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Refused Patent Applications in India in the Field of 'Traditional Knowledge Biotechnology'

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The governance of bio-technology patent is a complex process especially in the field of 'Traditional Knowledge Biotechnology'. The critical aspect with biotechnological inventions is establishing 'novelty'. It is noted in every patent application that there is an examination report which mentioned objections including of 'novelty' by the examiner. Further, it is noted that most of applications found by the examiner 'obvious' or 'non-inventive' in view of cited art as indicated in the examination reports, although many inventions having some value additions over the prior-art as replied by the applicant during prosecution of such applications differentiating the applied invention from the cited art. This study analyzes, around 100 patent applications filed in India during year 2004 to 2021 and enlist the main grounds of refusal of patents in the field of 'Traditional Knowledge Biotechnology'. The aim of the study is to explore the patenting aspects and related issues of biotechnological products from traditional knowledge.

Keywords: Traditional Knowledge Biotechnology, Indian Patent Applications, Refusal Grounds, IPR Ownership, Traditional Knowledge Digital Library, Field of Invention, Biological Diversity Act, 2002

Many developing and underdeveloped countries have high bio-resources and the associated knowledge and India is one of such countries of conventional practice of custom and indigenous knowledge. Such bio-resources and the associated knowledge are the common resource especially for poor people who have high dependency on them since long and therefore such resources need to be regulated without prejudicing the access by such people. Traditional Knowledge (TK) is imperative to local people and is passed on from generations in various forms of values, languages, customs, arts and agricultural practices. Therefore, it is significantly important to protect, conserve and sustain such traditional values.[1,2]

The applied biotechnology is a prospective tool for extenuating the future inventions in various domains in developing countries like India. IPR ownership, particularly the patent is one of the major factors in deciding the success of invention in the market. Biotechnology is an outcome when human intelligence and knowledge is applied to the technical and biological processes. In recent years, biotechnology has evolved and many new inventions like new products and processes are being developed by people both from public and private sectors including companies, universities and research institutes. The human intellect and its efforts justify its protection in view of its belongingness with the creator or the concern institution. Like property, such invented things may be commercialized. The term 'Traditional Knowledge' (TK) or Indigenous Knowledge (IK) is any knowledge, information, innovation, or practices of the indigenous local communities that may ensure the sustainable use of the biodiversity's and its conservation.[3-5] From Washington State, Tulalip Tribes once remarked that open sharing does not robotically grant a right to make use of the indigenous people's traditional knowledge.[6] TK includes knowledge, skills and practices, developed in long course of time, well-sustained in community and gradually passed through generations to next within a community as a part of its own cultural exclusivity.[7] TK having living nature, is typically not documented by local indigenous communities, moves through many generations by word of mouth based on biological natural resources and surrounding environment.[8] One interesting case is of *Hoodia gordonii*, commonly called Bushman's hat, belongs to family- *Apocynaceae* and used for food, water and therapeutic remedy by Kalahari desert's natives.[9] It is very sad and a point to ponder that hard

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work to keep this knowledge and practice alive through generations is taken away from these local people without benefit sharing.[10]

Globally, protection of TK is hardly legislated unlike other IPR. Every year numerous inventions inspired from TK specially based on traditional medical knowledge and other TK associated with bio-resources are applied for patent world-wide including in India. Such patent applications sometime granted for patent and sometime rejected. Many times it has been observed that the knowledge behind such applied invention are not 'novel' but the part of public domain as being traditional in nature. Unfortunately, due to lack of such information in codified form as required to access by the patent offices, wrongly understood 'novel' and 'inventive' by the patent office and causing wrong grant of patents. Therefore, in order to make such prior-art accessible to patent offices, some countries initiated framing databases of the indigenous traditional knowledge so that the patentability criteria particularly the 'novelty' may be accessed. India is the first country who developed such a long awaited database and named Traditional Knowledge Digital Library (TKDL) which got worldwide recognition and have been recognized by World Intellectual Property Organization (WIPO) as one of the key document on the TK. Many other countries have inspired from TKDL and have initiated a similar work to codify their country TK.

