

CHAPTER IV

AN ANALYTICAL STUDY OF THE IPR LAW REGIME IN U.S.A., U.K., GERMANY, AUSTRALIA, JAPAN, INDIA AND SOME OTHER COUNTRIES FOR PROTECTION OF TRADITIONAL KNOWLEDGE OF MEDICINAL PLANTS

INTRODUCTION

In the backdrop of all bio-piracy incidents and movement against it all over the world, where patents were granted in foreign countries on the medicinal properties of the huge number of plants of India, to the multinational corporations and who have been manufacturing medicines by using those active bio-chemical ingredients of those plants, earning huge profit and restricting others to do the same and not paying substantial amount of money for commercialising using the properties which is not their invention, has raised hue and cry in India and other traditional knowledge rich countries. These incidents also have raised serious doubt about the effectiveness and appropriateness of the legal frameworks of these countries and concern about the effective protection of the traditional knowledge of medicinal properties of the plants and biological resources in the foreign countries. When the traditional knowledge enriched countries and their people suddenly discovered in that their knowledge of the medicinal values of plants, which they have been applying in their daily lives, was not theirs anymore, they were shocked. It was in fact their own invention after decade long research and study spending exceptionally huge amount of money. Their own intellectual property to which they have every right to commercialise it throughout the world, did not belong to them anymore. These countries were not even aware that they had an intellectual property relating to traditional knowledge of medicinal plants and that they were being stolen and robbed of it. This clearly shows that the traditional knowledge in the source countries was unprotected and the government did not take any step to give full protection. In India, the centuries old traditional knowledge of the society was not safe in the hands of all the previous indifferent governments who were supposedly the trustee to preserve and protect the society's knowledge which had immense commercial value. That is why, there is a need to understand the patent laws of some of the countries-who are the victims of bio-piracy and also those who are the causes of it. Hence, patent laws of some of countries have to be explained and analysed only to show that how bio-piracy is happening and where it is happening. This analysis can suggest where the correctional measures need to be taken and what would be those corrective measures. This can lead

towards better patent laws regime which will not allow any kind of bio-piracy anywhere in the world and would do justice to the holders of the knowledge. Here in this Chapter, patent law of India is explained and analysed because many traditional herbal medicines were patented in so many developed countries. The patent laws of some developed countries also i.e. USA and UK, Germany, Australia and Japan have been explained and analysed because by these countries the incidents of bio-piracy occurred.

DEFINING PATENT AS INTELLECTUAL PROPERTY

Intellectual property originates from the creations of human ingenuity and innovativeness. There are various types of temporal and eternal creations of human intelligence. These creations i.e. inventions, designs, trademarks or artistic works etc. are considered property and are protected from unauthorised commercialisation for certain period of time. Basically, property is of two kinds-tangible property and intangible property. Intellectual property is one of the intangible types. It is the result of intellectual exercise along with innovative mind with a quest for creation. This world progressed immensely in different dimensions due to this continuous creation of the objects and processes by human mind's endless cognitive exercise over the centuries in different ways. There are various intellectual property rights in the national and international legal frameworks. Patent is a right to protect intellectual property from unauthorised commercial uses of the invention. "Patent indicates a statutory grant of the exclusive right to a person for a limited period in consideration of the disclosure of the invention."¹ It is a right granted to an invention for commercial use or protection from unauthorised commercial use, to the exclusion of all others. This can be either a new product or a process which provides, in general, a new way of doing something, or offers a new technical solution to a problem, for example, making, using, offering for sale, selling, importing of a particular product in case of a product patent. In case of process patent, from the act of using, offering for sale, selling and importing for those purposes the product according to that process. Through a patent, the patentee can monopolize commercialization and exclude others from using a protected innovation and is assured of returns for the investments in research and product development.

An invention must, in general, fulfil the following conditions to get protection of patent.

*It must have industrial application which means that invention is capable of being

¹ K.S.BHATI, "The Intellectual Property Rights Law-Evolution and Development" SHIB SAHAI SINGH, "THE LAW OF INTELLECTUAL PROPERTY RIGHTS," P s15, Deep & Deep, Delhi, 2004.

made or used in an industry. *It must show the elements of novelty, that is, some new characteristics or characteristic which is not known from the body of existing knowledge in that field or does not form part of it. *It should not be some semblance of newness but must add some value to the present level of knowledge. Novelty is quantitative in nature. The body of existing knowledge is called 'prior art'. The invention must show an inventive step or non-obviousness which could not be deduced by a person with a general knowledge of that field. This criterion is definitely qualitative in nature. *It is not obvious and expected from a person having ordinary skill in that matter to invent the same thing either making the product or following the process. Further steps were possible due to the reason of hard work, serious study, research, experiment and observation by a person who acquires special skill and knowledge in that particular subject which cannot be done or anticipated by ordinary skilled persons.

It prevents an applicant from obtaining a patent if the claimed invention is 'anticipated' by the prior art, that is, if the invention is not 'new' or novel. If these requirements are not met, then a claimed invention is not 'new' because it is fully disclosed in a reference that is accessible to the interested public. Additionally, the reference must enable a person of ordinary skill in the field of the invention to make and use the invention. In terms of non-obviousness requirement, references that qualify as prior art, but do not by themselves anticipate the claimed invention, can be combined to show that the invention is obvious. In other words, the combination of references shows that all of the claimed elements are present in the prior art and that a patent should not issue (or if issued should be revoked) for the claimed invention.

This is where the difficulty lies regarding the potentiality of a product or process belonging to traditional knowledge especially in medicinal plants. Prior art already exists in medicinal plants. Most of the commercially used products, their sources, method of preparation and purpose for which they are used, were already in existence and yet individual could obtain patent on them without attributing anything new.

**TRADITIONAL KNOWLEDGE IS NOT PATENTABLE: AN THEORETICAL
ANALYSIS BY PROF.N.S.GOPALAKRISHNAN:² A VERBATIM
TRANSCRIPTION FROM HIS ARTICLE**

(a).Concept of Novelty and Traditional Knowledge: The most important element of the concept of novelty is the non disclosure of the invention to the public. This presupposes that there should not be any prior knowledge of the invention by the public. The information must have been kept secret for the purpose of claiming novelty. The two requirements to find out whether an invention is disclosed or not are (a) prior publication and (b) prior use. The prior publication include (1) the publication of the information through the patent claims already filed before the authorities anywhere in the world or (2) the existence of the information in any publication or document available for public examination irrespective of whether any member of the public including the person claiming the invention has read it or not. The prior use is the use of the information in the course of the trade by a person or is within the common knowledge of the public or those involved in the trade. That is to say that the product based on the invention is already in the market or in case of process, it is in use for the manufacture of a product. Thus it is only that information in the form of a product or process not already in the public domain that is qualified for patent protection.

On an examination of the classification of the traditional knowledge, it is clear that in all most all cases the information is in the public domain. It is also not necessary that all these information are concerning a product or process. In the first case the novelty is lost in as much as the common public is aware of the invention and it is in use i.e., there is prior knowledge and prior use of the invention. In the second case the novelty is lost by prior publication since the invention is already documented and available to the public for examination irrespective of whether it is read by the public or not. In the third and fourth cases it may be possible to argue that there is no prior publication to the larger public and novelty is not lost by reason of long secret use. It appears that keeping these information as trade secrets seems more profitable than taking patents. But in the context of technological developments it may be difficult in many cases to keep it in secret. In this context one can categorically argue that majority of the existing products

²Prof. N.S.Gopalakrishnan, IMPACT OF PATENT SYSTEM ON TRADITIONAL KNOWLEDGE, Cochin University Law Review, 1998 p.219.

and processes based on traditional knowledge will not satisfy the test of novelty. The lack of novelty will disqualify the products based on the knowledge to be treated as invention for the purpose of patent protection.

(b).Concept of Inventive step and Traditional Knowledge: One of the objectives of granting patent is to reward the person who has contributed to the progress and development of knowledge that is useful to the society. The requirement of inventive step is to demonstrate that the invention is the creation of the individual or individuals claiming monopoly. This is to ensure that substantial intellectual labor of the inventor is involved in the creation of the new invention. So the test applied by the courts is to examine whether there is any application inventive faculty of the inventor. The quantum of application of independent thought, ingenuity and skill of the inventor is the matter of inquiry in this regard. This is achieved by asking whether the invention is obvious to a person skilled in the same field. The standard applied is that of a normally skilled but unimaginative person in the art at the relevant time. This presupposes the demonstration of the individual contribution of the inventor for claiming patent for the new invention. It is possible to have more than one individual as inventor in case of joint inventions. Thus it is not the availability of novelty but the existence of individual contribution that holds the key factor for claiming patent protection. This requirement thus distinguishes the prior art from the new art and also recognizes the intellectual labor of the individual.

One of the significant features of the traditional knowledge is the fact of it being passed on to the present generation by the previous one. This gives a prima facie impression that the present custodians of this knowledge are not the creators but only the successors in interest of the earlier creators. It is thus obvious that the present claimants have not contributed any independent thought, ingenuity or skill to establish a valid patent claim. Thus it is clear that unless we demonstrate the individual fresh contribution of the present claimant of the traditional knowledge, it is not possible for getting patent protection for any of the above classifications of the traditional knowledge. Even the products and processes kept in secret use will not satisfy this requirement. In this context the existing traditional knowledge will remain as a prior art rather than a new art for patent protection. This also negatives the second condition for claiming patent, i.e., stating the name or names of inventor in the patent application, in majority of the cases.

INDIAN LAW ON PATENT-SOME RELEVANT PROVISIONS

(A).PATENTABLE INVENTION

'Invention' means a new product or process involving an inventive step and capable of industrial application.³ The definition clearly shows the requirement of three important elements of invention. Firstly, it must be new; secondly it is inventive step and the third is industrial application.

(B).INVENTIONS WHICH ARE NOT PATENTABLE

An invention which is frivolous or which claims anything obviously contrary to well established natural laws.⁴ An invention the primary or intended use or commercial exploitation of which could be contrary to public order, morality or which causes serious prejudice to human, animal or plant life or health or to the environment.⁵ The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances, occurring in nature.⁶The mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.⁷A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance.⁸ Mere arrangement or re-arrangement or duplication of known devices, each functioning independently of one another in a known way.⁹ A method of agriculture or horticulture.¹⁰ Any process for the medicinal, surgical, curative, prophylactic(diagnostic therapeutic) or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.¹¹ Plants or animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species

³ Section 2(j), Patent Act 1970.

⁴ Section 3(a), Patent Act 1970.

⁵ Section 3(b), Patent Act 1970.

⁶ Section 3(c), Patent Act 1970.

⁷ Section 3(d), Patent Act 1970.

⁸ Section 3(e), Patent Act 1970.

⁹ Section 3(f), Patent Act 1970.

¹⁰ Section 3(h), Patent Act 1970.

¹¹ Section 3(i), Patent Act 1970.

and essentially biological processes for production or propagation of plants and animals.¹² A mathematical or business method or a computer program *per se* or algorithms.¹³ A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions.¹⁴ A mere scheme or rule or method of performing mental act or method of playing game.¹⁵ A presentation of information.¹⁶ Topography of integrated circuits.¹⁷ An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.¹⁸

(C).GRANTING OF PATENTS

When the invention, either process or product, fulfils all the three criteria of novelty, non-obviousness and industrial application and the invention itself does not fall under any of the categories of non-patentability, after following some procedures, patent is granted to the inventor with some special and exclusive rights.

(D).REVOCAION OF PATENTS

A patent can also be revoked, on a petition of any interested person or of the Central Government or on a counter-claim in a suit for infringement of the patent, by the High Court on any of the following grounds¹⁹-(a) that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of either priority date contained in the complete specification of another patent granted in India; (b) that the patent was granted on the application of a person not entitled under the provisions of this Act to apply there for; (c) that the patent was obtained wrongfully in contravention of the rights of the petitioner or any person under or through whom he claims; (d) that the subject of any claim of the complete specification is not an invention within the meaning of this Act; (e) that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or

Section 3(j), Patent Act 1970.

Section 3(k), Patent Act 1970.

Section 3(l), Patent Act 1970.

Section 3(m), Patent Act 1970.

Section 3(n), Patent Act 1970.

Section 3(o), Patent Act 1970.

Section 3(p), Patent Act 1970.

