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Statement of Problem

God has bestowed man with the unique quality of thinking and intellect distinguishing him from all other creatures made by God. Man has utilized his intellectual mind for his own benefits as well as benefits at all society at large intellectual property is one such outcome of the exercise of intellectual faculty by human beings and it is because of his unique faculty from individual to individual which has been accepted from personal property of the individual exercising his intellectual faculty for a particular purpose which needs protection by law.

The grant of IPR and their proper enforcement facilitated fair trade and access of consumers to quality products while ensuring the safety to human and animals, product’s price shelf life and degradation etc. The new technology developments, particularly in biotechnology, demonstrate the significance and usefulness of traditional knowledge for development of new products of commercial importance. Research and creativity originating from research institutions in the field of science and technology like institutions of technology, university and industrial Houses engaged in R&D activities.

The fast technological metamorphosis and globalization require constant exploration of emerging issues in IPR. The WIPO Agenda on the Global Intellectual Property issue aims at enhancing of the coterminous, proximate and reciprocal relationships between intellectual property and traditional knowledge, bio-technology and biological diversity and collateral aspects of economic, social, cultural and technological development. The overall objective of the Global Intellectual Property Issue Division (Global Issues Division-GID) is promoted the constant viability, enhanced efficiency and broader coverage of the intellectual property system. In a world increasingly epitomized as the “global information society”, the rapid emergence of modern
information technologies, an increasing awareness about traditional knowledge and its spiritual, cultural and economic values have become central to human discourse.

Traditional knowledge (TK) is a collectively owned property and is integral to the cultural or spiritual identity of the social group in which it operates and is preserved. Traditional Knowledge is now at the centre of the discussions on intellectual property rights and has assumed immense significance. India does not have any specific legislation for protecting traditional knowledge. But the Patents Act, Plant Variety Protection and Farmers Rights Act, Biological Diversity Act, 2002 and Geographical Indication of Goods (Registration and Protection) Act, 1999 have provisions that can be utilized for protecting traditional knowledge. The concept of benefit-sharing, which is an integral part of protecting traditional knowledge, has been analysed in detail with specific reference to the Biological Diversity Act and also the Plant Variety Protection and Farmers Rights Act. The case study of Jeevani drug gives an insight into the concept of benefit sharing. The importance of traditional knowledge is highlighted in the revocation of patent granted to derivatives of neem on the ground that they were part of the traditional knowledge of our country and that fungicide qualities of the neem tree and its use had been known in India for over 2,000 years. A discussion of the patent granted to turmeric that was effectively challenged by the CSIR based on the ancient Sanskrit text also figures in the paper. Along with this, a case study of Basmati has also been done. The thesis also focuses on the international initiatives at protecting traditional knowledge including the Convention on Biological Diversity, International Undertaking on Plant Genetic Resources for Food and Agriculture and the Agreement on Trade Related Aspects of Intellectual Property Rights. But there are no uniform norms regarding the protection of different types of traditional knowledge owned by local communities. The reason for this divergence of laws is that the international community never had an occasion to look at the protection of
traditional knowledge in its entirety. Measures to ensure that traditional knowledge is protected should be taken at the auspices of the World Trade Organization which should lay down general mandatory provisions to be complied by member countries.

The pressing need of the hour is to enact a *sui generis*, or alternative law to protect traditional knowledge. The history of patent reform in India started from 17th century. The Government of India has offered its citizens of the country an opportunity to protect their intellectual property for almost 150 years. In 1856 the first IPR legislation was enacted in British India, to grant certain privileges. This Act was modified in 1859 in which patent monopolies were granted known as exclusive privileges. Again a comprehensive law was enacted by the British rulers in 1911 replacing the earlier Act of 1859. This was known as Patent and Designs Act, 1911.

This Act was designed to serve the foreign interest and for control over markets for finished goods by multinational corporations. In case of pharmaceuticals almost 85 percent were supplied by the multinationals. Kefauver Committee of USA showed in its report that the prices of antibiotics and other medicines in India were highest in the world. Soon after the independence, two committees were appointed in 1949 and 1959 presided by Justice Bakshi Tek Chand and Justice Rajgopala Ayyangar. For further 23 years various commentators and commissioners debated the propriety of such a law to India's economic needs Based on the recommendations of these two prominent Committee reports a bill was framed which ultimately came in the shape of The Patents Act, 1970. The Patent law has gone through the several reforms in itself.