In recent times, bio-research is focused towards biotechnological products and patenting of the same as there seem to be a potential growth in the particular domain. 'Traditional Knowledge Biotechnology' is one of the fields of invention out of twenty three 'field of invention' as categorized by Indian Patent Office and all such fields can be accessed on their official webpage.[11]

In India, a variety of advancements has been made to protect such skills, knowledge, teachings, innovations, learning's and practices. Other than documentation (evidence) like publishing, these may be registered like patent or by *sui generis* system (PPVFRA). However such limited norms of intellectual property rights so far didn't protect the interest of the indigenous and local communities who carrying such precious TK since long. So it becomes essential to frame legal norms and forms for protection of traditional knowledge and to attain international consent on the solutions obtained.[12] Proper documentation on bio-resources and the associated TK could help in checking bio-piracy but it could be a double-barreled shotgun. Thus in case of prior art, one can easily go through them for the inventions based on such materials and knowledge.[13] As there is a relationship between patents and various additional inputs within the scaffold of economic policies, norms and regulatory processes, a clear cut appropriate insight of the fundamental facts and inputs in the innovation process in biotechnology sector is necessary leading to successful commercialization of new technologies.[14, 15] Following the cases pertaining to patenting of turmeric, neem, basmati, etc. and the revocation of these patents on the grounds of lack of fulfillment of patentability criteria particularly the 'novelty', the inventions in the field of 'TK biotechnology' imposed the need for rightful tailoring of patent.[16] To avoid such instances of wrong bio-patenting, NISCAIR one of the institution under CSIR (a Government R&D organization) in India had created a Traditional Knowledge Digital Library (TKDL) which has been shared with international patent offices so that there would be a fair examination of the application and minimizing such wrong grants of patents.[17]

The regulations of biotechnology patent are a multifaceted process especially in the field of traditional knowledge. Many applications are rejected on the grounds of 'novelty' and 'obviousness' or 'non-inventive' in view of prior art as found by the examiner, although most of such inventions argued having some value additions over existing or the cited prior-art. Thus, the objective of this paper is to understand and comprehend the legal framework for patenting inventions in the field of bio-resources and the associated TK and highlight the grounds of refusal of such patent applications in India.

Methodology

All applications for patents filed in India are tagged by the Patent Office under their relevant field of invention and total 23 'field of inventions'.[11] The 'field of invention' selected for the present study is 'Traditional Knowledge Biotechnology'. The applications may be accessed by their 'dynamic status' like 'in process', 'granted', 'refused', 'abandoned' and 'withdrawn'. For the present work of study, only the applications for patent in the subject having status 'refused' are studied. The various fields of the database are: date of filing, application no., office, title of invention, applicant name, publication date,

applicant country, biological entities, utility, section objecting inventiveness, TK, remark (including comments regarding whether the refusal justification).

Guiding Principles related to obviousness are mentioned in "Guidelines for Processing of Patent Applications relating to Traditional Knowledge and Biological Material". In India, patent applications based on 'Traditional Knowledge Biotechnology' are refused on certain parameters which is not been clearly addressed in the IPO guidelines.[18] Thus, to emphasis the grounds for refusal of 'Traditional Knowledge Biotechnology' patent applications, the study was carried out with around 100 patent applications filed in India during year 2004 to 2021.

One hundred patent applications in India in the field of invention 'Traditional Knowledge Biotechnology' during year 2004 to 2021 have been refused as per the Patents Act, 1970 till 5th July 2021 which were accessed at IPO official site using various options like patent number, opponent, section, decision date, application number and applicant name which were applied.[19]

In the present study, the search criteria considered was 'application number' used from the list of examined traditional knowledge biotechnology patent applications was identified till 2021. The data was analyzed and categorized under various fields as filing date, application no., office, invention title, applicant name, date of publication and applicant, country, biological entities, utility, section objecting patentability, TK, remark and refusal. All such data was maintained in database, which was captured from the dynamic tool of the patent office to analyze and elaborate present carried study.

Results and Discussion

Dynamic status of patent applications as per field of invention can be accessed at official web-portal.[11] The status of patent applications in field of invention, 'Traditional Knowledge Biotechnology' has been gathered using the said government portal (Table 1).

Table 1 — Status of patent applications in the field of invention 'Traditional Knowledge Biotechnology' during 2017-2021

S. No.	Status/ Year	2017	2021
1	In process	1142	320
2	Granted	35	269
3	Refused u/s (15)	76	213
4	Abandoned u/s 21(1)	200	576
5	Withdrawn after 15 months	13	19
Total		1466	1397

The trend of disposal is very fast as relates to earlier. As the number of pending applications is reduced to 320 from 1142 within 4 years in spite of having new filings both from domestic and foreign applicants, it is clearly indicated that the examination of the application is at very fast pace. Also, the number of granted patents is more than number of refused applications indicating inclination of more patentable innovations in the field of invention 'Traditional Knowledge Biotechnology'. It is noted that earlier 35 patents were granted in year 2017 while in 2021 the number of granted patents are 269 which indicates that the applied applications in the field have fulfilled all the patentability requirements.