Section 64(1), Patent Act 1970.

publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in section 13; (f) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used or what was published in India or elsewhere before the priority date of the claim; (g) that the invention, so far as claimed in any claim of the complete specification, is not useful; (h) that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection; (j) that the patent was obtained on a false suggestion or representation; (k) that the subject of any claim of the complete specification is not patentable under this Act; (l) that the invention so far as claimed in any claim of the complete specification was secretly used in India, otherwise than as mentioned in subsection (3), before the priority date of the claim; (m) that the applicant for the patent has failed to disclose to the controller the information required by section 8 or has furnished information which in any material particular was false to his knowledge; (n) that the applicant contravened any direction for secrecy passed under section 35 or made or caused to be made an application for the grant of patent outside India in contravention of section 39; (o) that leave to amend the complete specification under section 57 or section 58 was obtained by fraud; (p) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention; (q) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.

(E).APPLICABILITY OF LAW OF PATENT IN INDIA FOR PROTECTION OF TRADITIONAL KNOWLEDGE OF MEDICINAL PLANTS: AN ANALYSIS

Patent law of India deals the granting of patent only to patentable inventions. It takes into account the exceptions, non-patentable inventions, necessary documents, procedure for examining the patent application and opposition to grant of patent etc. By following this process, it grants patent and confers rights to the patentee. Even after the patent is granted, there is also a mechanism in the law itself for its revocation for reasons that either the documents were manipulated or it was not decided accurately so on and so

forth. However, as to whether it protects a society or a community's traditional knowledge of herbal medicine of India? The answer lies with the following analysis of its patent law.

When Indian law gives patent protection only to an invention, it is quite expected that there has to be a clear and unambiguous definition. This itself becomes problematic because definitions tend to be rigid and restrictive. It is rather advantageous not to have a proper definition with the object of giving it a flexible and dynamic content. It is desirable that the term must include some objective examples or criterion within its scope. Indian law on patent is clearly lacking here. This is one of the shortcomings of Indian legal framework for patent. Moreover, the term 'invention' is defined but it is not sufficient for various reasons. The definition says that 'invention' means a new product or process involving an inventive step and capable of industrial application. Though, the definition lays down three essential requirements i.e. (1). new or novel, (2). inventive step or non-obviousness and (3). industrial application, at the second stage, there is lack of clarity and unambiguousness. This is due to the reason that the term 'new or novelty' is not defined and there are no objective examples or illustrations of criterion of newness or novelty. 'Inventive step or non-obviousness' is defined as a feature that makes the invention not obvious to a person skilled in that art, but no criteria is suggested what determines the obviousness and non-obviousness or level of skill of the person in that art.

Indian patent law protects traditional knowledge of medicinal properties of plants as a society oriented intellectual property right which is unique in itself. It recognises the contribution of the indigenous community or the society as a whole for the invention and preservation of the knowledge. It prevents any individuals either Indians or foreigners, whether foreign or Indian multinational or national companies, to obtain Indian patent on medicinal plants irrespective of whether traditional knowledge is informal or formal, codified or un-codified. Even if patent is granted on medicinal plant, where knowledge of medicinal value of a plant for a particular ailment originated from traditional knowledge, it can be revoked as well, for not fulfilling the criteria of novelty, non-obviousness or industrial application or for falling under the exceptions clause where traditional knowledge has been accepted as a ground for rejecting a claim of patent. To achieve this, a new provision is added to the grounds of opposition and revocation process regarding the prior art of traditional knowledge. The oral or documented knowledge available with general society or indigenous community in India or elsewhere are treated as prior art. It is significant to see that oral knowledge of communities is recognized as valid for the purpose of considering prior art. This bold

step is required to ensure that the vast undocumented (according western methodology) knowledge of India is kept out of patent system. This is also significant because this has established a good example in the world of traditional knowledge protection. Through this, India achieves moral authority to persuade and pressurize other unwilling countries to incorporate this provision in their legal frameworks. Moreover, this step is also helpful to constitute a strong block of all the bio-rich countries that have similar TK protection to enter into a hard bargain and negotiate with the developed countries. Additionally, the applicant must also disclose the source and geographical origin of the biological material in the specification column. The obligation is to provide not only the details of the source from where the material is obtained but also of its geographical origin. It is implied that this information would check bio-piracy since one of the purposes of disclosure in the specification is to enable the patent office to find out the prior art and inventive step. Patent on wound healing property in turmeric would not have been possible under Indian law. Hence, Indian law has some elements of a model type of patent protection for the traditional knowledge about the medicinal property of a plant.

Even with this merit of Indian patent law, there are two inherent drawbacks which did not attract any notice so far. Due to these drawbacks, patent protection is not up to the mark with in India. It also cannot be said that it is complete in nature. It is a major concern that in India medicine companies have been commercially exploiting traditional knowledge of various types of medicinal properties of different plants and earning huge profits, by producing and selling ayurvedic medicines in national and international market. Apart from giving licence fees to start and carry on manufacturing activities or income tax returns for the income from business and profession of medicine manufacturing, they are not sharing their benefits with the state or the community or giving royalties, for commercially exploiting traditional knowledge of medicinal properties of plants which are the intellectual properties of the society or the indigenous community? There are umpteen numbers of examples of this kind of activities in India in the medicinal worlds-either in ayurvedic medicine or aopathic medicine where there are active ingredients of medicinal plants. Obviously, the companies have picked them up from the written documents or age old traditional practice of the society. Ordinarily they would be required to pay for the commercial use of the property which is not their own novel and non-obvious invention and also pay for the commercialisation of intellectual property of another i.e. indigenous community or the society. But there is flagrant violation and traditional knowledge regarding medicinal plants are being used without IPR authorisation for commercial purposes. This type of marketing rights is absolute negation of a viable and complete intellectual property right protection regime

for the traditional knowledge of medicinal plants and biological resources. It means that the existing traditional knowledge is not protected so far.

In spite of strong legal prohibition that 'an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components' cannot be patented, patents have been granted to the so-called non-original inventors of the medicinal properties of plants in India. In this flagrant violation and abuse of traditional knowledge, there is no novelty, no innovation and no invention. Yet in many cases patents have been granted.

First incident is non-recognition and the second incident is blatant violation. Moreover, another very serious shortcoming of the Indian patent law is that there is no such provision for suitable punishment for violation and appropriate compensation or refund of money for earning illegal profit. This directly encourages the violation. It means that for a wrong and illegal patent, the patent holder can earn huge profit from the business as long as the patent continues but after the revocation also can be the legitimate owners of the profit money. The patent holders also are not supposed to give compensation for the loss of business of the original holders of the knowledge. Until and unless, there is proper punishment and penalty and fair compensation and refund of money, it cannot be said that there is sufficient safeguards for traditional knowledge of medicinal plants and biological resources in the Indian patent law.

Another shortcoming is that the law is silent on non-original invention, an invention originated and developed from the existing public domain knowledge. Prof. N.S.Gopalakrishnan in one of his articles has shown his reservation about this accepted norm in the jurisprudential approach of all intellectual property laws worldwide: "The legal norms relating to the formal intellectual property rights based on copyright, patent, design etc., were developed to tackle the social problems that emerged due to the scientific developments during industrial revolution in the West. The legal norms crystallized to protect the new knowledge have a significant bearing on the manner in which the western system looked at science and scientific developments. Thus the concept of 'originality', 'novelty', 'utility', 'non-obvious or inventive step' etc., used to find out the items that are to be protected through the formal intellectual property system addressed only the scientific developments based on the western understanding of science. Similarly the insistence of the identity of the creator of the new knowledge - author or inventor as the case may be - for the purpose of affording protection also reflects the individual private property jurisprudence underlying the protection of intellectual property. These concepts kept the traditional knowledge and the products

based on it outside the scope of formal intellectual property system and treated it as knowledge in the public domain without owners for exploitation without authorization. Thus the knowledge base of the community remain without any legal protection where as the creators of new knowledge based on it using modern science were afforded protection by the formal system. The provisions in the TRIPs Agreement are a clear indication in this direction. This calls for a different jurisprudential approach for the protection of traditional knowledge.”²⁰

Moreover, the type of protection whatever is found in Patent Act is mostly negative in nature. If some positive power is visible in Biodiversity Act, it is very limited and negligible. In pursuance of ‘knowledge economy’ to make India as one of the most economically powerful country, exploration of traditional knowledge associated with medicinal plants is one of the strategies. For that reason, there has to be positive protection of this TK is very crucial. First of all, at present there is no law especially in India for TK protection on genetic resources of medicinal plants. Whatever is there in Biodiversity Act is insufficient. ‘positive protection’ is manifold. To make the law positive, the concept of ‘positive protection’ has to be wider enough to include preservation, conservation, sustainable use, augmentation, to protect from extinction etc. The ‘concept of positive protection’ includes within its ambit to do further research on the genetic resources of the medicinal plants on modern lines either to add value to the existing lines inventing making non-original innovations or inventions to thwart or preempt any of the attempts of others to claim their invention as the subject matters of standard patents or petty patents. It also takes account proper documentation and publication according to internationally accepted method. And finally, a pro-active power and authority must be given to the authority or trust to commercializing the knowledge in collaboration with others as joint owners of the intellectual property or by giving license to the others to commercialize the knowledge in return of royalties or most important positive protection is by establishing manufacturing unit on its own to produce ayurvedic medicines and other products and selling them in the market. All these are lacking in India’s legal framework either due to lack of legal framework or insufficiency in the law itself. Non-granting of patents or enough scope to revoke bio-pirated patents in different forms obviously has importance but there are other important avenues to have a full and holistic protection.

²⁰ Prof.N.S.Gopalakrishnan, PROTECTION OF TRADITIONAL KNOWLEDGE - THE CHALLENGES, This paper was presented in the WIPO Symposium on Teaching Intellectual Property held at Peking University, Beijing, June 1999.

USA LAW ON PATENT-SOME KEY AREAS²¹

(A).INVENTIONS PATENTABLE²²

The patent is for invention only; invention of product or process. 'Patentability of inventions' states that whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

(B).CONDITIONS FOR PATENTABILITY; NOVELTY AND LOSS OF RIGHT TO PATENT²³

A person shall be entitled to a patent unless-(a)the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b)the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or (c)he has abandoned the invention, or (d)the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or (e)the invention was described in- (1) an application for patent, published under section 122(b), by another, filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or (f)he did not himself invent the subject matter sought to be patented, or (g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved

²¹ Part II-Patentability of Inventions and grant of Patents-Chapter 10-Patentability of Inventions, 35 U.S.Code.

²² Section 101, 35 U.S.Code.

²³ Section 102, 35 U.S.Code.

therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

(C).CONDITIONS FOR PATENTABILITY; NON-OBVIOUSNESS SUBJECT MATTER²⁴

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(b)(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and non-obvious under subsection (a) of this section shall be considered non-obvious if- (A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and (B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person. (2) A patent issued on a process under paragraph (1)-(A) shall also contain the claims to the composition of matter used in or made by that process, or (B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

(3) For purposes of paragraph (1), the term "biotechnological process" means-(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to-(i) express an exogenous nucleotide sequence, (ii) inhibit, eliminate, augment, or alter

²⁴ Section 103, 35 U.S.Code.

expression of an endogenous nucleotide sequence, (iii) express a specific physiological characteristic not naturally associated with said organism; (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and (C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

(c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. (2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if—(A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made; (B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and (C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement. (3) For purposes of paragraph (2), the term “joint research agreement” means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

(D).RE-EXAMINATION AND REVOCATION OF PATENTS-AN EX PARTE REEXAMINATION OF PATENTS PRIOR ART CITATIONS TO OFFICE

CITATION OF PRIOR ART²⁵

Any person at any time may cite to the Office in writing prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent. If the person explains in writing the pertinence and manner of applying such prior art to at least one claim of the patent, the citation of such prior art and the explanation thereof will become a part of the official file of the patent.

²⁵ Section 301, Chapter 10, 35 U.S.Code.

REQUEST FOR RE-EXAMINATION²⁶

Any person at any time may file a request for re-examination by the Office of any claim of a patent on the basis of any prior art cited under the provisions of section 301, which must be in writing. The request must set forth the pertinence and manner of applying cited prior art to every claim for which re-examination is requested.

DETERMINATION OF ISSUE BY DIRECTOR²⁷

(a) Within three months following the filing of a request for re-examination under section 302, the Director will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. On his own initiative, and any time, the Director may determine whether a substantial new question of patentability is raised by patents and publications discovered by him or cited under the provisions of section 301 of this title. The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.

(b) A record of the Director's determination under subsection (a) of this section will be placed in the official file of the patent, and a copy promptly will be given or mailed to the owner of record of the patent and to the person requesting re-examination, if any.