With the enactment of the Act, Indian companies, specifically the pharmaceutical sector grew with a sharp pace and their market share and availability of drugs went up to 85 percent. Along with this the prices of
medicines became the lowest in the world. The major provisions which were enacted and implemented in the Act of 1970 specially in favour of pharmaceutical sector were the process patent regime (industrial sector was covered by process patent only) there was no product patent for food, chemical and pharma products the term of patent was 7 years from the date of application or 5 year from the date of sealing of patent whichever was lower though in other areas terms of patent was fixed for 14 years. A provision of licence of right was introduced for the pharmaceutical sector. There were no constraints on exports. The Introduction of Drug Price Control order along with the implementation of the new Act of 1970 showed the sudden differences in the prices of drugs in the country. The process of reverse engineering became a major factor for the availability of cheap drugs and medicines in the pharmaceutical sector.

With the advent of Trade Related Aspect of Intellectual Property (TRIPS) Agreement in the international scenario, all the countries signatory of WTO and TRIPS Agreement, become bound to mandate certain drastic changes in the patent systems through out the world. Under the TRIPS Agreement it is the obligation of the member countries where their patent laws are not consistent with the TRIPS provisions of the agreement, to take steps to modify their legislation to make them consistent. The TRIPS Agreement provide a period of 5 years from 1995 for developing countries to implement the TRIPS provisions further it also provide a additional period of 5 years to developing countries like India to comply with the TRIPs Agreement.

The major change which needed to be introduced in the patent law was the product patent regime. India had a long transition phase which ended on January 1, 2005. During this transition phase the product patent applications could be filed from 1 Jan 1995 and kept in the 'mail box' which were to be taken out after the completion of the transition phase on 1 Jan 2005 certain Exclusive Marketing Rights (EMRs) were also granted for 5 years by India
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before the patent on product was either granted or rejected in India. These changes were introduced in the patent law by the first amendment Act in 1999. In addition it had for compulsory licensing\(^1\) and mailbox facility\(^2\) for pharmaceuticals and agro chemicals.

In 2002 the Parliament passed the second Amendment Act considered as Patent (Amendment) Act, 2002. This Act make the Indian patent law not only TRIPs compliant but also incorporate safeguards for protection of public interest, national security, biodiversity, traditional knowledge etc. Important changes included in the amended Act were definition of invention has been \(\text{modified};\) uniform term of patent protection extended to 20 years for all categories of invention and changes in compulsory licencing provision, a provision for hearing of appeal use of invention by the central government was also incorporated. India's traditional knowledge is also added as non patentable by this amendment.

The gaps which were still remain after the amendment of 2002 required to be filled by another amendment in 2005. But the main objective behind the introduction and passing the Patent (Amendment) Act, 2005 was to meet India's deadlines 31 December 2004 to comply with the TRIPs Agreement. This amendment introduced product patent regime in new Patent Act. The Patent (Amendment) Act, 2005 was the out come of TRIPs Agreement and Doha Declaration.

For public health proponents TRIPs enhanced the interests of transnational pharmaceutical companies and industrializes countries with large pharmaceutical industries especially the US, Japan and European Union at the express of access to affordable medicines by millions in genuine need. Concern for public health protection led to the Doha Declaration in 2001 and followed

\(^1\) The Patents (Amendment) Act, 1999 Sec. 24C and 24D
\(^2\) Id., Sec. 5 (2).
by the implementation of paragraph 6 Decision 2003. This was the point of time when public needs protection takes primacy over trade.

The new patent law addresses three sets of issues that could have immediate impact first is the adoption of a new definition for "pharmaceutical substances," which should be a new entity involving one or more inventive steps. Second is the exclusion of mere discovery of a new form of a known substance and new use for a known substance from the ambit of patenting which could prevent grant of patents on formulations. And the third one is to protecting the interests of producers who are already producing the production that may be granted patent protection in new regime.

Provisions related to compulsory licence are another important feature of the Amended Patent Act, 2005. This is meant to facilitate the Indian industry to drugs to those Least Developed Countries (LDCs) that do not have adequate domestic manufacturing capabilities. After the amendment there was insertion of the additional provision for pre-grant opposition along with the provision for filing post-grant apposition. In recent time pre-grant opposition has been filed by Indian pharma companies. The most highlight case related to pre-grant opposition is Gleevec case.

An insight to India pharmaceutical industry tells the position of IPI. It rank 4th in terms of volume and 13th in terms of value. Indian firms produce approximately 1.5% of the global pharmaceutical market of $ 480 billion. The Indian pharmaceutical industry meets around 70% of the country’s demand. IPI provides direct employment to 5, 00,000 people. And indirect employment to approximately 24, 00,000 people.

"The Indian pharmaceutical industry is a success story providing employments for millions and ensuring that essential drugs at affordable prices are available to the vast population of this subcontinent." Said Richard Grester.
India is emerging favoured destination for level of expenditure on R & D is about 5% of turnovers, which is much lower compared to most of the developed countries which is 15 to 20%. Some of the leading firms who take the initiative in the investment in R & D are Dr. Reddy’s and Ranbaxy.