The number of applications for patents abandoned is more than number including both granted and refused applications indicated that many earlier pending applications have either not fulfilled patentability criteria or were lacking prosecution of the examined applications. The data reveals that total 19 applications have been withdrawn by the applicants. The reason of such withdrawal can only be stated after communicating to the concerned applicants because it is best known to them and not in the records of the patent office. Also, 69 applications were not completed by the applicants. The reason for such difference in number of applications seems for the fact that such applications were filed provisionally only and were not completed within the prescribed time of one year from the date of provisional filing.

The results showed that, most of the applications are under process and the trend of pendency was reducing continuously. The number of the refused applications was more than number of granted patents in the subject. However, the number of granted applications was continuously increasing and the rate of growth in numbers was more than refused applications. It was noted that patent claims attracted the provisions of various Sections of the Patents Act, 1970 including Section 2 on definitions and interpretation, Section 3 regarding what are not inventions and Section 29 to Section 34 on anticipation. More particularly, the applicable provisions are Sections 2(1) (j); 3(d); 3(e); 3(i); 3(p); 10(4)(ii)(D); 59 of the Patents Act, 1970. It is noted that most of such applications were abandoned due to lack of prosecution. It seems that after receiving First Examination Report (FER) by the concern applicant/agent from the patent office, either it was so understood by the applicant and their agent that their application was unable to fulfill the patentable criteria that may be in view of lacking criteria of non-obvious

or lacking inventiveness and therefore resulting in either no reply submitted to rebut the examination report or an unsuccessful reply. Thus, most of such application got abandoned due to lack of prosecution.[20]

Observations regarding the objection, as seen in rejected patent applications and as indicated in the examination reports issued from Indian Patent Offices are:

(i) As the applications for patent studied here are classified under 'Traditional Knowledge Biotechnology', however in around 50 % of the applications, there is no objection under of Section 3(p) in the Examination Report on the ground of traditional knowledge.

(ii) Though the applications are categorized in the field 'Traditional Knowledge Biotechnology' however, they were having herbal or ayurvedic formulations or the process of preparation of the same.[19]

(iii) The most common Sections of the Patents Act, 1970 as amended so far, as attracted towards non-patentability of such inventions are Sections 2(1) (j); 3(d); 3(e); 3(i); 3(p); 10(4)(ii)(D); 59 (Table 2).

(iv) Out of three essential criteria of patent, most applications were fulfilling the two criteria- 'novelty' and 'utility/industrial application', while were lacking in 'inventiveness' and this was usually objected in the Examination Report and is one of the main issue considered during prosecution of any patent application.[20]

Most of the objections are on patentability and other regulations including need to disclose source and geographical origin of the bio-materials used to prepare the invention; Need of any technical advancement like inventive step/non-obviousness in view of the cited prior-art documents; a combination in order to achieve inventiveness must be showing enhanced efficacy or synergistic results. The specification which does not contain any such enhanced efficacy or synergistic results, be considered failed to disclosed anything beyond the traditional knowledge. Newly added process claim is not allowable under the Act.

Requirements under Biological Diversity Act

Section 6 (1) of the Biological Diversity Act, 2002 provides that "no person shall apply for any intellectual property right, by whatever name called,

