounds upon which compulsory licenses could be granted.

The negative impact of product patent protection is already being felt and unless mechanisms are put to control prices, the new patented products that will be introduced in future will be very expensive. There is tension between the need to promote innovation and development of new healthcare technologies and the promotion of sustainable access to affordable medicines is not new and it has come to the fore in many developing countries, as a result of their implementation of certain provisions of the TRIPs Agreement. Developments in India have impact not only in India but well beyond its borders, covering global market, especially in developing and least developed
countries because of low cost supply of quality Indian generic pharmaceutical products.

The new amended to the Indian patent Act as such does not affect the rich and elite class of consumers. It however does seriously affect the availability and affordability of medicines for the people of the nation by the amendment of national patent system in India. The concerns of the poor and the overall critical health scenario should have been the guiding factor. The Co-relation of the Patents Act of 1970 with the National Health Policy is also an important factor to ensure success of the health policy. Similarly, there should have been co-relation of the patent system with the National Pharma Policy for strengthening the pharma industry and the National R&D policy for strengthening the Research base. The patent regime be devised so that the utmost priority is granted to securing the people’s rights of access to affordable and quality healthcare, without monopoly.

It is to be noted that, Directive Principles of state policy of Constitution of Indian , 1950 in Articles 39 (e), 39 (f), 42 and 47 touch on the subject of health bearing on the right to health. No direct reference on right to health can be found in any of the rights mentioned under Part III of Fundamental Rights. The Fundamental Rights under the Indian Constitution are enforceable and

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6 Article 39. Certain principles of policy to be followed by the State: The State shall, in particular, direct its policy towards securing:
(e) that the health and strength of workers, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength;
7 Article 39(f) that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom and dignity and that childhood and youth are protected against exploitation and against moral and material abandonment
8 Article 42. Provision for just and humane conditions of work and maternity relief The State shall make provision for securing just and humane conditions of work and for maternity relief
9 Article 47 speaks about, Duty of the State to raise the level of nutrition and the standard of living and to improve public health The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health
guaranteed by the constitution of India, on the contrary and through judicial decisions rendered in the area of right to health has been read into the fundamental right guaranteed under Article 21\textsuperscript{10}, which guarantees right to life and personal liberty which also include the health.

The area of research also includes issue of Right to life, which is guaranteed under Article 21 of the Indian Constitution has been questioned. Right to life under Article 21 gives scope for widest amplitude of rights. It shelters various rights such as right to privacy, human dignity, health and drugs, etc., Right to life which includes right to health implies “The right to a variety of facilities and conditions necessary for the realization of the highest attainable standard of the health”.

1.3 - SCOPE & OBJECTIVES OF THE STUDY

**SCOPE :** The importance of framing some sort of an international agreement for co-operation among nations for the protection of intellectual property was realized as early as in the year 1883 when the Paris Convention for the Protection of Industrial Property was adopted. This was the very first instrument to protect intellectual property rights in general. The year 1995 was landmark as W.T.O., a rule based multilateral trade system which was conceived, it includes 60 trade agreements, and the TRIPs is also one of such agreement to protect trade related aspects of intellectual property Rights.

The Indian Patents Act, 1970 and Patent Rules, 1972 works under the framework of the 1883 Paris Convention which is administered by the United Nations world Intellectual Property Organizations (WIPO) to serve the public interest by balancing rights and obligations of the patent holder. This Act was revised through Patent Amendment Act of 1999, 2002 and 2005 Amendment.

\textsuperscript{10} Protection of life and personal liberty No person shall be deprived of his life or personal liberty except according to procedure established by law
Universal Declaration of Human Rights and Indian Constitution Provides for right to health and it are as well engrossed under the International Covenant on Economic Social and Cultural Rights. The study focuses mainly on how far the Right to Health as well as interest of patent holders are balanced and enforced in a globalized world.

**OBJECTIVES OF STUDY:**

1. To discuss how far the domestic and international legislations are balancing right to health of common man and patent holders right.

2. To examine how far the major objective of the TRIPs Agreement in the protection and enforcement of IPR is benefitting the society as a whole, by balancing the rights of common man and patent holders rights.

3. To examine whether India can insist on developed nations not to interfere in matters relating to the domestic laws of the developing nations which are well within the room for flexibility granted under and in accordance with the TRIPs agreement.

4. To examine the impact on the Indian pharmaceuticals industries and Indian economy as a result of recognition of product patent.