FDI confidence survey, 2004 at Kearney has rated India as the 3rd most attracting investment destination (Behind China and USA) compared with 15th position two years ago and 6th last year. FDI in pharmaceutical sector in India has a direct relation with strong patent regime. Before the product patent regime the IPI rise by the process of reverse engineering with the advent of product patent regime there is an increase in FDI inflow in pharmaceutical sector. In 2004 there was a sharp increase in FDI, it declined in 2005 but again it increases in 2006.

Today contract research contract manufacturing formation alliances in research & development between the Indian and foreign pharmaceutical companies have strengthened the prospects of the Indian pharmaceutical sector in post Jan, 01.2005 regime. The Indian pharmaceutical companies’ mergers and acquisitions of foreign companies is another evidence of its rise of Indian Pharmaceutical Industry.

The Indian traditional medicines also have a significant presence in the Indian Pharmaceutical Industry. The Indian system of medicine was prevalent about 1500 years over Southeast Asia. It comprises of 3 major systems namely Ayurveda, Siddha and Unani this traditional medicines now comes under the Indian system of Medicine. In 1995 to boost the growth of traditional medicines The Department of Indian system of Medicine and Homeopathy (now has been known as AYUSH) was established by the Ministry of Health & Family welfare.

The immense biotech wealth of India has approximately 7000 species reportedly used for the medicinal purposes, mostly for the extraction of rare
drugs. Utilization extent shows that there are about over 0.36 millions Ayurveda practitioners, 29.7 thousand Unani and 11.6 thousand Siddha specialists in India. Village based health traditions are still carried on by housewives birth attendants and vaid-hakems (herbal healers), making it 70% of the health care need so India which is dependent on the medicinal plants. The global market of herbal medicines was estimated at $ 16.5 billion in 1997, which rose to $ 22 billion in 2000.

The Patents Act of 1970 did not talk about the protection of Indian traditional knowledge. It was after 2002 when the Patent Act kept the traditional knowledge out of the ambit of patentable invention and considered it as non patentable. Basically the traditional knowledge relates to traditional medicinal knowledge. Through ages knowledge about use of medicinal plants and herbs exist in the form of local folklore available with families, tribes and cultures, handed down from generation to generation.

It is said, 'knowledge is valuable only, when shared' but when this concept of sharing start causing threat to the vary knowledge and its holder then the need arises for the protection of traditional knowledge this threat may be by the way of exploiting the knowledge and claiming monopoly right over such knowledge. This threat has been created by the western world.

There are many aspects of traditional knowledge but here it deals only with the protection of knowledge of farming community concerning wild as well as domesticated varieties and the knowledge of heaters concerning medicinal properties of plants. The World Health Organization has stated 80% of the world's population depends on traditional medicine for its primary health care.

Many tribal and social communities survive on the bases of their traditional knowledge. The products they use and manufacture is a part of their

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3. The Patents (Amendment) Act, 2002 Sec. 3 (p).
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livelihood. Even today in Asian countries many indigenous communities fulfill their basic needs from products of their traditional knowledge plant extracts and several herbs of medicinal properties are the source of their medication.

With the development of science and technology the traditional knowledge is drawing global attention. The modern manufacturing industries (textile, handicrafts, pharmaceutical, seed etc) commercially exploit the traditional knowledge using new technology without the permission and sharing of profits with the communities.

There are about 7000 species of medicinal plants and over 15,000 medicines are based on herbal formulations in different system, growing attention to the Ayurvedic and Unani medicines because of the side effects of allopathic making the traditional medicinal system popular not only in India but also at global level. Protection of traditional knowledge is the need of hour, to avoid the misappropriation and exploitation. Traditional knowledge needs protection to improve the livelihoods of TK holders, benefits to national economy, conservation of environment and prevention of biopiracy.

Certain national and international efforts have been taken for the protection of traditional knowledge. The World Trade Organization has taken some steps to protect the traditional knowledge at the international level. The TRIPs Agreement also does not much recognize the importance of traditional knowledge. Though there has been a constant demand to review the Article 27.3(b) and also a review of the whole agreement. TRIPS agreement in reference to protection of traditional knowledge only required the member countries to protect the plant varieties. By a ‘sui-generis system’ the sui-generis system would recognize the traditional knowledge relating to genetic resources and promote access and benefit sharing.
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The Convention on Biological Diversity has recognized the rights of the indigenous people over the genetic resources. Article 1 and 8(j) of the Conventions deals with equitable benefit sharing that arise out of the use of traditional knowledge.

Art 8(j) said, state parties are required to "respect preserve and maintain knowledge innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote the wider application with the approval and involvement of the holders of such knowledge innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge innovation and practices".  

CBD says that a prior informed consent is required from the local community, for the utilization of the biological resource. But the consent is not required if the knowledge is already in the public domain. Example of Arogyapacha of Kani Tribes is a landmark in case of access benefit sharing and prior informed consent. 50% of the gains from Arogyapacha were given to the Kani Tribe and a 2% of royalty from the sate of the drug also given.