Table 2 — Main Sections of the Patents Act, 1970 cited in FERs

Sections of the Patents Act, 1970	Remarks
10(4) (ii)(D)	The source and geographical origin of the bio-materials used to prepare the invention are not indicated in the specification, which are required to be disclosed as per Section 10 (4) (ii) (D) of the Act
2(1) (j)	Application does not constitute an invention under Section 2(1) (j) of The Patents Act 1970 (as amended); The Claim(s) of the instant application lacks inventive step/non-obviousness in view of the cited prior-art documents; The 'invention' does not reflect any technical advancement in the subject and the claimed 'invention' is not patentable for lacking in inventive step under Section 2(1) (j) of the Act
3(d)	Claim(s) define new form of known substance which is already disclose in prior art document
3(e)	Claim(s) are no clear synergistic & comparative data of this claimed composition and also with prior art. Hence, Claim(s) fall within the scope of such clause (e) of Section 3.
3(i)	Claims related to a process (medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment) of treatment to human beings or animals to render them free of disease or to increase their economic value or that of their products
3(p)	Invention which in outcome of a traditional knowledge or in aggregation or duplication of known properties of traditionally known component(s). A skilled person having prior knowledge of traditional medical use of part a specific plant may always be motivated to make a combination which will be useful for of various diseases at the same time. Such a combination in order to achieve inventiveness must be showing enhanced efficacy or synergistic results. The specification which does not contain any such enhanced efficacy or synergistic results, be considered failed to disclosed anything beyond the traditional knowledge. Illustration: The use of a combination of ingredients which are traditionally known as immune-potentiators as a dietary supplement composition, which enhances the vitality and immunity level of the person consuming the said composition is a mere aggregation or duplication of known properties of traditionally known components and therefore not considered an invention u/s 3(p).
59	Newly added process claim is not allowable under Section 59 of the Patents Act, 1970 (as amended)

in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of National Biodiversity Authority (NBA) before making such application". It means that a prior approval of National Biodiversity Authority is needed by an applicant who wishes to get patent in India for an invention using bio-resource obtained from India.[21]

The invention as disclosed in the specification of many applications appears to use bio-material from India but lacking such approval. Hence, necessary permission from the competent authority i.e., NBA shall be obtained and the approval need to be submitted to the patent office before the grant of patent. It is noted that such provision needed applicant to interact with another government authority which may further delay the patent process. Thus, it may be suggested, rather the Patent Office itself should receive such information from the applicant(s) which would certainly be in the interest of applicant(s), hence making it more time efficient. Similar system is noted where the invention fall in the field of atomic energy, the Patent Office themselves forward the application to the defense authority for further instruction whether to proceed for patent or not.[22]

Non- Patentability of Traditional Knowledge Related Inventions

It is noted in numerous examination reports of patent application which indicated that the applied inventions are related to traditional knowledge and therefore have mentioned Section 3(p) of the Patents Act. This particular Section is articulated as, "an invention which in effect, is a traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component(s)" and considered the invention not patentable. During prosecution, some of the submissions from the applicant's side are as follows:

Traditional Knowledge definition as given by WIPO is "traditional knowledge (TK) is knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity". According to Oxford Dictionary: adjective traditional means "existing in or as part of a tradition; long-established-produced, done, or used in accordance with tradition: a traditional fish soup".[23]

From the above it is very clear that every plant / herb / metal / mineral used in Ayurvedic medicine does not come under definition of 'traditional medicine' as long as the specific use of a specific substance i.e., plant, root, fruit, metal, mineral is not described for a specific disease or disorder; described a specific process of formulation. Therefore, it is absolutely illogical, unfair and against the interest of the scientific and research community to make every plant, herb, mineral, metal, fruit which has a mention in Ayurveda as non-patentable. Formulations mentioned as prior-art by either patent examiner or the opponent, if any objecting patentability of the invention applied for patent sometimes indicated multiple applications like medical usage in a non-specific way. This should not be construed as being 'prior art'. It would almost mean that almost all Ayurvedic ingredients can be used for almost every medical condition may be remotely effective, slightly effective, moderately effective or very effective or 'probable' to be effective-without any back up data or rationale. It cannot be called as 'traditional knowledge'. 'Traditional knowledge' should construed to be a successful therapy based on the knowledge handed over from generations to generations and practiced by people who inherit such knowledge and get concrete results from such therapy. Accepting such vague data as 'traditional knowledge' and the premise that everything that has to be done has already been done in herbal medicines and there is no more to do in this important area would be highly unscientific and counter-productive.[24]