(c) A determination by the Director pursuant to subsection (a) of this section that no substantial new question of patentability has been raised will be final and non-appealable.

RE-EXAMINATION BY DIRECTOR²⁸

If, in a determination made under subsection 303(a), the Director finds that a substantial new question of patentability affecting any claim of a patent is raised, the determination will include an order for re-examination of the patent for resolution of the question. The patent owner will be given a reasonable period, not less than two months from the date a copy of the determination is given or mailed to him, within which he may file a statement on such question, including any amendment to his patent and new claim or

²⁶ Section 302, Chapter 10, 35 U.S.Code.

²⁷ Section 303, Chapter 10, 35 U.S.Code.

²⁸ Section 304, Chapter 10, 35 U.S.Code.

claims he may wish to propose, for consideration in the re-examination. If the patent owner files such a statement, he promptly will serve a copy of it on the person who has requested re-examination under the provisions of section 302 of this title. Within a period of two months from the date of service, that person may file for the re-examination, a reply to any statement filed by the patent owner. That person promptly will serve on the patent owner a copy of any reply filed.

CONDUCT OF RE-EXAMINATION PROCEEDINGS²⁹

After the times for filing the statement and reply provided for by section 304, have expired, re-examination will be conducted according to the procedures established for initial examination under the provisions of sections 132 and 133. In any re-examination proceeding, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301, or in response to a decision adverse to the patentability of a claim of a patent. No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a re-examination proceeding.

APPEAL³⁰

The patent owner involved in a re-examination proceeding, may appeal under section 134, and may seek court review under sections 141 to 145, with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent.

CERTIFICATE OF PATENTABILITY, UNPATENTABILITY AND CLAIM CANCELLATION³¹

In a re-examination proceeding, when the time for appeal has expired or any appeal proceeding has terminated, the Director will issue and publish a certificate cancelling any claim of the patent finally determined to be un-patentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent any proposed amended or new claim determined to be patentable.

²⁹ Section 305, Chapter 10, 35 U.S.Code.

³⁰ Section 306, Chapter 10, 35 U.S.Code.

³¹ Section 307, Chapter 10, 35 U.S.Code.

Any proposed amended or new claim determined to be patentable and incorporated into a patent following a re-examination proceeding will have the same effect as that specified in section 252 of this title for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation for the same, prior to issuance of a certificate under the provisions of subsection (a) of this section.

(E).LAW OF PATENT OF U.S.A. VIS-A-VIS TRADITIONAL KNOWLEDGE OF MEDICINAL PLANTS: AN ANALYSIS

In U S Code, apart from laying down the conditions for patentability of inventions with the accepted exceptions, there are processes of examination of the patent application, processes of review of patent decisions to ascertain that the patent request is genuine and according to law and finally the processes of issuance of patent, dealt with elaborately. Even after the issuance of patents, there is a process of re-examination and revocation. The patent grant might be a wrong decision for various reasons; so there is a way to correct the mistakes or illegality.

By analysing the law, keeping in mind the main objective i.e. protection of centuries old Indian traditional knowledge of herbal medicine, it can be said in no uncertain terms that U.S.A patent law does not give enough protection of society or community oriented traditional knowledge. This is due to the reason that TRIPS through its silence and non-recognition of some of the basic rights i.e. traditional knowledge, gives enough space and flexibility, to the US and other developed countries in their IPR law, to protect their own interest, disregarding the legitimate expectation and right of the societies of the developing countries and indigenous communities in different parts of the world. As a result in USA itself there are thousands of biopiracy incidences of Indian traditional knowledge.

In the knowledge hub of the world, invention is of two types- original invention and non-original invention. There are patents based on modern research which may have invented (actually discovery)³² a new medicinal property in a plant and as such has novelty and non-obviousness. But the real concern is about the patents for non-original inventions in the traditional knowledge systems of the developing world, where so

³² In the arena of patent law a new discovery is also termed an 'invention'. The word 'invention' is not used in its strictest sense and includes 'discovery'.

called inventors get all the leads from the documents and oral description. There are two systems of processes of innovation. One is formal system of innovation and the other is informal system of innovation. Though as a usual practice, formal system of innovation is documented and gets legal recognition just to ensure clarity and specificity, but it cannot undermine the significance and contributions of informal systems of innovation which are mostly undocumented, passed on from generation to generation. Such innovations have already taken place, are taking place and will take place in future. There are more instances of traditional knowledge residing in oral traditions than documented texts. Many societies in the third world have nurtured and refined systems of knowledge of their own, relating to as diverse domains of fields as geology, ecology, botany, agriculture, physiology and medicine etc. These informal innovators have, therefore, generated a rich store of traditional knowledge in those countries. As in US, prior existing knowledge is recognized, if it is published in a journal or is available on a database. It is not accepted if it has been passed down through generations of oral and folk traditions. There is also no such specific exclusion clause of traditional knowledge of the society about the herbal medicine from patentable inventions. This raises an important question about the vulnerability of traditional knowledge to patenting in non-source countries like India. For example, in cases relating to Neem and Turmeric, the main reason that resulted in the revocation of patents was the presence of printed materials which was presented as proof of prior art. The problem of challenging patents would have reached a frustrating end, had there been no printed materials which document the presence of the traditional knowledge of the medicinal values of turmeric and neem in the public domain of India since centuries.

This informal system of innovation has some similarity with common law system. According to common law practice, law is either developed through interpretation of the present principle in a different situation or a new principle is added to the existing legal framework to meet the new situations most of the time, without a formal process of legislation. It is a system where customary practices are valued and have the force of law. In this way common law is developed-either by judiciary, or by the society or by the executives. Traditional knowledge of medicinal plants and biological resources is also customary in nature. That is why, it is quite surprising that U.S.A, also a common law country refuses to recognize the informal system of innovation in different areas including traditional knowledge of medicinal plants, by not taking into account their existence as part of prior art. Non-recognition of informal 'prior art' of traditional knowledge in U.S.A legal framework, even being common law country, where the legal system is substantially informal and based on custom, goes against the basic tenets of

common law principle. Moreover, it is absolutely irrational if prior art does include only formal system of documented knowledge and exclude informal knowledge.

The criticisms thrown at the US patent law are of two types. It violates true spirit of international law and it violates the national patent laws of bio-rich TK holding countries. But little attention was drawn on the fact that it violates US Constitution-Intellectual Property Clause. This is a new dimension of the criticism. The statutory provision of US Patent Code on requires classification of information as relevant or non-relevant based on its territorial origin and form a conflict with the very source of its power, the US Constitution. Article 1, section 8, clause 8 of the U.S. Constitution i.e. Intellectual Property Clause, authorizes Congress to grant exclusive rights for limited times to actual and true inventors for the purpose of promoting the progress of the useful arts. As the Constitution requires that any patent system created by Congress must promote the progress of useful arts, the Supreme Court of USA ³³ has interpreted this phrase as providing a clear limitation on Congressional power in this area: Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of useful Arts.' This is the standard expressed in the Constitution and it may not be ignored. As described above, foreign public knowledge or use, as a class of information, is now as 'publicly accessible' as foreign patents and printed publications were in 1836. By explicitly allowing the patenting of such publicly accessible information, the S 102(b) geographical limitation does not promote the progress of the useful arts and thus violates the 'standard criterion expressed in the Constitution.' Consequently, it violates the Constitutional provisions.

Margo A. Bagley observes that "it is possible that in 1836, the geographical limitation was not unconstitutional because difficulties associated with obtaining and verifying evidence of foreign public knowledge or use caused the bulk of such knowledge to be effectively inaccessible to the interested public and thus outside the public domain. Due to advances in technology and changed world conditions, such reasoning is no longer tenable because evidence of foreign public knowledge or use is arguably as accessible in

³³ Graham vs. John Deere, 365 U.S.1 (1966).

the twenty-first century as foreign patents and printed publications were in 1836.”³⁴ At the inception it was a set of reasonable classification, but at present there is no intelligible differentia and no reasonable nexus between the object sought to be achieved and the basis of classification.

Hence section 102's territorial limitation excludes evidence of foreign public knowledge or use of an invention from consideration in both novelty and non-obviousness if the evidence is not contained in a patent or printed publication. As foreign public use is irrelevant, the present geographical limitation according section 102 on prior art allows the patenting of inventions which are already in the public domain. Its effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available and particularly problematic with respect to public knowledge or use of inventions in traditional knowledge enriched bio-diversity countries. This geographical limitation facilitates and legalises bio-piracy of by preventing evidence of foreign traditional knowledge of the genetic resources of the Indian plants or its use from being considered in patentability and patent validity proceedings.

PRIOR ART AND THE INTELLECTUAL PROPERTY CLAUSE

How is the Section 102(b) of US Code repugnant to US Constitution? “Section 102(b)'s geographical limitation on foreign public knowledge or use currently conflicts with the constitutional objective of providing time-limited exclusive rights to inventors in order to promote the progress of the useful arts. The nature of this conflict can be gleaned from an analysis of the purposes underlying the constraints of the Intellectual Property Clause and changes in the public accessibility of foreign public knowledge or use. The Intellectual Property Clause is unique among constitutional provisions in being the only grant of authority to Congress expressing the precise way in which Congress was to exercise that authority. This unique aspect of the Clause is important because it establishes that the Intellectual Property Clause is not just an express grant of power, it also contains limitations on that power. Congress may grant exclusive rights, but the grants must be for limited times, they must be to inventors, they must be for discoveries, and they must tend to promote the progress of useful arts. These are constitutional constraints, and at least one of them, the requirement that the patent system promote the

³⁴ Margo A Bagley, *Patently Un-Constitutional: The Geographical Limitation on Prior Art in a Small World*, MINNESOTA LAW REVIEW [Vol 87:679] Page 687.

progress of useful arts, is violated by the S102(b) limitation on foreign public knowledge or use.”³⁵

What was the thinking of the US constitution framers? “Accordingly, the Framers created within the Clause a balance between two competing needs: the need to encourage innovation and the need to avoid monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’ To comply with this intent, Congress required the applicant is the first and true inventor of the claimed invention, and required that an invention be novel (not before known or used) and useful. Congress later made express the implied requirement that a patentable invention be more than the mere work of a skilled mechanic, i.e., that it be non-obvious to a person of ordinary skill in the art. Requiring novelty and non-obviousness in patentable inventions was a way of ensuring that ‘old’ technologies and industries could not be removed from the public domain by a patent grant.”³⁶

Intellectual Property clause does prohibit the grant of patents on inventions in the public domain, i.e., inventions that are not novel and non-obvious as they are open to the people of this country, as well as of others, upon reasonable inquiry. But actually by going just the opposite direction the current geographical limitation on prior art allows the patenting of inventions in the public domain, it is unconstitutional and must be eliminated. It is not novelty, there is no-nonobviousnes, only has industrial application. The inventors are not the true inventors and not causing the progress of useful arts in the true sense of the term. Thus, section 102 is more like a long-lived aberration, inconsistent with the intent of the Framers and the strictures inherent in the Constitutional text and allows bio-piracy-one of the most un-ethical things in IPR world.

(F).MARGO A BAGLEY: A CRITIQUE

“It is past time for the United States, through Congress or the Supreme Court, to comply with the Constitution and acknowledge that the world is too small for the continued exclusion of evidence of foreign public knowledge or use from patentability analyses. Public knowledge or use of an invention anywhere in the world is something that we all share as part of the global public domain.

³⁵ Margo A Bagley, *Patently Un-Constitutional: The Geographical Limitation on Prior Art in a Small World*, MINNESOTA LAW REVIEW (Vol 87:679) Page 704-705.

³⁶ *Ibid*, Pages 706-708.

Over the past twenty years we have witnessed the ever expanding scope of subject matter deemed eligible for utility patent protection under 35 U.S.C 101. As the Supreme Court and Congress have made clear, 'anything under the sun that is made by man' is patent-eligible, regardless of geographic origin. If that is indeed the case, then certainly the prior art against which the patentability of that subject matter will be measured must be equally as inclusive without regard to the geographical origin of the information. The Intellectual Property Clause of the Constitution only authorizes Congress to secure exclusive rights to inventors for the purpose of advancing the progress of the useful arts. "The clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.' To the extent Section 102's geographical limitation allows for the reward of patent rights without the requisite concomitant advance in the useful arts, it is unconstitutional. Elimination of the hypocritical and imperialistic practice of denying the value and legitimacy of foreign knowledge or use simply because it did not occur within U.S. borders is also long overdue. Changing the definition of prior art is not a complete solution to the problems engendered by patents covering foreign knowledge or use; however, it is a necessary action for the United States to take in this small, small world."³⁷

Importantly, elimination of Section 102(b)'s geographical limitation will prevent foreign public knowledge or use from being used in the invention process. This section has another threat to society's traditional knowledge protection as it says that a person shall be entitled to a patent unless the invention was patented. As the traditional knowledge of the society over the medicinal values of plants are not patented in India or cannot be patented in India, so there is no impediment in its getting patented in USA. There might be a sui-generis system of intellectual property protection for traditional knowledge of the society but it is not a patent as such and only as patented invention gets protection in USA, USA law of patent simply cannot deny patent to it.