World Intellectual Property Organization (WIPO) began its work on TK in 1978. WIPO has brought traditional knowledge and intellectual property rights under Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore constituted in 2000.

In its various works committee considered a study prepared by WIPO on disclosure requirement in patent law that were relevant to traditional knowledge or genetic resources used in course of developing a claimed invention.

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Agenda 21, International Labour organization (ILO, United Nations, Draft Declaration on the Rights of the Indigenous people, United Nations Food and Agriculture Organization (FAO), United Nations Development Programme (UNDP) and the IBRD or the world Bank, and United Nations Conference on trade and development (UNCTAD) all these organizations have taken various initiatives to talk about the protection of traditional knowledge as well as the rights of the TK holders.

Though, India does not have a specific sui-generis legislation to protect traditional knowledge and folklore. National initiatives taken by the Government of India are in the form of statutes passed. Important among the passed statutes is the Biological Diversity Act, 2002. This legislation provides for conservation of biological diversity sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources. Under the Act, National Biodiversity Authority (NBA) keeps check on the appropriation of biological resources.

The Protection of Plant Varieties and Farmers’ Rights Act, 2001 is another legal instrument which acknowledges the concept of effective benefit sharing. Mandatory disclosure of geographical location from where the genetic material has been taken and information relating to the contribution of farming community evolved is required.

The Geographical Indications of Goods (Registration and Protection) Act, 1999 is another step taken by India for the protection of traditional knowledge. Along with this Patents (Amendment) Act, 2002 introduced certain provisions for mandatory disclosure of source and geographical origin of the biological material used in the invention of a product while applying for patents in India. If there is no disclosure or wrong disclosure of such source the patent application will be rejected and if the patent has already been granted same
will be revoked. The Copyright Act, 1957, The Design Act, 2000 and the Trade marks Act, 1999 also at some extent protect the traditional knowledge.

Patentability of plant breeding got recognition from the decision of German Court in Diamand v Chakraborty after the formation of WTO in mid 1990 all WTO member countries were committed through TRIPS agreement to promote effective protection of intellectual property right in all fields of technology. The TRIPS Agreement requires that its members shall provide for the protection of plant varieties either by patenting or by an effective *sui-generis* system.

The enacted Act of plant varieties protection primarily extends to protect the rights of the farmers while at the same time protecting the rights of plant breeders contribution of the farmers in conserving, improving and making available the plant genetic resource for the development of new plant varieties is also protected by the Act which is reciprocal to the protection of traditional knowledge.

The Protection of Plant Varieties Act, 2001 provides adequate protection to the traditional knowledge of the farmers by recognizing their role as cultivator and conserver. Farmers do not breed in ideal laboratory conditions but on actual knowledge of the environmental conditions through national selection and continuous evolving process. Indian farmer's house evolved many varieties that are resistant to salt, flood, drought etc. if the breeders who develop a new variety from the existing genetic resources, have a right of develop the new variety, the farmers also have a right of identifying, conserving and developing the traditional variety. It is the farmer who has safeguarded the tremendous biodiversity that breeders and seed industry use as a raw material.”

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So the farmers and breeders have also been covered under the Plant Variety Protection Act, 2001 by considering the fact that protecting the farmers and breeder’s right is protecting the Indian traditional knowledge.

Biopiracy refers to the appropriation, generally by means of patents, of legal rights over indigenous knowledge especially traditional biomedical knowledge without compensation to the indigenous groups who originally developed such knowledge. In recent years there has been increasing number of reported cases of misappropriation & commercial exploitation of TK under patents and other IPRs. In many cases claims in the patents on plants and their genetic resources are not fundamentally different from the practices applied by the traditional communities in the utilization of these plants as food, cosmetics or traditional medicines. Though some of these cases of misappropriation have been successfully challenged but other still remain to be challenged. This raises the legal protection of traditional knowledge. Important cases among them are of Turmeric, Neem, Basmati rice etc. at national level and at internationally Hoodia cactus case is the prominent one.

Thus the present study aims to throw light on the existing product patent system to accord legal protection to traditional knowledge and it also highlights the need to have a sue-generis protection for the traditional knowledge, so that the intellectual as well as customary rights of traditional Holders can be respected, recognized and rewarded.

Review of Literature

The present study required in depth of study and understanding of patent system, TRIPS Agreement, DOHA Declaration, position of Indian pharmaceutical sector and issue of “access to medicines” thereby, help from many books, journals, articles, websites have been taken besides the bare act of Patent Act, 1970. The prominent among them were:
Kotwal/Banarjee’s Biodiversity Conservation in managed and Forests and Protected Areas. (1998) In the recent years, the concern of the Government towards the conversation of biodiversity has grown considerably. In a bid to contributing towards to cause of biodiversity conservation, the Indian Institute of Forest Management organized a National Workshop titled “Biodiversity Conservation in managed and Forests and Protected Areas” from November 29 to December 01, 1995 in which a number of variant issues related to the subject. This book is an outcome of the selected papers contributed by many authors.