Traditional knowledge should not be a sole property of an individual, it should benefit community on large. In the present situation, TK worth is increasing, and the most important issue now becomes that traditional community's contribution in protecting and carrying this forward through generations is aptly considered and recognized. Local communities are using TK as a tool of their sustainability and community development since they are closely related to natural environment, overall benefitting society at a large.[25] A protective mechanism should exist that protects TK of a community from people claiming patents over it.[26] There exists an IPR protection aspect for TK of such communities which provides protection, prevents exploitation, give benefit and empowers.[27] For an example, the indications given in an opposition Exhibit 13 (1962/MUM/2008): "It is strength promoting, aphrodisiac, immuno-potentiator, anti-ageing, anti-oxidant, complexion promoting, maintains pregnancy, intellect promoting, immuno-

modulator, mood elevators, promoting bodily bulk, slimming, scarification, luster promoting, memory enhancer, nutrient, providing longetivity, anti-wrinkle, strengthening capacity of all sense organs, male infertility, tuberculosis, pyrexia, diseases of female genital tract, seminal disorder, diseases of the spleen, piles, anorectal mass, haemorrhoids, anaemia, hyper-bilirubinaemia, malabsorption syndrome, inguinal hernia, vomiting, abdominal lump, ozaena, sinusitis, hiccup, cough/bronchitis, anorexia, dyspnoea, disease of the abdomen, leucoderma, vitiligo, dyspnoea, psychoneurosis, cachexia, insanity,mania, epilepsy, diseases of the mouth, diseases of the eye, diseases of the head, flatulence, constipation, diarrhoea, menorrhagia, metorrhagia, jaundice, urinary disorder, liver disease, tumor, abscess, fistula, haemorrhagic disorder, excessive perspiration, spleen disease, scorpion bites, toxicity due to contaminated food, poisoning, premature grey hair, marasmus, obesity, chronic suppurative otitis media, phimosis, immuno suppresive, emaciating disease".[28]

It seems that considering the above said formulation with multi-ingredient (>25) and non-specific, unsubstantiated and endless indications as a 'prior art' to invention applied for patent having specific composition with a single indication -proved by the modern scientific tests is absolutely unreasonable; against the spirit of intellectual property. As per the applicant unsuccessful submission, "There is no single mention of the treatment of 'sickle cell disease' in the prior-art. Treatment of 'anemia' cannot be equated to treatment of "sickling" of RBCs which is a well-defined genetic disorder and you need a composition which has effect on sickling of RBCs. Otherwise general anemia could be present in pregnancy, malnutrition, protein deficiency, Iron deficiency etc. Our product is not meant for correcting such anemia."

Many of applicants during prosecution of their applications for patent have submitted that their invention is something which is never known to any one because the inventor(s) have developed painstakingly a composition with specific herbals for specific disease. These cannot be considered a traditional medicine in the first place. The drug is meant to be holistic in the sense it caters to different complications, present in the disease and make the person lead almost normal life. Discovering other species of a plant having same activity by routine experimentation is not considered inventive (Patent Application No. 31/DEL/2008).[29]

Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Materials[30]

It has been noticed that the Indian Patent Office is granting patents on the invention based on bio-resources obtained from India and the associated use of traditional knowledge.[31] Surprisingly, in-spite of the fact that many patent office world-wide are denying grant of such applications for patents particularly on the basis of the prior art which may be retrieved from the Traditional Knowledge Digital Library (TKDL) of India. Therefore, it is necessary that due-diligence be exercised while processing such patent applications relating to TK and/or biological materials. Accordingly, the following compliance guidelines are issued in the matter.

Application Screening

All applications for patent relating to TK are identified, screened and classified as 'traditional knowledge' by RECS Section. The RECS in-charge should take due care that no case relating to TK should be wrongly screened and classified. The traditional knowledge application screening is an administrative process to facilitate the examination and to indicate that the subject-matter of the application is significant and has significance in the context of traditionally known substances, articles or processes used for preparing them or their use. System administrator may make parted screening fields in the module namely, TK-Chemical, TK-Biotechnology and TK-Mechanical. Inspite of the strict screening at office, it seems that some applications might have been wrongly classified in other fields like 'Traditional Knowledge Chemical' instead of 'Traditional Knowledge Biotechnology', for example, Patent No. 312803.[32]

Application Examination

As per the guidelines, the Examiner needs to carry out a careful prior-art search in TKDL and other databases for application using bio-material or the associated TK. The copy of the citation (English translated) which are made from TKDL should be sent along with the Examination Report (FER). However, in practice, it was noted that hardly such translated citation was arranged with the examination

report; but the same may be arranged on the applicant's request.

Assessment of Novelty and Inventiveness

The following guiding principles are followed in assessing the novelty and inventive step for inventions based on bio-diversity and/or the associated TK:[24]

(i) Guiding Principle 1: Applications where the claim(s) relates to extracts/alkaloids and/or isolation of active ingredients of plants, which are naturally/inherently present in plants, such claims cannot be considered as novel and/or inventive when use of such plants are part of TK.

a. *Illustration*: An application where the claims of alleged invention relate to an extract of *Withania* plant. The application can be objected based on the prior art, that the extract of *Withania* root would be useful in treatment of chronic stress disorders such as insomnia, gastric ulcers, hyperacidity, restlessness and depression. Thus, the claims may not be considered 'novel'.