Another unfairness of U.S patent law is that it does not appreciate and recognize the elements of the collective knowledge of society and the right of the community over the knowledge. In India and some of the developing countries, community ownership of property or ownership of the society is prevalent which is unique in itself. It recognizes intellectual property rights only as private rights and private ownership of the property.

³⁷ Margo A Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, MINNESOTA LAW REVIEW (Vol 87:679) Pp 741-742.

There is a reflection of one of the basic principles of western culture and civilization in that country's national laws. Basically western civilization is based on individualism. Accordingly, present patent system is centred around the concept of individual rights. USA does not appreciate the importance of community and society oriented concepts; community ownership of knowledge and property is alien to the American philosophy.

(G).DR. VANDANA SHIBA: A CRITIQUE

“When applied to knowledge related to biodiversity, reductionism isolates chemicals and genes and treats this act of separation as an act of creation, both intellectually and materially. The leads for useful traits in biological organisms are obtained from indigenous knowledge. Nine-four per cent of the top-selling plant-derived drugs contain at least one compound that has a demonstrated use in traditional medicine related to primary therapeutic use. The appropriation of indigenous knowledge and of the uses of biodiversity is not a creative act at either the intellectual or at the material level. Intellectually, the innovation has already been done as part of indigenous knowledge systems. Materially, the traits and properties for which the patent has been claimed already exist in nature. Their isolation and separation cannot be claimed as creation. Treating translation and transfer of existing indigenous knowledge and isolation of useful traits of life forms as acts of ‘creation’ and ‘invention’ is rooted in the philosophical assumptions of the industrial society which defines non-western cultures as inferior to the industrial west and perceives nature as inert, dead matter. The creativity of both nature and other cultures is negated and appropriation of that creativity is then interpreted as an act of creation.

With knowledge plurality mutating into knowledge hierarchy, a horizontal ordering of diverse but equally valid and diverse systems is converted into a vertical ordering of unequal systems, with the epistemological foundations of the system being imposed on others to invalidate them. This translation of knowledge diversities into knowledge hierarchies is then used to claim acts of translation as acts of invention. Translation is misconstrued as the ‘creation’ of knowledge. A sociological shift is thus fallaciously treated as an epistemological shift. This fallacy of sociological and cultural displacement as an epistemological shift generating new knowledge is made possible as a result of colonial biases which have treated western knowledge as exclusively scientific and non-western knowledge systems as unscientific.³⁸

³⁸ Vandana Shiva, *Patents: Myths & Realities*, Penguin Books, New Delhi, 2001, P 50.

In the same book, the noted author has highlighted various categories of bio-piracy. U.S and U.S alike countries' IPR regimes have become the instruments of bio-piracy at three levels: 1.Resource Piracy in which the biological and natural resources of communities and the country are freely taken, without recognition or permission and are used to build up global economy; 2.Intellectual and cultural piracy in which the cultural and intellectual heritage of communities and the country is freely taken without recognition or permission and is used for claiming IPRs even though the primary innovation and creativity, has not taken place through corporate investment; 3.Economic piracy in which the domestic and international markets are usurped through the use of trade names and IPRs, thereby destroying local economies where the original innovation took place and hence wiping out the livelihoods and economic survival of millions.³⁹

In her famous book-*The Plunder of Nature and Knowledge*, she criticizes the attitude of Western corporations supported by their respective national laws in line with TRIPs likely to USA. She is of the view that for western corporations, indigenous systems of knowledge and indigenous rights do not exist. Thus, a publication of the pharmaceutical industry, which depends heavily on indigenous knowledge for many of its plant-based drugs, speaks of Third World bio-diversity rights not as intellectual rights of the people or as customary rights evolved over centuries, but as a newly asserted property right derived from a geographical accident.⁴⁰ Moreover, taking the basic information from the knowledge from indigenous communities through bio-prospecting is to develop an IPR-protected industrial system which market its commodities but are not based on the ethical, epistemological or ecological organization of that knowledge system. Producers of such commodities use bio-diversity fragments as raw material to produce biological products protected by patents that displace bio-diversity and indigenous knowledge, both of which they have exploited. Thus, as was discussed earlier that this exclusivity of legal framework which disregard other's knowledge is a hindrance towards the path of actual globalization of IPRs. In her famous book-*The Plunder of Nature and Knowledge*, while discussing about IPR and the Destruction of Intellectual Diversity, she says: Special Clause 301 of U. S. Trade Act and IPRs are the prescriptions for a monoculture of knowledge. These instruments are being used to universalize The U.S patent regime worldwide, which would inevitably lead to an intellectual and cultural

³⁹ Ibid, Page 62.

⁴⁰ Vandana Shiva, "Biopiracy: The Plunder of Nature and Knowledge", in "Biodiversity and People's Knowledge, RFSTE, New Delhi, 1997, Page 75.

impoverishment by displacing other ways of knowing, other objectives for knowledge creation and other modes of knowledge sharing.⁴¹

U K PATENT LAW-SOME RELEVANT AREAS

(A).PATENTABLE INVENTIONS

A patent may be granted only for an invention in respect of which the following conditions are satisfied: (a) the invention is new; (b) it involves an inventive step; (c) it is capable of industrial application; (d) the grant of a patent for it is not excluded by subsections (2) and (3) or section 4A below; and references in this Act to a patentable invention shall be construed accordingly.⁴² It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of - (a) a discovery, scientific theory or mathematical method; (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever; (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer; (d) the presentation of information; but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such.⁴³ A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.⁴⁴ For the purposes of subsection (3) above exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it.⁴⁵ The Secretary of State may by order vary the provisions of subsection (2) above for the purpose of maintaining them in conformity with developments in science and technology; and no such order shall be made unless a draft of the order has been laid before, and approved by resolution of, each House of Parliament.⁴⁶

⁴¹ Ibid, Page 10.

⁴² The Patents Act, 1977, Patentability, Section 1 (1).

⁴³ Ibid, section 1 (2).

⁴⁴ Ibid, Section 1 (3).

⁴⁵ Ibid, Section 1 (4)

⁴⁶ Ibid, Section 1 (5).

(B).NOVELTY

An invention shall be taken to be new if it does not form part of the state of the art.⁴⁷ The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.⁴⁸ The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied, that is to say (a) that matter was contained in the application for that other patent both as filed and as published; and (b) the priority date of that matter is earlier than that of the invention.⁴⁹

(4) For the purposes of this section the disclosure of matter constituting an invention shall be disregarded in the case of a patent or an application for a patent if occurring later than the beginning of the period of six months immediately preceding the date of filing the application for the patent and either - (a) the disclosure was due to, or made in consequence of, the matter having been obtained unlawfully or in breach of confidence by any person - (i) from the inventor or from any other person to whom the matter was made available in confidence by the inventor or who obtained it from the inventor because he or the inventor believed that he was entitled to obtain it; or (ii) from any other person to whom the matter was made available in confidence by any person mentioned in sub-paragraph (i) above or in this sub-paragraph or who obtained it from any person so mentioned because he or the person from whom he obtained it believed that he was entitled to obtain it; (b) the disclosure was made in breach of confidence by any person who obtained the matter in confidence from the inventor or from any other person to whom it was made available, or who obtained it, from the inventor; or (c) the disclosure was due to, or made in consequence of the inventor displaying the invention at an international exhibition and the applicant states, on filing the application, that the invention has been so displayed and also, within the prescribed period, files written evidence in support of the statement complying with any prescribed conditions.⁵⁰ In this

⁴⁷ Ibid, Section 2 (1),

⁴⁸ Ibid, Section 2 (2).

⁴⁹ Ibid, Section 2 (3).

⁵⁰ Ibid, Section 2 (4).

section references to the inventor include references to any proprietor of the invention for the time being.⁵¹

(D).INVENTIVE STEP

An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above).⁵²

(E).INDUSTRIAL APPLICATION

An invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.⁵³

(F).INVENTIONS NOT PATENTABLE-METHODS OF TREATMENT OR DIAGNOSIS

A patent shall not be granted for the invention of- (a) a method of treatment of the human or animal body by surgery or therapy, or (b) a method of diagnosis practiced on the human or animal body. (2) Subsection (1) above does not apply to an invention consisting of a substance or composition for use in any such method. (3) In the case of an invention consisting of a substance or composition for use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art. (4) In the case of an invention consisting of a substance or composition for a specific use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if that specific use does not form part of the state of the art.⁵⁴

⁵¹ Ibid, Section 2 (5).

⁵² Ibid, Section 3.

⁵³ Ibid, Section 4 (1).

⁵⁴ Ibid, Section 4A (1).

(G).REVOCAION OF PATENTS

POWER TO REVOKE PATENTS ON APPLICATION

The court or the comptroller may by order revoke a patent for an invention on the application of any person including the proprietor of the patent on any of the following grounds, that is to say -(a) the invention is not a patentable invention; (b) that the patent was granted to a person who was not entitled to be granted that patent; (c) the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art; (d) the matter disclosed in the specification of the patent extends beyond that disclosed in the application for the patent, as filed, or, if the patent was granted on a new application filed under section 8(3), 12 or 37(4) above or as mentioned in section 15(9) above, in the earlier application, as filed; (e) the protection conferred by the patent has been extended by an amendment which should not have been allowed.⁵⁵

(2) An application for the revocation of a patent on the ground mentioned in subsection (1) (b) above-(a) may only be made by a person found by the court in an action for a declaration or declarator, or found by the court or the comptroller on a reference under section 37 above, to be entitled to be granted that patent or to be granted a patent for part of the matter comprised in the specification of the patent sought to be revoked; and (b) may not be made if that action was commenced or that reference was made after the end of the period of two years beginning with the date of the grant of the patent sought to be revoked, unless it is shown that any person registered as a proprietor of the patent knew at the time of the grant or of the transfer of the patent to him that he was not entitled to the patent.⁵⁶

COMPTROLLER'S POWER TO REVOKE ON HIS OWN INITIATIVE

If it appears to the comptroller that an invention for which a patent has been granted formed part of the state of the art by virtue only of section 2(3) above, he may on his own initiative by order revoke the patent, but shall not do so without giving the proprietor of the patent an opportunity of making any observations and of amending the

⁵⁵ The Patents Act 1977, Section 72 (1).

⁵⁶ Ibid, Section 72 (2).

specification of the patent so as to exclude any matter which formed part of the state of the art as aforesaid without contravening section 76 below.⁵⁷

(H).LAW OF PATENT OF U.K. VIS-A-VIS TRADITIONAL KNOWLEDGE OF MEDICINAL PLANTS: AN ANALYSIS

Like the legal frameworks of India and USA, UK's patent law has all those systems including revocation part of it. However, this analysis aims to find out whether the U.K. law has a mechanism for protecting the documented and non-documented traditional knowledge of a country.

The present UK patent law is pretty good and therefore appreciable. This is due to the reason that in this legislation, the term 'invention' is quite clear. It says that an invention is new or novel if it does not form part of the state of the art. Though, like the Indian system, an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components, is not excluded from the term 'invention' and from patentability itself, though it has been done in another way. According to the law in U.K., an invention is not within the state of the art when it, has at any time before the priority date of that invention, been made available to the public, whether in the United Kingdom or elsewhere, by written or oral description, by use or in any other way. This is really a very important aspect of UK law which proscribes the formal or informal, documented or non-documented traditional knowledge of medicinal plants of any country including India being patented in UK. Hence, it has some safeguards for traditional knowledge. This explanation of prior art and its scope is wide enough and has the potentiality for including prior individual as well as collective knowledge about the invention within the ambit of prior art. Theoretically also, the legal recognition of formal or informal, documented or non-documented, individual as well as collective traditional knowledge of medicinal plants, in UK legal regime, is at par with the traditional and old common law system in UK. While common law gives importance and recognizes unwritten non-statutory evolution of tradition and customary practices being developed either by judiciary or by people and accepts them as law with effectiveness, this also finds its recognition with legal sanction in its patent law as well, whether it is from UK or elsewhere from any country in the world. So, there is no danger of any sort of biopiracy from UK. This significant aspect of UK patent law is lacking in US, though US is also a

⁵⁷ Ibid, Section 73 (1).

common law country. Being a common law country, India also recognizes this common law principle in its legal framework. In UK common law is the protector of the traditional knowledge of the medicinal values of the genetic resources derived from the Indian plants and shrubs. USA just should take notice of it and give up stubborn attitude.