Justin Malbon and Charles Lawson’s Interpreting and Implementing the TRIPS Agreement, Is it fair. (2008)? This edited collection enjoins the global intellectual property debate by offering a range of perspective about how the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is and should be interpreted and implemented.

P.C. Trivedi’s Medicinal Plants: Traditional Knowledge. (2007) This book is a well documented and comprehensive review of significant investigation on traditional medicinal plants which covers holistic information on medicinal plants, their uses, ethno-botanical importance, commercial potential and standardization of herbal formulations etc, with special reference to India. An article on some sacred trees and their medicinal uses has added value to the book.

Elezabelth Verkey. The law of Plant Varieties Protection (2007). The author trace out the historical aspect of plant varieties protection. He has discussed the protection given to plant verities in Europe and the *sui generis* protection given in India the author also gone.

Dr. M.K Bhandari’s Law Relating to Intellectual Property Rights. (2006) The book is an outcome of intense study made by the author,
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long teaching and research experience of the subject and continuous participation and interaction of author with several legal scholars, lawyers, scientists, entrepreneur who are one way or other concerned with the intellectual property system. All possible efforts have been made to give comprehensive coverage to the various aspects of the intellectual property system and include all latest amendments and case law developed by High Courts, Supreme Court and even the newly established Intellectual Property Appellate Board (IPAB).

C.B. Raju, intellectual Property Rights (2007). This book is an assemblage of 20 research articles of eminent scholars in India having rich teaching experience. These articles focus on law relating to intellectual property rights such as copyright, patent, trademarks, industrial designs, geographical indications etc. some articles in this books have been discussed in the light of new economic policy and intellectual property regime. Some articles such as product patent Regime: Challenges and opportunities, protection of Traditional Knowledge a case for concern has been specifically gone through by the researcher.

Ramesh Chandra, Issues of intellectual Property Rights (2007). Protection of intellectual property has always been a different task as it is not a thing that can be kept in a close of protection the author of this book has examine the intellectual property rights and its use in the society. The author also covered the aspect of technology, information infrastructure and digital dilemma dimensions of intellectual property inventions, which has discussed in details.

Philippe Cullet’s Intellectual Property Protection and Sustainable Development (2005) This book analyses certain recent developments in the field of intellectual property protection. More specifically two main lines of enquiry are pursued. Firstly this book examines the rapidly evolving
international legal and institutional framework for intellectual property rights and for sustainable development. Secondly it examines some of the challenges that have surfaced in India as the country has grappled with the need to implement its international commitments through the adoption of new legislative instruments and major amendments to existing legislation, in particular of the Patents Act 1970.

W.R Cornish’s Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights; (2000). The look is valuable in understanding patent system. It highlights the characteristics of patent and holds it to be a system deep rooted in capitalist society.


Keith E Masker’s; The WTO Intellectual Property Rights and the Knowledge Economy (2004) is a collection of various articles helping in understanding social costs and benefits of introducing patent protection for pharmaceutical drugs in developing countries. In one of its articles “Do stronger patents induce more innovations? (By Mariko Sakakileara and Lee Bransteter) and by giving evidence from the 1988 Japanese patent law reform and concludes that no evidence of an increase in innovative effort or innovative output that could be plausibly attributed to patent reform.

Luis Mariano Genovesi’s Compulsory Licenses after Doha Declaration on the TRIPS Agreement and Public Health (2005). The article analyses the interpretation of TRIPS Agreement under the Doha Declaration and suggest caution measures to be adopted by the developing/least developed countries so as to make optimum advantages of the loopholes provided in TRIPS Agreement [Article 7, 8, 30, 31 etc.]
Biswa Dhar's Post 2005 TRIPS Scenario in patent protection in the pharmaceutical sector: The case of the generic pharmaceutical industry in India at http://www.iprpatents.html. The writer has thrown light on the development of Indian Pharmaceutical sector [in tabulation form] and critically analyzed the TRIPS Agreement compliant patent amendment Acts.

Ronald D. Kayanja's Anti Retroviral Drugs for All? Obstacles to Access to HIV/AIDS Treatment at http://www.panosaids.org. The article is study of 5 countries (Ethiopia, Haiti, India, Nepal, Zambia) And makes research of the experience and needs of people living with HIV/AIDS. It gives knowledge of broad challenges before the accessibility of HIV/AIDS drugs and possible cures.