5. To examine how far the right to life guaranteed under Article 21 under the Indian Constitution is negated by the introduction of product patent regime.
6. In the background of the above national and international commitment towards right to health with emphasis on right to life, it is necessary to examine how far these commitments have resulted in providing adequate health to the common man.

7. The study further analyses and presents options available and makes recommendations for policy makers, including using flexibilities under the patent law to the fullest which may be critical to promote the revival of a robust generic industry.

8. To find out whether flexibilities provided within the new patent Act, are interpreted in favour of public health by decision makers and courts.

9. What is the attitude of the judiciary in developing an exclusive jurisprudence on right to health especially for the developing countries?

10. To find out whether development meant only to attain economic progress or to cover other issues to address the problem facing it, like the right to development and the consequential impact on right to life and right to health.

**1.4 - RELEVANCE OF THE STUDY**

1. The present subject of research “Legal Implications of Trips on the Indian Patent Act: A Study with Special Reference to Pharmaceutical Industry in India” assumes importance, since are the pharmaceutical industries in developing countries like India are crucial for economic development and sustainable development.
2. The legal implications arising out of various international trades related policies bring in drastic impact on the National economy specially related to the affordability of pharma prices and its effect on common man.

3. It is well known that the constitution of India has given various protections to the citizens. However on becoming parties to multilateral treaty agreements, any changes in the scheme of things have been brought about

1.5 - HYPOTHESIS

1. Trips implied patent Act has drastically affected affordability and availability of drugs in India.

2. India has not been successful in enforcing Right to health in strict sense (included in right to life), as the world has changed its attitude towards human right.

3. The aim of Universal Declaration of Human Rights to attain that everyone has the Right to standard of living including right to health is not achieved and still a distant dream.

1.6 –RESEARCH METHODOLOGY

Keeping the aforesaid topic and the hypothesis in view, the research is carried out on the subject by the doctrinal method of research. The aid of reputed UN documents, WTO agreements, TRIPS, Patent Act and its amendment Act, text books, reports, articles, and policies, law reporters, law journals and other publications relating to the area of research has been scanned to get an insight of the subject of research. The various judgments of Supreme Court of India on the area of research are analyzed for effective examination of the topic. Since the internet is a virtual world library on desktop, have also been used for
collection of data/materials. The Uniform method of quoting the citation is used.

1.7 - OVERVIEW OF THE LITERATURE

The study reveals how right to health is also an integral part of right to development and in the present study the review of literature brings out that there is no study in respect of, and in the context of developing India but at the international level there are studies on this but not in Indian context. There is not much study on the point that health is not merely health but it includes overall aspects and whether this right to health will also find place in fundamental rights of our constitution.

1.8 - PLAN OF STUDY

The researcher after evaluation and researching the present problem has designed the plan of study by framing 7 chapters and has discussed the research topic in detail. The following are the chapters of the study.

SCHEME - CHAPTER WISE STUDY

The study is planned in seven chapters;

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

The Second Chapter, “An overview of the evolution and development of Intellectual Property Rights from early times to the present” will have an overview of how intellectual property rights evolved from early times that is from Paris Convention for Protection of Industrial Property 1883 to the present globalized era which covers TRIPS and other related agreements on the topic.


The Fourth Chapter “Pharmaceutical Industry and Public Health concerns in India: An Assessment” deals about pharmaceutical industries in India and its impact on public health. Post 1970 developments on patent laws in India in compliance with international conventions and its impact on pharmaceutical industries in India.

The Fifth Chapter “The TRIPS and their legal implications on developing countries with special reference to India” discusses about evolution of TRIPS, and how, The Agreement on Trade Related Aspects of Intellectual
Property Rights (TRIPS) is the most notable step taken towards harmonization. It introduced this intellectual property law into the international trading system and all the member countries towards a level of uniformity. India being a member of WTO has implemented TRIPS Agreement in totality. Its legal implications on developing countries. It will go to ascertain the implications on India and how the right to development is also included in this.

The Sixth Chapter “The Patent Amendment Act of 2005 an analysis and their implications on Pharmaceutical industry” makes an analysis on the prevailing problems and implications associated with Indian pharmaceutical industries in the era of post 2005 amendment of Indian patent Act. Whether this is in compliance with TRIPs with special reference to availability and affordability of drugs in India.

Thus in the Seventh Chapter “Conclusion and suggestions” on the basis of the study, an attempt is made to draw certain conclusions directed against mitigating the evil effects of implications on patent act. How availability and affordability of medicines are balanced by government of India, by taking all necessary measures. It has also listed certain recommendations for improving performance of pharmaceuticals in India.

“Last chapter includes all the suggestions, conclusion and review provisions.