(ii) Guiding Principle 2: Plant combinations with identified therapeutic effects with further plants with the same identified therapeutic agents wherein all plants are previously known for the treatment the same disease is usually considered to be an obvious amalgamation.

a. *Example:* Patent Application No. 188/DEL/2004, wherein the specification does not show that the particular amounts of components in combination as claimed, delivers enhanced results than if used in other amounts. In lack of some unanticipated results from the claimed parameters, the claimed working conditions are considered obvious.[33]

(iii) Guiding Principle 3: In case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that an amalgamated product encompassing this identified active component would be effective for the treatment of same disease. Implementing such principles, most of applications were found to be obvious. It may be understood, either such value additions which may not be patented, may be protected either some other tools like 'Utility Model' which have easy norms to get such IPR protected or may be the trade secret. Therefore, a skilled artisan familiar with the cited references and interested in improving the efficacy of the compositions/ formulations taught in the cited documents, would have sufficient guidance to add, without the exercise of inventive skills.

a. *Example 1:* Patent Application No. 1734/DEL/2007, where, three ingredients (neem, camphor and sesame) as claimed, together in a single composition useful in treatment of eczema where the said prior art documents do not teach the specific amounts of the components and the process parameters as claimed in the instant application. However, it would be obvious to a 'Person Having Ordinary Skill in the Art' to modify conventional working conditions such as amounts, temperature, pressure etc. This is needed because it is deemed to be merely a matter of sensible choice and regular optimization and which fits within the purview of the skilled artisan.[34]

b. *Example 2:* Patent Application No. 1735/DEL/2007, where a skilled artisan familiar with the cited references and interested in improving the efficacy of the compositions/ formulations taught in the cited documents, would have sufficient guidance to add, without the exercise of inventive skills, the ingredients (*Piper nigrum* and *Iris ensata* Thumb) as claimed, together in a single composition for use in the treatment of sinusitis.[35]

c. *Example 3:* Patent Application No. 172/DEL/2007, where the experimental results of Clinical studies on vitilago submitted during the hearing show that the instant claimed composition have a better effect, yet this is not enough to prove the alleged unexpected results because a person having ordinary skill in the art would have enough guidance after reading the cited prior art documents to expect such success after combining babchi, bhangra, sulphur and geru. In lack of some unexpected results from the claimed parameters, this optimization of working conditions is considered obvious.[36]

d. *Example 4:* Patent Application No. 1397/DEL/2005, where that as *Schisandra chinensis* is known for treatment of ailments associated with diabetes, then it is obviously expected by a skilled artisan that a combination having the said known ingredient with other ingredient *viz*. *Cannabis indica* and *Hippophae rhamnoides*, which possess active ingredients having protective effects on vital organs, must be effective for treatment of diabetes related ailments. The above teachings provide rational anticipation of success that would

motivate a person skilled in the art to use the said plant extracts to develop such the claimed composition.[37]

(iv) Guiding Principle 4: Discovering the optimum or workable ranges of traditionally known ingredients by routine experimentation is not inventive. In case of inventions related to best selection of or feasible sequence of ingredient, this is to be kept in mind that the combination of an exact range of identified ingredients is not inventive since the selection of best or workable range is well within the expectation of a person skilled in the art.

a. *Example 1:* Patent Application No. 1695/DEL/2006, where based on the teachings of the prior-art documents, it can be concluded that as the ingredient neem is known for prevention against storage insects, then it is obviously expected by a skilled artisan that a combination having the neem as known ingredient with other known pesticidal ingredients (*Rauwolfia* and *Eucalyptus)* must be effective for control of storage pests, therefore, inventive merit of the claims cannot be acknowledged. It is observed that the said prior art documents do not teach the particular part of plant used and their ratio's as claimed in the instant application. However, it would be obvious to a person having ordinary skill in the art to modify required traditional working conditions as it is supposed to be merely a matter of well-judged selection and which is well within the purview of the skilled artisan. In lack of some unexpected results from the claimed parameters, this optimization of working conditions is may considered obvious.[38]

b. *Example 2:* Patent Application (No. 1734/DEL/2007, 1735/DEL/2007, 172/DEL/2007, 1346/DEL/2006, 1397/DEL/2005, 1864/DEL/2006) which does not disclose any example or data to show any surprising or unexpected results of the composition as claimed. Also, there are no examples or data to show that the particular amounts of components in combination as claimed delivers enhanced results than if used in other amounts. In absence of some demonstration of unexpected results from the claimed parameters, this optimization of working conditions is considered obvious. It is noted that the prior art as mentioned by the examiner, do not teach the specific ratio's of the composition and process parameters as claimed in most of the applications for patent.