Laura Bloodgood's Competitive conditions for Foreign Direct Investment in India July 2007 at http://www.google.com. This article is of great help when it comes to pharmaceutical FDI in India. It analyses the growth of patent law and its impact on the FDI in pharmaceutical sector. Through its many figures it argues that only post 1999 reforms by product patents there has been advent of pharmaceutical FDI in India.

(Pre 2005) and Pakistan, it brings out the differences in the prices of medicines in the process and product patent regime and thereby denial of accessibility to medicines.

**India is Considered to be a ‘Next Wave’ Country for HIV/AIDS” at** [http://www.expresspharmaonline.com](http://www.expresspharmaonline.com). It is conversation between Arsliya Khan (journalist) and T.Vijay Kumar (Senior Manager-Export Formulations, Aurobindo Pharma) regarding the ARV market in India. It helps in having a quick look of growth, characteristics, opportunities for ARV market and speculations rose by WHO on the quality of drugs in India and see the hand of powerful western drug manufacturers in the WHO speculation.

**K.P.S Mahalwar & Vishal Mahalwar’s Protection of Traditional Knowledge and Intellectual Property Rights: India & International Perspectives.** This article is of great help to understand the concept of protection of traditional knowledge need for the protection of TK the author trace out the areas of IPR where the TK has been protected. Along with this a study has been done on the efforts and initializes taken at national as well as international level for the protection of traditional knowledge.

**Saleem Akhtar’s, New Patent Regimes: Protection of Indian’s Heritage:** In this article author has pointed out the effect of new patent regime in the protection of Indian’s Traditional Heritage. Traditional Knowledge generally refers to the knowledge related to medicines. The author has made a competitive study of five countries and its cost structure of the drugs in patent protected regime and non patent protected regime. The author also analyzed the fundamental requirements of a patent grant. India is a big source of traditional knowledge neem, tulsi turmeric are in everyday use of an Indian theft of Indian’s traditional knowledge has been challenged and has always been won the author has also borough out the trends in patents for herbal products from
1990 to 1999. In last author has suggested planning a national strategy to counter biopiracy.

**Dr. Sreenivasulu N.S. and Subha Malhai’s, Sui Generis system for the Protection of Plant Varieties and Farmers’ Rights in India.** This article emphasizes on the IPR protection given to plant varieties and farmers’ rights. Author throws light on the provisions for the protection of plant varieties under Indian *sui generis* system for the protection of plant verities. Term of Protection, rights and privileges and compulsory licensing infringement of rights conferred and relief provided for that & infringement has also been discoursed the author also examine the administration in case of protection of plant varieties.

**R.M. Dungawat’s, Protection of Traditional Knowledge, National and International Perspectives.** Author focus on why traditional knowledge is needed to be protected. Protection of TK at International level and national level has been given a detailed study Asia Traditional Medicine Network at International at floor and at national floor it has been categorized as Governmental efforts and non-governmental efforts and legislative initiatives. Article is concluded with the proposed bill the Indian 2000 drafted by N.S. Gopala Krishnan.

**Mayank Kumar’s, Parallel Imports in the Pharmaceutical sector:** Benefits for Developing and least Developed the author has analyzed the legal statues of parallel imports in the pharmaceutical sector in developing and least developed countries in the light of TRIPS and Doha trade round the author deliberates its impact on price of pharmaceuticals and benefits/drawbacks associated with it. In addition to this the article also highlights potential policy considerations on the same issue.

**Shashi Sharma,s, New Patent Regime in India Challenges and Future of the Pharmaceutical Industry.** This article reflect the intense views
of the author regarding the challenges going to be face by the Indian pharmaceutical industry and future of Indian pharmaceutical industry in new patent regime. Author has divided the article in four parts. First, dealing with an overview of Indian pharmaceutical industry and its progress by moving towards adopting to emerging new business models such as contract research contract manufacturing and to marketing alliances second part deals with new patent regime in Indian mentioning the background of patent Regime in India to the newly amended patent law considered as TRIPS Compliant further the author discuss the challenges for Indian pharmaceutical industry mentioning the Novartis case Yoga, generic pharmaceutical manufacturing prices of drugs and access to medicines for the poor. Because of cheap manufacturing capabilities in China, Indian pharmaceutical industry is expected to face challenge from china pharmaceutical industry. Discussing the business avenues the author also draws attention to traditional knowledge aspect and measures to protect it.

N. Lalitha’s, Doha Declaration and Public Health issues this article brings out the flexibilities given by the Doha Declaration which are directly related to the public health issues. Author pinpointed the option of compulsory licensing clause which eases the access of necessary medicines. The Doha Declaration provides for access to medicines particularly by simplifying the compulsory licensing clause. The amendments carried out by the Indian government also facilitate production of generic versions of patented drugs that would facilitate exports under the CL option as well. The author says that however in order to facilitate the options available in the Doha Declaration, countries will have to incorporate the necessary changes in their national laws.