In UK there are provisions for patent revocations on some specific grounds. But the problem lies in the fact that if a patent is granted to anyone who has not disclosed that there was prior art, where though the invention was known to the public because the prior art was of traditional knowledge of medicinal plants and genetic resources, there is no such mechanism which prescribes that the huge profits from the proceeds of royalty is to be given back to the original holders of the traditional knowledge or the country of origin. After the grant of patent and before its revocation by the patent office, during that time, the patentee can commercialize the patent and can earn huge profit, which the patentee is not required refund as per law. There is also no such mechanism which directs the authority to impose huge fine on the patentee for the illegal and wrongful patent and earning money out of it. Mere revocation of patent or its cancellation is quite inappropriate and denial of justice to the community or society that holds traditional knowledge. Appropriate punishment including refund of profit to the community or the society is required. It is also a denial of 'pleasure and pain doctrine' of J.Bentham in his own country though English jurisprudence originates from J. Bentham.⁵⁸ Under legal framework for patent, pleasure is more and pain is less for the wrongful conduct of intellectual dishonesty. There is no balance between the two-wrongful conducts and punishments. Same thing is true in USA law and Indian law of patents. Lack of punishment or stringent measures for obtaining wrongful patent and biopiracy of traditional knowledge of medicinal plants have made the law toothless and less effective. As a result, it can be said that it is encouraging biopiracy of medicinal plants and biological resources. There is no such punishment on the patent office also whose duty is to check whether there was any prior art in it or not and there was negligence or not performing of duties for various reasons either in UK, or India or USA. Had there been any such accountability and duty to be ensured and punishment to be imposed on the patent office itself, for non-performance of duties, there would not have been biopiracy cases of medicinal plants and related traditional knowledge.

⁵⁸ J.Bentham, "The Theory of Legislation", N.M.Tripathi Pvt. Ltd. Bombay, 1979, Page 16.

PATENT LAW OF GERMANY⁵⁹-SOME KEY AREAS

(A).CRITERIA OF PATENTABILITY AND NO-PATENTABILITY

Patents shall be granted for inventions which are new, involve an inventive step and are susceptible of industrial application.⁶⁰

Patents shall also be granted for inventions within the meaning of subsection (1) whose subject matter is a product that consists of or contains biological material or whose subject matter is a process by means of which biological material is produced or processed or which makes use of it. Biological material which is isolated from its natural environment or produced by means of a technical process can also constitute the invention's subject matter if it naturally existed beforehand.⁶¹

The following in particular shall not be regarded as inventions within the meaning of subsection (1): 1.discoveries, scientific theories and mathematical methods; 2.aesthetic creations; 3.schemes, rules and methods for mental acts, games or business activities and programs for computers; 4. presentations of information.⁶²

The human body in its individual stages of origin and development, including the gamete, as well as the mere discovery of one of its components including the sequence or partial sequence of a gene cannot constitute a patentable invention.⁶³

An isolated component of the human body or a component that was produced in another way by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if this component's structure is identical to the structure of a natural component.⁶⁴

⁵⁹ German Patent Law (as of 01.10.2009), Available at http://www.aspenlawschool.com/books/kieff_nack/custom1materials/490GermanPatentLaw.htm. Visited on 18th March, 2011 at 12.34.PM.

⁶⁰ Part 1, Section 1 (1).

⁶¹ Ibid, Section 1 (2).

⁶² Ibid, Section 1 (3).

⁶³ Part 1, Section 1a (1).

⁶⁴ ibid, Section 1a (2).

In the application, the industrial applicability of a sequence or partial sequence of a gene is to be described precisely by stating the sequence's or partial sequence's function.⁶⁵

If the subject matter of an invention is a sequence or partial sequence of a gene whose structure is identical to the structure of a natural sequence or partial sequence of a human gene, its use, whose industrial applicability according to subsection 3 is described precisely, is to be included in the patent claim.⁶⁶

No patents are granted for inventions whose industrial application would be contrary to public policy or contra bonos mores; such infringement cannot be derived simply from the fact that the utilization is prohibited by law or an administrative provision.⁶⁷

Patents are especially not granted for 1. processes for cloning human beings; 2. processes for modifying the genetic identity of the human being's germ line; 3. the use of human embryos for industrial or commercial purposes; 4. processes for modifying the genetic identity of animals which might cause these animals to suffer without essential medical benefit for the human being or the animal, as well as animals created by means of such processes. When applying numbers 1 to 3, the respective provisions of the Law for Embryo Protection shall prevail.⁶⁸

Patents are not granted for 1. plant varieties or animal breeds as well as essentially biological processes for the growing of plants and breeding of animals. 2. methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply for products, in particular substances or compositions, for use in any of these methods.⁶⁹

Patents can be granted for inventions 1. whose subject matters are plants or animals if the invention's description is not limited to a specific plant variety or animal breed; 2. whose subject matter is a microbiological or other technical process or a product obtained by means of such process, as far as this is not a plant variety or animal breed.⁷⁰

⁶⁵ Ibid, Section 1a (3).

⁶⁶ Part 1, Section 1a (4).

⁶⁷ Part 1, Section 2 (1).

⁶⁸ Part 1, Section 2 (2).

⁶⁹ Part 1, Section 2a (1).

⁷⁰ Part 1, Section 2a (2).

(B).STATE OF THE ART

An invention shall be considered to be new if it does not form part of the state of the art. The state of the art comprises all knowledge made available to the public by means of a written or oral description, by use or in any other way, before the date relevant to the priority of the application.⁷¹

(C).INVENTIVE STEP

An invention shall be considered to involve an inventive step if it is not obvious to the person skilled in the art from the state of the art. If the state of the art also includes documents within the meaning of Section 3 (2), these documents shall not be considered for the decision as to whether or not an inventive step is involved.⁷²

(D).INDUSTRIAL APPLICATION

An invention shall be considered susceptible of industrial application if its subject matter can be produced or used in any kind of industry, including agriculture.⁷³

(E).REVOCATION OF PATENTS

The patent shall be revoked (Section 61) if it becomes obvious that 1. the subject matter of the patent is not patentable according to sections 1 through 5; 2. the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art; 3. the essential elements of the patent were taken from the descriptions, drawings, models, appliances or equipment of another person, or from a process used by another person, without his consent (usurpation); 4. the subject matter of the patent extends beyond the content of the application as originally filed with the competent authorities; the same shall apply if the patent was granted on a divisional application or on a new application filed in accordance with Section 7 (2) and the subject matter of the patent extends beyond the content of the earlier application as originally filed with the competent authorities.⁷⁴

⁷¹ Part 1, Section 3 (1).

⁷² Part 1, Section 4.

⁷³ Part 1, Section 5.

⁷⁴ Part 1, Section 21 (1).

if the grounds for revocation affect the patent in part only, the patent shall be maintained in the form of a corresponding limitation. The limitation may be affected in the form of an amendment to the patent claims, the descriptions or the drawings.⁷⁵

In the event of revocation, the effects of the patent and of the application shall be deemed not to have existed ab initio. In case of restricted maintenance, this provision shall apply mutatis mutandis.⁷⁶

(F).LAW OF PATENT OF GERMANY VIS-À-VIS TRADITIONAL KNOWLEDGE OF MEDICINAL PLANTS: AN ANALYSIS

It is quite surprising to see that in spite of expressed legal protection of traditional knowledge in Germany that prior art includes written document or oral description, biopiracy incidences have happened in umpteen numbers of cases in Germany. On analysis, it can be inferred that when the law is very clear and easy to understand that the criteria of 'newness' or 'novelty' i.e. an invention shall be considered to be new if it does not form part of the state of the art. The state of the art comprises of all knowledge made available to the public by means of a written or oral description, by use or in any other way, before the date relevant to the priority of the application; there is no reason at all not to follow it by refusing the grant of patents. This criteria clearly says that any knowledge-individual or collective, traditional or not, which is available and known to the public, is not 'state of the art. So, when the GPO granted patents on the medicinal value or property of the extracted bio-chemical components of the plants grown, cultivated and found in India, it is a clear case of violation of law. This violation might be intentional only to favour the companies or persons for the benefit of the country itself. There is no sufficient mechanism to search and find the existence of 'prior art' or 'state of the art' in the public domain in that particular subject or there is no mandatory disclosure requirement about the source of the knowledge by the claimant or no such 'statement of truth' on behalf of the claimant that this is bona-fide invention or it is not biopiracy or there is no traditional knowledge on this invention. It is also ample clear that the law does not make it obligatory for the GPO to search the 'state of the art' before considering the patent application or they do not search the 'prior art' properly. This is a major weakness of this law of patent. Like to the laws of patent of Brazil, United Kingdom, German patent law also does not ask the wrong patentees to refund the

⁷⁵ Ibid, Section 21 (2).

⁷⁶ Ibid, Section 21 (3).

profit to the wronged persons or countries nor does it ensure that reasonable compensation money is to be given to the sufferers nor it guarantees different types of appropriate punishment to the wrong and illegal patent holders for this violation. The law of patent of Germany is not complete and due to these weaknesses in the law itself intentional violation, biopiracy is getting encouragement and India is becoming the victim of biopiracy.

AUSTRALIA'S LAW OF PATENT-SOME RELEVANT PROVISIONS

A).PATENTABLE INVENTIONS

Patentable inventions for the purposes of a standard patent

Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim: (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and (b) when compared with the prior art base as it existed before the priority date of that claim: (i) is novel; and (ii) involves an inventive step; and (c) is useful; and (d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.⁷⁷

Patentable inventions for the purposes of an innovation patent

Subject to subsections (2) and (3), an invention is a patentable invention for the purposes of an innovation patent if the invention, so far as claimed in any claim: (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and (b) when compared with the prior art base as it existed before the priority date of that claim: (i) is novel; and (ii) involves an innovative step; and (c) is useful; and (d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.⁷⁸ Human beings, and

⁷⁷ Section 18 (1), Patent Act (compiled on 1 January 2011 as amended by Act No. 1 of 2010). Available at http://www.jpo.go.jp/shiryou_e/s_sonata_e/fips_e/pdf/australia_e/e_tokkyo.pdf. Viewed on 28.05.11 at 10.25 AM.

⁷⁸ Ibid, Section 18 (1A).

biological processes for their generation, are not patentable inventions.⁷⁹ Certain inventions not patentable inventions for the purposes of an innovation patent (3) for the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions. It does not apply if the invention is a microbiological process or a product of such a process.

(B).NOVELTY OF THE INVENTION

For the purposes of this Act, an invention is to be taken to be novel when compared with the *prior art base* unless it is not novel in the light of any one of the following kinds of information, each of which must be considered separately: (a) prior art information (other than that mentioned in paragraph (c)) made publicly available in a single document or through doing a single act; (b) prior art information (other than that mentioned in paragraph (c)) made publicly available in 2 or more related documents, or through doing 2 or more related acts, if the relationship between the documents or acts is such that a person skilled in the relevant art would treat them as a single source of that information; (c) prior art information contained in a single specification of the kind mentioned in subparagraph (b)(ii) of the definition of prior art base in Schedule 1.⁸⁰

(C).INVENTIVE STEP OF THE INVENTION

For the purposes of this Act, an invention is to be taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed in the patent area before the priority date of the relevant claim, whether that knowledge is considered separately or together with the information mentioned in subsection (3).⁸¹ The information for the purposes of subsection (2) is: (a) any single piece of prior art information; or (b) a combination of any 2 or more pieces of prior art information; being information that the skilled person mentioned in subsection (2) could, before the priority date of the relevant claim, be reasonably expected to have ascertained, understood, regarded as relevant and, in the case of information mentioned in paragraph (b), combined as mentioned in that paragraph.⁸²

⁷⁹ Ibid, Section 18(2).

⁸⁰ Ibid, Section 7(1).

⁸¹ Ibid, Section 7(2).

⁸² Ibid, Section 7(3).