It is noted that the process steps, as claimed in many such applications for patent are routine experimentation steps and are general state of art for a person having ordinary skill in the art who would be motivated to use the same for reaching at the claimed composition in view of the cited documents. In this context, there is an observation made "Even if information is neither disclosed by a specific item of prior art nor common general knowledge, it may nevertheless be taken into account as part of a case of obviousness if it is proved that the skilled person faced with the problem to which the application for patent is addressed would obtain particular information as a matter of practice. For example, if the problem is how to formulate a particular pharmaceutical substance for administration to patients, then it may be shown that the skilled formulator would as a matter of fact begin by establishing definite chemical and physical features of that substance (e.g. its aqueous solubility) from the available data and literature or by simple routine testing. If so, it is rightful to acquire that information into account when reviewing the obviousness of a specific formulation. But that is, because it is apparent for the skilled person to attain the information, not because it is of common general knowledge.[39]

It is noted that numerous applications failed to comply Section 3 (e) where the specification does not disclose any example or data to show any surprising or unexpected results of the composition as claimed. Also there is no example or data to show that the particular ratio of components in combination as claimed delivers enhanced results than if used in other ratios. In deficiency of some unexpected outcome from the claimed parameters, such optimization of effective conditions is considered not inventive. It is observed that the claimed process step(s) as in many patent applications are mere usual testing step(s) and are general state of art for a person having ordinary skill in the art who would be motivated to use the same for getting at the claimed composition in view of the said citation(s).It is noted in the matter of rejected patent application that the fact that the applicant has failed to comply with the requirements of outstanding objections, Assistant Controller of Patents and Designs refuse to proceed further with such patent application.[40]

(v) Guiding Principle 5: It is observed that in many such applications, the cited reference(s) do not specifically teach adding the ingredients in the amounts claimed by the applicant, however the references does teach the ingredients of the claimed composition. The amount of a specific ingredient in a composition that is used for a particular purpose is a result effective parameter that a person having ordinary skill in the art would routinely optimize. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. It would have been customary for a person having ordinary skill in the art to determine the optimum amount of each ingredient to add in order to best achieve the desired result(s). Therefore, no inventive merit may be acknowledged in the selection of ranges of particular ingredient.

It is observed that many specifications do not disclose any example or data to show any surprising or unexpected results of the composition as claimed. Also there are no examples or data to show that the particular amounts of components in combination as claimed delivers enhanced results than if used in other amounts. In absence of some revelation of unanticipated results from the claimed parameters, these changed working conditions are considered obvious. In an application no. 308/MUMNP/2008, it was observed that the references as cited educate that the anti-plasmodial activity of *Brucea* plant which is not exactly *Bruceamollis.*[41]

If one species of the plant possess anti-plasmodial activity, there shall be reasonable expectation of success and motivation for a person having ordinary skill in the art to use another species of the said plant part for testing the anti-plasmodial activity. The cited prior arts teach methanolic chloroform and methanolic aqueaous extracts of *Bruceamollis* roots. Discovering other species having same activity by usual testing may not be considered inventive where the general conditions of a claim are disclosed in the prior art.[42]

(vi) Guiding Principle 6: Application where multiple ingredients are known to have the same therapeutic activity as per associated TK, taking out one single ingredient out of them cannot be considered as inventive.

Illustration: Claim(s) relate to extract of *Zingiber zerumbet* treating inflammation and also helpful for Asthma and other related allergic disorder. Prior-art discloses use of *Zingiber zerumbet* along with few other ingredients for the treatment of inflammation and Asthma and therefore, the multi-component formulation comprising *Zingiber zerumbet* have the same therapeutic activity (i.e. anti-bronchial asthmatic), cannot be surprising. Hence, a person like person having ordinary skill in the art would have been motivated to arrive at the invention without exercise of inventive skills.