Varressa Brad ford Kerry and Kelley lee’s, TRIPS, the Doha Declaration and Paragraph 6 Decision, What are the Remaining Steps for Providing Access to Medicines? The author begins this article by briefly,
reviewing progress to date on the public health protections available under the TRIPS agreement. It describes how, despite these important clarification, there remain concerns about the capacity of LMICS to implement specific measures. The article consider the further threat posed by TRIPS plus measures and calls for their critical assessment. Central to debate about implementation and TRIPS plus is an understanding of fundamental unbalances in power and influence, both within and across countries, defining what interest can influence trade policy decisions. The author concludes by reviewing potential ways forward to ensure that access to medicines by the poor is secured within all trade agreements.

Gopakuman G Nair, Impact of TRIPS on Indian Pharmaceutical Industry. In this article author has discussed the significance of the new IP regime on pharmaceutical industry in India, the amendment to the patents Act, 1970 making it TRIPS compliant. Along with this related developments in other fields of IP as well as enforcement of new patent regime on pharmaceutical industry are compressively discussed. The author also gives a brief description of regulatory interfaces of patents in the Indian and international context. The key elements of the TIPRS agreement which led to the three consecutive amendments to the patents Act 1970 has been highlighted. The author examines the significance of the patent amendments in 1999, 2002, 2005 and as well as need for such amendments in fulfillment of TRIPS obligations. The author finally study the impact of post TRIPS scenario in Indian pharmaceutical industry with special reference to the international operations and the regulatory interfaces, the related fields like biodiversity and plant varieties has also been touched by the author.

N.S. Gopala Krishnan’s, TIPRS Agreement and Public Health An Overview of International Issues. The author in this article deals with brief
overview of the developments of international provisions on IPR related to public health. Here he also discusses the flexibilities before and after TRIPS agreement and difficulties faced by developing countries in implementing TRIPS obligations and protecting public health. The author also examine the reasons for the Doha Declaration and issues relating to implementation of para 6 of the Declaration. He also discusses the inadequacy in the compulsory licence based approach to solve public health arises and argues for a more comprehensive approach to find a long term solution to the public health issues.

Elezabelth Verkey's, The law of Plant Varieties Protection (2007). The author trace out the historical aspect of plant varieties protection. He has discussed the protection given to plant verities in Europe and the sui generis protection given in India. The author also gone analyzed the Plant Variety Act and its procedural aspect along with farmers’ rights, breeder’s rights and researcher’s rights. International initiatives taken for the protection of plant varieties has also been discussed.

Sajeev Chandran, Archanan Roy, Lokesh Jain, Implications of New Patent Regime on Indian Pharmaceutical Industry Challenges and Opportunities. This paper gives an overview of pharmaceutical industry in India and the likely impact of product patent regime on it. It also review the existing patent and drug control laws in Indian and how they affected the growth and structure of pharmaceutical industry in the country. Author also discussed the strategies to meet the new challenges and opportunities that TRIPS agreement present to pharmaceutical industry in India.

C.B. Raju, Intellectual Property Rights (2007). This book is an assemblage of 20 research articles of eminent scholars in India having rich teaching experience. These articles focus on law relating to intellectual property rights such as copyright, patent, trademarks, industrial designs,
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geographical indications etc. some articles in this books have been discussed in the light of new economic policy and intellectual property regime. Some articles such as product patent Regime: Challenges and opportunities, protection of Traditional Knowledge a case for concern has been specifically gone through by the researcher.

Ramesh Chandra, Issues of intellectual Property Rights (2007). Protection of intellectual property has always been a different task; as it is not a thing that can be kept in a closet of protection the author of this book has examine the intellectual property rights and its use in the society. The author also covered the aspect of technology, information infrastructure and digital dilemma dimensions of intellectual property inventions, which has discussed in details

Objective of the study

1. To find out the historical aspect of patent law in India.
2. To identify the changes occurred by the three amendments in the patent law.
3. To analyze the position of Indian herbal medicine industry and factors affecting the growth of Indian pharmaceutical industry in new patent regime.
4. To study the national and international efforts taken for the protection of traditional knowledge.
5. To know the status of protection given to the Indian traditional knowledge.
6. To assess the role of CBD in protecting the biodiversity and traditional knowledge.
7. To examine the role of Plant Varieties Protection and Farmers’ Rights Act, 2001 for the protection of traditional knowledge.
8. To assess and evaluate the role of judiciary in case of biopiracy.
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Research Methodology

Present study is based on the doctrinal and non-doctrinal method of research. The research has drawn help from various books, articles, newspapers, journals, gazettes, reports of commission and committees and judicial decisions. The researcher has used both primary and secondary sources of data.