(D).INNOVATIVE STEP

For the purposes of this Act, an invention is to be taken to involve an innovative step when compared with the prior art base unless the invention would, to a person skilled in the relevant art, in the light of the common general knowledge as it existed in the patent area before the priority date of the relevant claim, only vary from the kinds of information set out in subsection (5) in ways that make no substantial contribution to the working of the invention.⁸³ For the purposes of subsection (4), the information is of the following kinds: (a) prior art information made publicly available in a single document or through doing a single act; (b) prior art information made publicly available in 2 or more related documents, or through doing 2 or more related acts, if the relationship between the documents or acts is such that a person skilled in the relevant art would treat them as a single source of that information.⁸⁴ For the above mentioned purposes of subsection (4), each kind of information set out in subsection (5) must be considered separately.

(E).RE-EXAMINATION OF STANDARD PATENTS

Re-examination of complete specifications

Subject to this section and the regulations, if: (a) a request and complete specification relating to an application for a patent has been accepted; and (b) the patent has not been granted; the Commissioner may re-examine the complete specification. Subject to this section and the regulations, where a patent has been granted, the Commissioner may and must, if asked to do so by the patentee or any other person, re-examine the complete specification. Where the validity of a patent is disputed in any proceedings before a prescribed court under this Act, the court may direct the Commissioner to re-examine the complete specification and the Commissioner must re-examine the specification accordingly. Where relevant proceedings in relation to a patent are pending, the Commissioner must not re-examine the complete specification relating to the patent under subsection (2). Where (a) the Commissioner has started to re-examine a complete specification relating to a patent under subsection (2) and (b) relevant proceedings in

⁸³ Ibid, Section 7(4).

⁸⁴ Ibid, Section 7(5).

relation to the patent are started; the Commissioner must not continue the re-examination.⁸⁵

Report on re-examination-On re-examining a complete specification, the Commissioner must ascertain and report whether, to the best of his or her knowledge, the invention, so far as claimed in any claim and when compared with the prior art base as it existed before the priority date of that claim: (a) is not novel; and (b) does not involve an inventive step. For the purposes of subsection (1), the prior art base is to be taken not to include information made publicly available only through the doing of an act, whether in or out of the patent area.⁸⁶

(F).REVOATION OF STANDARD PATENT-RE-EXAMINATION AFTER GRANT

Where the Commissioner makes an adverse report on a re-examination under subsection 97(2), the Commissioner may, by notice in writing, revoke the patent, either wholly or so far as it relates to a particular claim, as the case requires. The Commissioner must not revoke a patent under this section unless the Commissioner: (a) has given the patentee a reasonable opportunity to be heard; and (b) has, where appropriate, given the patentee a reasonable opportunity to amend the relevant specification for the purpose of removing any lawful ground of objection and the patentee has failed to do so. The Commissioner must not revoke a patent under this section while relevant proceedings in relation to that patent are pending. The patentee may appeal to the Federal Court against a decision of the Commissioner under this section.⁸⁷

EXAMINATION OF INNOVATION PATENTS

Examination may be requested or Commissioner may decide to examine

After the grant of an innovation patent, the Commissioner: (a) may, if the Commissioner decides to do so; and (b) must, if asked to do so, in writing, by the patentee or any other person; examine the complete specification relating to an innovation patent.⁸⁸

⁸⁵ Ibid, Section 97(1)-(5).

⁸⁶ Ibid, Section 98 (1)-(2).

⁸⁷ Ibid, Section 101(1)-(4).

⁸⁸ Ibid, Section 101A.

What the Commissioner must do in examining a patent

(1) If the Commissioner examines an innovation patent under section 101A, the Commissioner must: (a) examine the complete specification relating to the patent to determine if the patent is invalid and should be revoked because a ground set out in subsection (2), (4), (5), (6) or (7) is made out; and (b) report on the grounds set out in those subsections. These are the only grounds for revocation under this section.⁸⁹

Grounds for revocation relating to validity

(2) The grounds for revocation under subsection (1) include the following: (a) that the specification does not comply with section 40; (b) that the invention, so far as claimed, does not comply with paragraph 18(1A)(a) or (b); (c) that the invention is not a patentable invention under subsection 18(2) or (3); (d) that the use of the invention would be contrary to law. (3) For the purposes of working out whether the invention does not comply with paragraph 18(1A) (b), the prior art base (referred to in that paragraph) is to be taken not to include information made publicly available only through the doing of an act, whether in or out of the patent area. (4) A further ground for revocation is that the patent claims as an invention: (a) a substance that is capable of being used as food or medicine (whether for human beings or animals and whether for internal or external use) and is a mere mixture of known ingredients.⁹⁰

RE-EXAMINATION OF INNOVATION PATENTS

Re-examination of complete specifications of innovation patents

(1) Subject to subsections 101K (2) and (3) and the regulations, after an innovation patent has been certified, the Commissioner: (a) may, if the Commissioner decides to do so; and (b) must, if asked to do so, in writing, by the patentee or any other person; re-examine the complete specification relating to the patent. (2) If the Commissioner re-examines an innovation patent under subsection (1): (a) the Commissioner must re-examine the complete specification relating to the patent to determine if the patent is invalid and should be revoked because a ground set out in subsection (3) is made out; and (b) the Commissioner must report on the grounds set out in subsection (3). (3) The grounds for the revocation of the patent under subsection (2) are whether the invention,

⁸⁹ Ibid, Section 101B (1).

⁹⁰ Ibid, Section 101B (2)-(4).

so far as claimed in any claim and when compared with the prior art base as it existed before the priority date of that claim: (a) is not novel; and (b) does not involve an innovative step. (4) There are no other grounds for the revocation of a patent under subsection (2). (5) For the purposes of subsection (3), the prior art base is to be taken not to include information made publicly available only through the doing of an act, whether in or out of the patent area.⁹¹

REVOCAION OF PATENT AFTER GRANT OF COMPULSORY LICENCE⁹²

Where a compulsory licence for patent is granted, an interested person may apply to the Federal Court for the revocation of that patent. After hearing the application and after being satisfied the court may make the order that reasonable requirements of the public with respect to the patented invention have not been satisfied and the patentee has given no satisfactory reason for failing to exploit the patent or the patentee is contravening Part IV of the Competition and Consumer Act 2010 or an application as per section 150A of that Patent Act 1990.

Reasonable requirements of the public⁹³

For the purpose of section 134, the reasonable requirements of the public about a patented invention are not satisfied. One of the grounds of requirements of public is that a trade or industry in Australia is unfairly prejudiced by the conditions attached by the patentee to the purchase, hire or use of the patented product, the use or working of the patented process.

REVCATION OF PATENTS IN OTHER CIRCUMSTANCES⁹⁴

The Minister or any other person may apply to a court for an order revoking a patent. After hearing the application, the court may revoke the patent, either wholly or partly to a claim, on one or more of the following grounds (a) that the patentee is not entitled to the patent; (b) that the invention is not a patentable invention; (d) that the patent was obtained by fraud, false suggestion or misrepresentation; (e) that an amendment of the patent request or the complete specification was made or obtained by fraud, false

⁹¹ Ibid, Section 101G.

⁹² Ibid, Section 134.

⁹³ Ibid, Section 135.

⁹⁴ Ibid, Section 138.

suggestion or misrepresentation; (f) that the specification does not comply with subsection 40(2) or (3).

(G).LAW OF PATENT OF AUSTRALIA VIS-À-VIS TRADITIONAL KNOWLEDGE OF MEDICINAL PLANTS: AN ANALYSIS

Though Australian law of patent follows the structures or patterns of India, USA or Germany's legal frameworks while granting patents, it has two unique features in its contents. First, there are two types of patents; the first one is standard patent and the other is innovative patent. Second, apart from an examination procedure before granting the standard patent, it has an additional re-examination procedure for standard patent along with the scope of revocation after that patent is granted. For the innovative patents there is a separate system. To find out the advantages or shortcomings of this patent law, for this study, the only criterion is incorporation of standard protection of traditional knowledge of medicine of India including other bio-rich countries. Judged by this sole criterion, the followings are the findings of the analysis:

The law is more dangerous for traditional knowledge protection. The inventions which do fulfill the criterion of novelty and inventive step and industrial application are granted standard patent. Those claims where degree of difference between prior art and present new knowledge is little, these small claims are called innovations and are granted innovative patent as they are only innovations, cannot claimed as invention as such and cannot deserve actual and full patent anywhere in any country in the world.⁹⁵ As a result, though the claim is little bit different (the claim can never be new or novel) by a matter of small variation from the some earlier traditional knowledge of the medicinal values of the plants which may be possible but anyway there is no non-obviousness or inventive-step, is also entitled to have a new type of intellectual property rights. Hence the traditional knowledge is doubly susceptible to biopiracy. Where patent cannot be granted under the existing legal frameworks, Australia offers a new type of patent right in the name of innovative patent. This practice puts the traditional knowledge under a two pronged attack.

⁹⁵ The word 'innovation' means to bring in new methods and ideas, make changes. Latin word 'innovare' means make new; alter. If we go by this meaning given in Oxford Dictionary, innovative patent will be granted if the ingredient or component is slightly varied like the cliché old wine in new bottle.

In this system of patent, while elaborating the patentable inventions, especially the criteria of novelty and inventive step, it does not ensure the required protection either expressly or impliedly of society or community related traditional knowledge of medicinal plants-herbal medicine which is mostly unwritten or not documented till date. It would be very clear if the meaning of 'prior art base' for the purposes of novelty and inventive step is just analyzed. To prove the claim of novelty and inventive step for an invention, it emphasizes that the prior art information is to be made publicly available in document(s) or through doing act(s). There is no space for prior art base or prior art information originating and stemming from knowledge of oral description. This is quite unlikely in a common law country where unwritten custom and tradition are immensely valued; sometimes even it is more valued than written law. The traditional knowledge of India including other bio-rich countries becomes more vulnerable because there is no accepted standard document in some areas as methodological documentation has not started yet or even where it is started but is yet to be completed. In this situation, it now clear how does the law deny the patent claim for non-original inventions and false inventions? Apart from this, there is no definition or explanation of the existence 'act' which is also a prior art base or prior art information whatever. Looking at Schedule 1, prior art base means: (a) in relation to deciding whether an invention does or does not involve an inventive step: (i) information in a document that is publicly available, whether in or out of the patent area; and (ii) information made publicly available through doing an act, whether in or out of the patent area; (b) in relation to deciding whether an invention is or is not novel: (i) information of a kind mentioned in paragraph (a); and (ii) information contained in a published specification filed in respect of a complete application where: (A) if the information is, or were to be, the subject of a claim of the specification, the claim has, or would have, a priority date earlier than that of the claim under consideration; and (B) the specification was published after the priority date of the claim under consideration; and (C) the information was contained in the specification on its filing date and when it was published. So there is no scope of oral and non-documented knowledge being considered as prior art base to determine novelty and inventive step.

This patent law is patently biased against the bio-rich countries and their traditional knowledge. Though there is strong demand of India and other countries for traditional knowledge protection which is becoming louder and louder day by day, Australian law has adopted a somewhat indifferent attitude to that. There is no exclusion clause by which an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components,

does not get patent protection. In no uncertain terms it can be said that the law itself allows and encourages biopiracy.

Now coming down on the part of examination, re-examination and revocation procedures at different levels and for different purposes, there are some points to be noted. Firstly, when the requirement of public is not satisfied, the patent can be revoked. It happens when that a trade or industry in Australia is unfairly prejudiced by the conditions attached by the patentee to the purchase, hire or use of the patented product, the use or working of the patented process. It is a double protection of Australia's interest. But because of Australian grant of patent and accordingly the conditions attached to the product or process which is about the traditional knowledge of India, the requirements of India or the interest of its people, is unfairly prejudiced, there is no revocation. Secondly, there are instances of granting of patents on some herbal medicines where there are printed documents. This happened in number of cases where either printed documents were not submitted or these were not searched for consideration so far. It is a clear case of fraud, misrepresentation, suppression and non-disclosure of documents. These are the grounds of revocation according to Australian law. So even with this limited scope to revoke the patent if it was obtained by fraud or misrepresentation etc, when there were sufficient prior art base-printed documents or materials, it is to be seen whether there is any grant of patent and subsequent patent revocation. Application of law matters most, not the provision. Application Now likely to India, USA, UK, Germany's legal frameworks, after the revocation of a patent for various reasons i.e. either wrong decision of novelty, or inventive-step or by suppressing the facts and document by fraud or misrepresentation etc, the patent was obtained or some other legal grounds, there is no provision for the enforcement of punishment for the wrongdoers-patent officers or patentees nor there is a system for payment of reasonable compensation to the holders of traditional knowledge nor there is any mechanism for the refund of profit from the proceeds of patent to the holders of such traditional knowledge. It means the law gives fair chance for bio-piracy.