(vii) Guiding Principle 7: Claim(s) where individual ingredients are known for the treatment of a disease as a part of associated TK, then it is obvious that a combination product comprising these known ingredients with further plants with the same known therapeutic effect would be more effective than each of the medicinal plants when applied separately (additive effect) and therefore cannot be considered inventive.

Illustration: An application for patent where the claim(s) relate to a composition comprising of ingredients of *Calendula officinallis*, *Aloe vera* and *Centella asiatica* as healing agent and for treatment of wound while prior-art discloses use of said plants for the treatment of wound and as a Cicatrizant/healing agent. Thus, the combination of these plants would be obvious for the treatment of skin diseases and healing of wounds and no way considered inventive. The combination of a plant with a known therapeutic effect with further plants with the same known therapeutic effect, wherein the ingredients of all such plants are already known for treating the similar disease is considered to be an evident combination. It would usually be anticipated the additive effect that combinations of ingredients of such plants would be more effective than each of the medicinal plants when applied, separately.

It is also noted that the representation by way of pre-grant opposition under Section 25 (1) of the Act was filed in some cases. The ground of such oppositions was traditional knowledge. Mostly such pre-grant opposition filed by opponent, Council of Scientific and Industrial Research, India. These representations were considered and a notice along with a copy of the representation was forwarded to the applicant's agent for filing reply statement and evidence, if any, within the prescribed time i.e., three months from the date of the said notice with an intimation to the opponent.

Non-Admissibility of Newly Added Amended Claim(s)

In many applications, it was observed that during prosecution, amended claim(s) which were newly added were not allowed as the amendments were not made by way of disclaimer, correction or explanation. The claims were not allowed as the scope of the claims had been changed from the extract and method (process) which was claimed earlier.[43] In some applications, where the claims as amended were not fully supported by the original description with working examples. Therefore, the amended claims were not allowed as they did not meet the requirements of Section 59 of the Patents Act, 1970. Various concerns such as TK should be included under which Intellectual property or on the first place should TK be considered as IP, or the present legal system for TK protection is good enough or not, case studies are to be addressed properly, ensuring proper control of local communities over TK and so many others. Addressing these issues correctly will protect the interest of local communities and administer improper use of TK.[44] There is a very vital need to protect and preserve TK on global level through rules, regulations and laws as the existing laws are insufficient enough to protect local TK.[45, 46] If these concerns are addressed properly with guidelines suitable enough to provide protection, then third party claims can be avoided.

Conclusion

This study overall highlights some major observations on refusal grounds of Patent applications in India in the field of 'Traditional Knowledge Biotechnology' and it aims at formulating clear cut basis for refusal of TK patent applications. In view of above discussed guiding principles, it can be concluded that claim(s) of such applications lacks both novelty and inventive-step(s) and hence does not amount to an invention under the Patents Act. In view of above discussion one can conclude that there are many tiny decisive factors which should be watched over during filing of a patent application. If these factors are considered and are taken care of, then filing of patent application in the field of traditional knowledge biotechnology in India will become more cost effective and time efficient. We can conclude with the remark on patent protection strategies and suggestions in the field of invention 'Traditional Knowledge Biotechnology' based on examination reports and the prosecution history that the trend of filing application for patents in this field is high, due to the rapid development of innovations based on traditional knowledge particularly associated with bio-resources or the biodiversity. However, due the patentability issues in the subject, especially in documented traditional knowledge, it is generally lower than that in other fields. However, as a typical experimental subject, patents in this field are faced with a situation of underestimating the innovation level of the invention during the examination process, due to the strong predictability and strong subjectivity of the examination of such applications. Meanwhile, some factors that affect patent examination in the field of biotechnology, such as social ethics, change rapidly with the rapid development of both society and technology. Such rapid change also changes the patent examination policies and standards correspondingly and frequently. For example, in order to meet the needs of technological innovation and social development, in the latest version of the Guidelines for Patent Examination and other similar official documents. It is important to understand and grasp such dynamic changes of the examination, which would help the applicant (or patentee) to obtain and maintain the patent rights, and protect legitimate rights and interests. Due to space limitations, the examination and trial dynamics in this technical field would be analyzed from the one hundreds articles and perspectives of data and sufficient disclosure of the description, support of biological resources and the associated traditional knowledge, and technical suggestion in inventiveness evaluation. Corresponding strategies and suggestions are provided on such bases.

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