Hypothesis

There is no law for the protection of traditional knowledge but traditional knowledge is protected under other IPR legislation such as Patent, Copyrights, Trademarks, Geographical Indication, Biodiversity and Plant varieties and India also amended its municipal laws in consonance of TRIPS agreement and different international conventions, treaties and protocols. Now the pertinent question is that whether our traditional knowledge and indigenous knowledge ought to be protected under any else legislation or not?

1. It is hypothesized that thought he TRIPS agreement under Article 27 talks about a *sui-generis* legislation and also for the protection of traditional knowledge but this does not specifically give any guidelines to protect the T.K.

2. It is hypothesized that most of our traditional knowledge is patented by developed countries. On large scale our traditional knowledge has been patented by US, Germany and other developed countries, should we opt for such a strong legislation which can prevent our traditional knowledge from being patented by these western countries?

3. Though India has already placed a legislation for the protection of farmers’ as well as breeder’s rights. Even than question arises what are the farmers’ rights to be enunciated in any sui-generis legislation for the protection of traditional knowledge, whether this legislation would be complementary to the protection of traditional knowledge?
4. It is hypothesized that India is among one of the twelve richest mega-biodiversity rich countries. Biopiracy is directly related to biodiversity and, a separate legislation has been framed to protect biodiversity of the country but the enactment and implementation of this law has no effective purview to prevent biopiracy.

5. It is hypothesized that along with biodiversity legislation to protect the traditional rights of the farmers and to protect the plant varieties, protection varieties Act is a significant form of *sui-generis* legislation.

6. It is hypothesized that India is the richest source of traditional knowledge not only in medicinal area but it has a rich heritage of folklore, Art, Music, Dance Handicrafts, and Skills etc. which needs protection through separate *sui-generis* legislation.

7. It is hypothesized that whether proposed *sui-generis* legislation would be recognized internationally in absence of international rules and guidelines for such a law?

The study is organized into five chapters.

**Chapter-I History of Patent System in India**

This chapter portraits the historical aspect of patent law in India and meaning, object, subject matter procedure for obtaining patent administration infringement of patent remedies, silent features of the three Patents Act as well as the role played by the patent law in the protection of traditional knowledge has been pointed out.

**Chapter-II Traditional Knowledge under IPR Regime**

This chapter deals with the concept of traditional knowledge, subject matter of TK, rationale behind the protection of TK. Current international development for the protection of TK, regional efforts, governmental and non governmental initiatives protection of TK and types of protection given under
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IPR regime has been discussed. An analysis of Indian efforts towards traditional knowledge protection and existing legal framework for the protection are also dealt here. An action plan has also been discussed for the protection of traditional knowledge.

Chapter –III Traditional Knowledge under WTO, TRIPS And Pharmaceutical Industry

This chapter has been divided into two parts, one part is confined to traditional system of medicine and traditional herbal drugs, second part give the overall performance of Indian pharmaceutical industry in the product patent regime. Chapter deals with the concept of traditional medicinal knowledge present in Ayurvedic, Unani, Siddha and homeopathic system, its contribution in Indian pharmaceutical industry. The other half covers the impact of TRIPS on pharmaceutical industry, and challenges faced by the Indian pharmaceutical industry in the new product patent regime. Impact of the product patent on prices of drugs and their accessibility has been discussed. Impact on the FDI in pharmaceutical industry has been analyzed.

Chapter –IV Traditional Knowledge under Protection of Plant Varieties And Farmers’ Rights Act

This chapter has been framed under two parts, one covers the protection given to plant varieties at international level specifically US and European countries, second part covers the national perspective. Chapter explore the rationale behind the protection of plant varieties, international developments through UPOV, CBD, Agenda 21, CGIAR, FAO, Sui-generis system and Plant Variety Protection, African model legislation as an example of sui-generis system. This chapter also deals with the Protection of Plant Varieties Act which discusses the object of the Act, varieties covered under the Act and Farmer’s rights and breeder’s right, rights of researchers’, protection of public interest
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and compulsory licencing, New Seeds Bill of 2004. Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006 are discussed keeping in view the initiatives taken for the protection of farmers’ traditional rights.

Chapter –V Traditional Knowledge under CBD and Biopiracy

This chapter has been devoted to biopiracy and role of CBD to counter biopiracy. This chapter is divided into two parts. First deals with traditional knowledge under CBD and the biodiversity and second with biopiracy. Biodiversity deals with meaning and significance of bio-diversity, role of CBD and protecting biodiversity and along with this Indian government has passed the Biodiversity Act, 2002 for the protection of biodiversity and prevention of bio-piracy at some extent.

The second part deals with biopiracy, difference between biopiracy and bio-prospecting, biopiracy of traditional medicinal knowledge, concept of access and benefit sharing and prior informed consent are the areas discussed under this part. The relevant case study of India and International cases has also been included.

Conclusion and Suggestion

This has been devoted to summary of findings. The work ends with conclusion and has been concluded with some suggestions.