So these are the major inherent drawbacks of Australian legal frameworks of patent posing challenge for traditional knowledge protection. This is not only a great concern not only for India but all bio-rich countries in the world. Australian law of patent has become an excellent piece of exploitation.

PATENT LAW OF JAPAN-SOME RELEVANT PROVISIONS

An invention is to be patented in Japan according to its law of patent. "Invention" means the highly advanced creation of technical ideas utilizing the laws of nature.⁹⁶

(A).CONDITIONS FOR PATENTABILITY

An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention, except for the following: (i) inventions that were publicly known in Japan or a foreign country, prior to the filing of the patent application; (ii) inventions that were publicly worked in Japan or a foreign country, prior to the filing of the patent application; or (iii) inventions that were described in a distributed publication, or inventions that were made publicly available through an electric telecommunication line in Japan or a foreign country, prior to the filing of the patent application.⁹⁷

'Working' of an invention means the following acts: (i) in the case of an invention of a product (including a computer program, etc., producing, using, assigning, etc.(assigning and leasing and, in the case where the product is a computer program, etc., including providing through an electric telecommunication line, the same shall apply hereinafter), exporting or importing, or offering for assignment, etc.(including displaying for the purpose of assignment, etc., thereof; (ii) in the case of an invention of a process, the use thereof; and (iii) in the case of an invention of a process for producing a product, in addition to the action as provided in the preceding item, acts of using, assigning, etc. exporting or importing, or offering for assignment, etc. the product produced by the process.⁹⁸ Where, prior to the filing of the patent application, a person ordinarily skilled in the art of the invention would have been able to easily make the invention based on an invention prescribed in any of the items of the preceding paragraph, a patent shall not be granted for such an invention notwithstanding the preceding paragraph.⁹⁹

(B).EXCEPTION TO LACK OF NOVELTY OF INVENTION¹⁰⁰

⁹⁶ Article 2(1), The Patent Act 1959, (up to the revisions of Act No. 109 of 2006, effective from September 30, 2007)-<http://www.cas.go.jp/jp/seisaku/hourei/data/PA.pdf>. Visited on 28.05.11 at 11.01 AM.

⁹⁷ Ibid, Article 29, Clause (2).

⁹⁸ Ibid, Article 2(3).

⁹⁹ Ibid, Clause (2).

¹⁰⁰ Ibid, Article 30.

In the case of an invention which has fallen under any of the items of Article 29 (1) by reason of the fact that the person having the right to obtain a patent has conducted a test, has made a presentation in a printed publication, has made a presentation through electric telecommunication lines, or has made a presentation in writing at a study meeting held by an academic group designated by the Commissioner of the Patent Office, such invention shall be deemed not have fallen under any of the items of Article 29(1) for the purposes of Article 29(1) and (2) for the invention claimed in a patent application which has been filed by the said person within six months from the date on which the invention first fell under any of those items.¹⁰¹

In the case of an invention which has fallen under any of the items of Article 29 (1) against the will of the person having the right to obtain a patent, the preceding paragraph shall also apply for the purposes of Article 29(1) and (2) to the invention claimed in the patent application which has been filed by the said person within six months from the date on which the invention first fell under any of those paragraphs.¹⁰²

In the case of an invention which has fallen under any of the items of Article 29 (1) by reason of the fact that the person having the right to obtain a patent has exhibited the invention at an exhibition held by the Government or a local public entity, an exhibition held by those who are not the Government, etc. where such exhibition has been designated by the Commissioner of the Patent Office, an international exhibition held in the territory of a country of the Union of the Paris Convention or a member of the purposes of Article 29(1) and (2) to the invention claimed in the patent application which has been filed by the said person within six months from the date on which the invention first fell under any of those items.¹⁰³

Any person seeking the application of paragraph (1) or (3) shall submit to the Commissioner of the Patent Office, at the time of filing of the patent application, a document stating thereof and, within thirty days from the date of filing of the patent application, a document proving the fact that the invention which has otherwise fallen under any of the items of Article 29(1) is an invention to which paragraph (1) or (3) of this Article may be applicable.¹⁰⁴

¹⁰¹ Ibid, Article 30, Clause (1).

¹⁰² Ibid, Clause (2).

¹⁰³ Ibid, Clause (3).

¹⁰⁴ Ibid, Clause (4).

Where an invention claimed in a patent application is identical with an invention or device excluding an invention or device made by the inventor of (the invention claimed in the said patent application) disclosed in the description, scope of claims or drawings (in the case of the foreign language written application under Article 36-2(2), foreign language documents as provided in Article 36-2(1)) originally attached to the written application of another application for a patent or for a registration of a utility model which has been filed prior to the date of filing of the said patent application and published after the filing of the said patent application in the patent gazette under Article 66(3) of the Patent Act 1959 or in the utility model bulletin under Article 14(3) of the Utility Model Act 1959 describing matters provided for in each of the paragraphs of the respective Article or for which the publication of the patent application has been effected, a patent shall not be granted for such an invention notwithstanding Article 29(1); provided, however, that this shall not apply where, at the time of the filing of the said patent application, the applicant of the said patent application and the applicant of the other application for a patent or for registration of a utility model are the same person.¹⁰⁵

(C).UNPATENTABLE INVENTIONS

Notwithstanding Article 29, any invention that is liable to injure public order, morality or public health shall not be patented.

(D).PATENT INVALIDATION

Where a patent falls under any of the following, a request for a trial for patent invalidation may be filed. In the event of two or more claims, a request for a trial for patent invalidation may be filed for each claim. (i) where the patent has been granted on a patent application (excluding a foreign language written application) with an amendment that does not comply with the requirements as provided in Article 17-2(3); (ii) where the patent has been granted in violation of Articles 25, 29, 29-2, 32, 38 or 39(1) to 39(4); (iii) where the patent has been granted in violation of a treaty; (iv) where the patent has been granted on a patent application not complying with the requirements as provided in Article 36(4)(i) or 36(6); (v) where matters stated in the description, scope of claims or drawings attached to the foreign language written application are not within the scope of matters stated in foreign language documents ; (vi) where the patent

¹⁰⁵ Ibid, Article 29(2).

has been granted on a patent application filed by a person who is not the inventor and has not succeeded to the right to obtain a patent for the said invention; (vii) where, after the grant of a patent, the patentee has become unable to hold a patent right under Article 25, or the patent has become in violation of a treaty; and (viii) where the correction of the description, scope of claims or drawings () attached to the application for the patent has been obtained in violation of the proviso to Article 126(1), Article 126(3) to (5) (including its application mutatis mutandis under Article 134-2(5)) or the proviso to Article 134-2(1).¹⁰⁶

Any person may file a request for a trial for patent invalidation; provided, however, that where a request for a trial for patent invalidation is filed on the ground that the patent falls under item (ii) of the preceding paragraph (limited to cases where the patent is obtained in violation of Article 38) or item (vi) of the preceding paragraph, only an interested person may file a request for a trial for patent invalidation. A request for a trial for patent invalidation may be filed even after the lapse of the patent right.¹⁰⁷ Where a request for a trial for patent invalidation has been filed, the chief trial examiner shall notify the exclusive licensee of the patent right and other persons who have any registered rights relating to the patent.

EFFECT OF PATENT INVALIDATION

Where a trial decision to the effect that a patent is to be invalidated has become final and binding, the patent right shall be deemed never to have existed; provided, however, that where a patent falls under Article 123(1) (vii) and where a trial decision to the effect that the patent is to be invalidated has become final and binding, the patent shall be deemed not to have existed from the time the said item first became applicable to the patent.¹⁰⁸

(E).LAW OF PATENT OF JAPAN VIS-À-VIS TRADITIONAL KNOWLEDGE OF MEDICINAL PLANTS: AN ANALYSIS

Untill recently, Japan's definition of prior art was exactly as that of USA, where Japanese Patent Act limited the geographical scope of relevant non-patent, non-published public knowledge or use to Japan only. But in 1999, Japan took a major step

¹⁰⁶ Ibid, Article 123, Clause (1).

¹⁰⁷ Ibid, Clause (2)-(4).

¹⁰⁸ Ibid, Article 125.

forward when the some significant amendments were incorporated in its law. One of the amendments eliminated geographical limitation and distinction of prior art. Now in Japan patent is not allowed for the inventions which are publicly known in its own territory or elsewhere or inventions which are publicly worked in its territory or elsewhere or inventions which are described in a distributed publication or made available to the public through electric telecommunication lines here or elsewhere prior to the filing of the patent application. In 1998, there was a report prepared by the Planning Subcommittee of Japan's Industrial Property Council. It identified three key reasons for revising the definition of novelty-destroying information. These are (1) allowing the patenting of technology in the global public domain gives the impression that Japan is an imitator, not a pioneer in technology development; and (2) while 'surveying' foreign known and worked inventions was difficult at the time the old law was enacted in 1959, it has now become relatively easy to access such information so the rule should be 'expanded to include the entire world.' What Japan recognised, U.S.A. and other countries consciously and deliberately decided not to recognise.

The patent law has all such structural components like other countries' patent laws. It has patent criterion, the exception clause, examination procedure for granting or refusing and patent invalidation process. Apart from patent it also has a utility model for small types of inventions under a different law. This country is also one of the WTO countries like India, USA, Germany and Australia and as part of that world trade body has the global and obligations and commitments as well. In spite of that if it wants it also has the sovereign power to protect traditional knowledge of herbal medicine and can also stop biopiracy. With this expectation in mind, let it be seen whether there are sufficient safeguards in its law for traditional knowledge and will not add any woe to India's concerns and anxiety. It is found out:

That specifically there is no mention of protection of traditional knowledge of the herbal medicine made with the active bio-chemical constituents of the plants. There is also no mention of this kind of knowledge protection offered to all bio-rich and traditional knowledge holding countries including India. There is no exclusion clause which excludes the society or community oriented traditional knowledge i.e. an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components, likely to India. The protection would have been more effective, had there been such in its law such an exceptional clause of patentable inventions. There is no express provision to recognize the prior art of oral description or unwritten and unpublished documents though there is practice in the society to apply the knowledge. But whatever conditions for patentable

inventions, un-patentable inventions and exception to lack of novelty of invention are incorporated in the present legal framework in Japan, patent is not supposed to be granted by the JPO where there is sufficient written and published documents or materials in India and other traditional knowledge enriched countries about the knowledge of the herbal medicine and its daily life application by the people to cure ailments or to develop resistance and immunity power in the body. But there are instances that in those cases also patents were granted by JPO and these are also clear cases of bio-piracy. These may be the cases where there is no written document for the traditional knowledge; what is there is the undocumented knowledge of oral description which is not a matter of consideration in Japan. These may also be the cases of simply just non-application of law-either for not performing duties properly or not investigating accurately to determine novelty or inventive step. These incidents of bio-piracy in Japan might also be happening by not disclosing and suppressing the prior art. These are all cases of bio-piracy on the basis of false claims of invention. But there is a good thing in Japan's patent law. Due to this, there is a less possibility to have these kinds of patents based on false claims and some other illegal and irregular activities. First there are criminal liabilities. Crime of fraud-Any person who has obtained a patent, a registration of extension of the duration of a patent right or a trial decision by means of a fraudulent act shall be punished by imprisonment with work for a term not exceeding three years or a fine not exceeding 3,000,000 yen. Crime of perjury, etc. - witness, an expert witness or an interpreter who has sworn under this Act and made a false statement or given an expert opinion or interpretation to the Patent Office or the court commissioned thereby shall be punished by imprisonment with work for a term between three month and ten years. Where a person who has committed the crime in the preceding paragraph has made a voluntary confession before a certified copy of the judgment on the case has been served or a trial decision has become final and binding, the punishment may be reduced or exculpated. There is civil liability also. Civil fine-where a person, who has sworn under Article 207(1) of the Code of Civil Procedure, has made a false statement before the Patent Office or a court commissioned thereby, the said person shall be punished by a civil fine not exceeding 100,000 yen.

There is again threat to traditional knowledge from Japan from Utility Model Act 1959. For something less than invention without novelty or inventive step, a new type of intellectual property right likely to innovative patent of Australia is granted in Japan with some kind of exclusive rights of commercialization. There is a probability of granting this kind of intellectual property right to the herbal medicine related traditional knowledge in this country. Under this system, though, it is impossible to prove novelty for minor variation from the existing prior art still it can claim utility model of

intellectual property protection. Though, a person ordinarily skilled in the art does not necessarily have that level of non-obviousness, still the claim is valid. So the traditional knowledge of India is really prone to be taken away.

Finally, there is a procedure of invalidation of patent. Though the object of this system is to bring fairness and to allow only the genuine patents are to be commercialized in Japan. It has also a very serious congenital defect. With this defect it cannot achieve the goals. Take for example, there is written document about the traditional knowledge and later on it was submitted to invalidate the patent of one non-original invention and subsequently it is invalidated. That is the end of the matter. This should not be the end of the matter. There must be a system of refunding of the profit to the original holders of the knowledge or there is a need of a system of payment of fair compensation to the original holders whose knowledge was illegally exploited for economic gain. These are lacking in Japan's law of patent.

CONCLUSION

After referring to some relevant provisions from the patent laws of India, USA, UK, Germany and Japan, an effort was made after every part, to highlight some of the very basic shortcomings of each of the legal frameworks. These shortcomings are some of the major constraints in the way of making of a fair and just intellectual property laws about patent aiming at protection of traditional knowledge of medicinal plants i.e. genetic resources. There are different types of shortcomings and demerits in each of the legal frameworks. Some of them are common in nature and present in all legal systems. Some of them are peculiar to a particular system different from others. The cumulative effect is that these are all leading towards the negation of the positive protection of existing public domain knowledge either for one reason or the other; or granting of patents disregarding the existence of 'prior art' in the subject; or no expressed or implied exclusion clause for written or unwritten traditional knowledge; or by non recognizing 'the written or oral description' as prior art; or though not granting IPR protection but allowing commercialization of existing public domain knowledge. As a result these laws are endorsing biopiracy in different ways. There is a point needs to explained to a new type of bio-piracy which was not considered as bio-piracy as such in any of the countries. Inventions based on traditional knowledge and genetic resources are still patentable as long as they are novel and non-obvious in view of prior art. There would still be no requirement in patent law that inventors compensate the TK holders or share benefits equally for sharing the knowledge to carry on research on and building something new or non-obvious. It is the utilization of knowledge which is in public

domain and accessible to everyone. This is also an improved and sophisticated form of bio-piracy, is allowed all the countries including in India. Hence, there are huge numbers of these kind of patents granted in India and in other countries as well. This form of bio-piracy would continue as long as the ownership issue of traditional knowledge which is in public domain is settled (more specifically if ownership is not conferred on it) by going against the present concept of its free and easy availability and accessibility. But the patent laws which were analyzed in some of the foregoing paragraphs do not accept the present concept of 'public domain knowledge' as something objectionable and unjustified.

There is no protection of the existing knowledge which is in public domain in the present intellectual property regime. In addition to that, as rightly pointed out by Vandana Shiva that "much of the background research that underlies any patentable development, has been publicly funded. Yet the results are often employed in applied research toward patentable discoveries, the rewards of which are appropriated privately."¹⁰⁹ Hence, one of the main concerns of the academicians, activists and the law makers is how to protect existing knowledge or 'prior art' and regulate non-original new knowledge derived from existing knowledge apart from making IPR law to stop conventional type of bio-piracy. The panacea is remodeling the existing IPR laws or making special laws for traditional knowledge. One approach is that traditional knowledge does not fit in the conventional criterion of intellectual property rights. It is a new type of intellectual property rights deserves a sui generis system, so make a sui generis law. Second approach is that mass revocation of all patents where there are written or oral traditional knowledge-prior art, compensation, punishment, and refund of profit, moratorium on future grants etc because it is a clear case of appropriation and bio-piracy-and for non-original inventions as the result of the use of public domain knowledge, either sharing of benefits or offering joint ownership. As long as public domain knowledge is used by anyone for the welfare of mankind without any profit motive, there must not be any restriction on its accessibility and utilization by the owners or the holders of such knowledge. This is Indian tradition and culture. This system if is adopted, it is the following and application of that great Indian tradition. Let all human beings of the world benefit from this traditional knowledge-to live a healthy and disease free lives. It would remain as common property-free for all. But the moment people by getting the information or lead and developing something, want to

¹⁰⁹ Vandana Shiva, "Biopiracy: The Plunder of Nature and Knowledge", in 'Knowledge, Creativity and Intellectual Property Rights', RFSTE, New Delhi, 1997, Page 17.

commercialize it in different ways, it ceases to be public property. This is the way to maintain a golden balance between the two sets of interests-motivation for individual intellectual exercise and the welfare of general public. These are all from the perspectives of ownership of the TK and associated rights.

Another is application of 'public trust doctrine' of environmental law-a common law principle. It is hoped that if this doctrine is applied in traditional knowledge protection, it will give a new direction and dimension to the protection. The doctrine was clearly explained in Kamal Nath vs M.C.Mehta judgment. It states that "The ancient Roman Empire developed a legal theory known as the "Doctrine or the Public Trust. It was founded on the ideas that certain common properties such as rivers, sea- shore, forests and the air held by Government in trusteeship for the free and unimpeded use of the general public. Our contemporary conceded about 'the environment' bear a very close conceptual relationship to this legal doctrine. Under the Roman Law, these resources were either owned by no one (res Nullius) or by everyone in common (Res Communis). Under the English common law, however, the Sovereign could own these resources but the ownership was limited in nature, the Crown could not grant these properties to private owners if the effect was to interfere with the public interests in navigation or fishing. Resources that were suitable for these uses were deemed to be held in trust by the Crown for the benefit of the public. Joseph L. Sax, Professor of Law, University of Michigan proponent of the Modern Public Trust Doctrine, in an erudite article "Public Trust Doctrine in natural resource law: effective judicial intervention". Michigan Law Review Vol. 68 Part-1 page 4/3 has given the historical background of the Public Trust Doctrine as under: "The source of modern public trust law is found in a concept that received much attention in Roman and English law - the nature of property rights in rivers, the sea, and the seashore. That history has been given considerable attention in the legal literature need not be repeated in detail here. But two points should be emphasized, First, certain interests, such as navigation and fishing, were sought to be preserved for the benefit of the public; accordingly, property used for the those purposes was distinguished from general public property which the sovereign could routinely grant to private owners. Second, while it was understood that in certain common properties-such as the seashore, highways, and running water- "perpetual use was dedicated to the public,".....The Public Trust Doctrine primarily rests on the principle that certain resources like air sea, waters and the forests have such a great importance to the people as a whole that it would be wholly unjustified to make them a subject of private ownership. The said resources being a gift of nature, they should be made freely available to everyone irrespective of the status in life. The doctrine enjoins upon the Government to protect

the resources for the enjoyment of the general public rather than to permit their use for private ownership or commercial purposes. According to Professor Sax the Public Trust Doctrine imposes the following restrictions on governmental authority. Three types of restrictions on governmental authority are often thought to be imposed by the public trust: first, the property subject to the trust must not only be used for a public purpose, but it must be held available for use by the general public; second, the property may not be sold, even for a fair cash equivalent; and third property must be maintained in particular types of uses". It is not true that Public Trust Doctrine as common law rule was the rule only in UK or USA. The concept of common property-natural resources and intellectual resources originated in ancient India and are recognized even today though in a limited way.

Like some of the natural resources of a country, century old oral or documented traditional knowledge of the medicinal values of Indian plants and shrubs-specifically its unique genetic resources has become the intellectual property of the society since time immemorial. No individual ever claimed or was granted exclusive monopolistic right or ownership over this common traditional knowledge in ancient times. The knowledge was dedicated for the welfare of the public in general not only for India but for the whole world. The sages after much study, experimentation and research when invented, did not do so even for their own interest. These intellectual properties have become an integral part of the heritage, culture and tradition of Indian people. Present generations are merely the holders, preservers and protectors of this great knowledge It means that they are in a true sense the trustees of this traditional knowledge of the medicinal values of the biological resources and the governments at different levels as the representatives of the people are holding these immense commercial value oriented traditional intellectual properties as trustees. As trustees of these valuable resources and associated knowledge, people and the governments have lot of duties, liabilities, responsibilities and accountability. There is a very strong logic to apply public trust doctrine here in this case with a little bit adaptation if the situation arises. Public domain knowledge i.e. existing Indian traditional knowledge on genetic resources is the property of the public trust under Public Trust Doctrine. As the doctrine imposes the three restrictions on government, first, the property subject to the trust must not only be used for a public purpose, but it must be held available for use by the general public; second, the property may not be sold, even for a fair cash equivalent, but it can be done for the greater benefit of the society or the people and third, property must be maintained in particular types of uses. It is equally incumbent on the other countries where public trust doctrine is operational in legal field to respect, recognize and regard the properties or resources covered under Public Trust Doctrine in India, with reciprocal arrangements.

With this jurisprudential approach, it would be easier to strongly protect, preserve and augment this TK oriented intellectual property. There is a paradigm shift to look at TK from two perspectives. First, there is no farther question of ownership over this TK, rather it is a intellectual property under trust. Second, the custodians of TK may be indigenous community or society-they have to follow inter-generational equity, to preserve them for future generations. The governments would be under strict legal scrutiny for all its decisions about traditional knowledge. On the other hand, strict restrictions would be put on the experimentation, research, invention of new knowledge-the process or the product, making innovations or utility models or commercialization in any form or in any manner using the present level of knowledge associated with biological resources either in this country or elsewhere. This is one of the viable ways to offer comprehensive positive and negative protection to the existing public domain traditional knowledge which has become the target of actual and imminent threat from the western new knowledge oriented IPR regime. This approach of PTD has the answer of all questions-conservation, augmentation of resources, development, sustainable use, taking action against biopiracy, regulating non-original inventions and innovations etc by exploiting or using the existing TK, direct commercializing as it is in public domain etc., in a word is truly protecting existing public domain traditional knowledge.

The root cause of all these unfair practices of bio-piracy supported by so called national or international laws is that what the laws define the word 'invention' (only invention with novelty, non-obviousness and industrial application has patent coverage) actually it is not the definition of the word "invention". Those countries and TRIPS have changed the meaning of the term 'discovery' into 'invention' and creating all sorts of problems to the advantage of them. The word 'discover' means¹¹⁰ (1) to disclose, or expose to view (anything covered up, hidden, or previously unseen), to reveal, to show; (2) to divulge; to reveal; to disclose to knowledge (anything secret or unknown); (3) to manifest; to exhibit or to display. (4) To bring to public notice; (5) to bring into fuller knowledge; (6) to remove the covering. The word 'invent' means (1) to find out or produce by mental activity; (2) to find out in the way of original contrivance; to create; to produce or to construct by original thought or ingenuity; to devise first; to originate. (3) To originate by bring into use, formally or by authority.¹¹¹The word 'invention' means (1) the

¹¹⁰ The Oxford English dictionary, Second edition, Volume IV, CLARENDON PRESS, OXFORD.

¹¹¹ The Oxford English dictionary, Second edition, Volume VIII, CLARENDON PRESS, OXFORD.

original contrivance, or production of a new method or means of doing something of an art, kind of instrument etc., previously unknown; origination. (2) Something devised or produced by original contrivance; a method or means of doing something, an instrument or art etc, originated by the ingenuity of some person and previously unknown. (3) The action of finding out (whether accidental or the result of research or effort).¹¹² The root cause of whole issue of bio-piracy of traditional knowledge associated with medicinal plants does originate from invention vis-à-vis discovery. The bio-pirators and the perpetrators of biopiracy are compelling to accept the discovery as an invention or rather by manipulating the legal framework get the 'discovery' accepted as invention. This is wrong. Discovery and invention linguistically are two different terms. If there is prior knowledge and information in different forms traditionally with the society or community or practice in the society, either documented or non-documented, how can it be 'invention'? Whatever they are doing it is just discovery, not invention and as it is not invention, there cannot be patent as it lacks novelty and non-obviousness.

But neither there is ownership over traditional knowledge including 'public domain knowledge nor these are declared as property under trust under any of the patent laws in the above mentioned countries. These are the root causes of injustice and biopiracy. On the perusal of these national laws, it found that the universal idea behind the intellectual property rights through patent protects only 'new' knowledge and collective knowledge of the society what already exists could not be protected as intellectual property. This psychological-legal constraint and studied reluctance to accept the arguments of TK enriched countries is the stumbling block to making of fair global IP regime.

¹¹² Ibid.