

Traditional knowledge patents: New guidelines or deterrents?

The Indian Patent Office (IPO), on November 8, 2012, has announced new guidelines for issuing patents based on traditional knowledge (TK).^[1] The IPO already has patent laws in place, and the new guidelines have evoked a strong response from the industry and scientific community.

At present, patents are not granted for – non-obvious inventions, for cases already documented in the literature, for compounds naturally occurring in nature such as piperine, taxol, baccosides and cultivars, for a novel use of a known substance and for frivolous inventions.

The IPO was prompted to draft a set of revised guidelines because certain issued patents had to be revoked on realizing that they were incorrectly granted for inventions related to biological resources obtained from India, without complying to the existing laws. However, many feel that the IPO has not sufficiently engaged experts in discussing these guidelines. Hardly two weeks were given for inviting comments and suggestions on such an important document. The final version of the guideline was released on the 18th of December 2012, without taking much cognizance of the responses and comments received from the scientific community. Sadly, no cogent reasons were offered for not accepting valuable suggestions from experts.

The new guidelines provide description of the existing laws for the TK patents, and acknowledge the pivotal role played by India in bringing protection of TK at the center stage of the International Intellectual Property System.

The guidelines also state that the IPO already has established laws for TK patents and since 'TK' by its very definition comes in the public domain, any patent application related to TK does not qualify as an invention under the section 2(1) (j) of the Patents Act, 1970. As per WIPO, though it is difficult to coin a concise definition of the term TK, "Traditional knowledge refers to knowledge systems, creations, innovations and cultural expressions which:

have been transmitted from generation to generation; are regarded as pertaining to a particular people or its territory; and are constantly evolving in response to a changing environment."^[2] Thus, the above guideline would exclude the patenting of even the convincing, independently developed inventions, which in some remote way would be relating to TK.

The aim of the patent system is to promote continuous improvement by encouraging innovation. It would then be easy to refute even the legitimate claims for patent based on TK inspired inventions on the basis of prior art. Hence, it is necessary to consider foolproof mechanism to understand and differentiate typical knowledge available in TK and TK inspired innovations. The important role of TK inspired innovations in health care and drug discovery is globally recognized.^[3]

As per the guidelines the claimant is required to declare the "geographical origin" of the biological material used in Form 1. The permission from the National Biodiversity Authority is essential for use of any biological material from India. If the biological material used is not from India, the claimant is required to declare the "country of source and geographical origin." Mentioning the geographical origin requires the tracing of the history or lineage of the material used. The source and lineage of the material used for exhibiting the efficacy would be unnecessary in some cases where patents are applied for innovative processes or steps applied in a process. The guidelines however, do not mention a clear relation between the nature of invention and the requirement to disclose source and geographical origin.

The guidelines further necessitate appropriate screening of the TK related applications by the examiner of the Patent Board. They state certain guiding principles for examination of TK applications and specify that screening should be carried out with a thorough anticipatory search of the Traditional Knowledge Digital Library (TKDL). The proposed practice will certainly be useful to the applicant to identify and rectify any deficiency on his part and to comply with the procedural requirement of the law. However, certain details given in these guidelines pertaining to "assessment of novelty" and "assessment of inventive procedure" such as those mentioned below need to be reconsidered.

The guidelines refute any claims for patents pertaining to

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the extracts/alkaloids of the plants already mentioned in the TKDL as “prior art.” They state that a similar effect is expected from the derivatives and extracts of the plant, when the plant itself has been mentioned in the TK as “prior art.” Hence, a claim made for patenting such extracts/ alkaloids does not stand on the “novelty” criteria. It is argued that credit should be given to the objective with which the compounds have been isolated and the manner in which they have been used in the invention, particularly when prior art does not mention the particular extract/alkaloid from the plant in a clear or implied manner and the patent application already mentions the reference to the plant as “prior art.”

The guidelines state specific guiding principles for the assessment of the “Inventive Step” criteria. These state that a “combination” of certain drugs which are already known to exhibit a particular action individually, cannot be considered as inventive because the “additive effect” of such drugs would be an obvious anticipatory consideration based on “prior art.” Also that, in case, a set of multiple ingredients are said to have a particular therapeutic effect, taking out one particular ingredient does not stand as innovation either.

However, to presume the additive effect of a combination of drugs, even when we know the individual properties of each of the ingredients, would be incorrect. Multiple ingredients in a combination may exhibit particular actions owing to several factors like synergistic effect, effect observed due to a mere admixture of particular ingredients or a combination where certain ingredients merely act as “adjuvants” and help in enhancing the effect of the drug. Research directed at designing novel preparations, extracts or formulations should be considered patentable because it requires immense effort, research and development to come up with combinations that show successful synergistic effects. The US patent issued for bioavailability enhancing action of piperidine is an example of this type.^[4] Giving importance to the problem which the invention seeks to solve is more important, and hence the validity of any application should be decided on a case to case basis.

Patents may be granted for “unique” combinations, like those involving the selection of specific ingredients, in specific proportions, processed under specified conditions. These unique formulations may be aimed at displaying better synergy or antagonistic activity, better stability and better absorption. These may even be unique with inventive steps like addition of perfume/flavor, stabilizers or penetration enhancers. Uniqueness may also be in the standardization of the product or in the devising of novel delivery systems with the help of special apparatus for enhanced effect.

While TK refers to the practices within the communities, the patent rights create monopolies restricting their benefits

to the owners of this knowledge. Any kind of knowledge is an entity which constantly evolves in response to a changing environment, and hence TK which is transferred from generation to generation needs continuous research and innovations.

These innovations may involve processes which aim at devising better extraction techniques, better dosage forms or stable formulations. Innovative processes may aim at improving the bioavailability of the drug or establish synergistic/antagonistic activities. These may involve biotechnological interventions with an aim of standardization, fractionation or isolation of active ingredients of the drug. Such research initiatives should essentially be made patentable, acknowledging the research and development efforts. These involve a lot of insight, time and money, which under no circumstances can be termed as obvious. Acknowledging the efforts provides essential motivation for scientists to undertake research and encourages the herbal/ biotech/ nutraceutical industries to file patents. This however, cannot be expected to happen under the newly proposed guidelines.

The very aim of the patent system is to encourage scholars/ investors to disclose their inventions for the good of the general public. In return for this, the investors are granted authority to prevent others from using or practicing their invention. Increasing the threshold for the novelty and inventive step assessments for grant of patents might prove detrimental to the filing of quality patents for products which are in any way related to TK. There is also the fear that such superfluous patent guidelines for TK might serve as a deterrent for research in these areas. The stringent patent laws would be a disincentive for the students of core sciences to work on any project inspired from TK involving traditional systems like Ayurveda, Homeopathy, Unani or Siddha.

Such a discriminatory approach would give rise to the practice of maintaining inventions based on TK as trade secrets and avoiding their protection with patents. Inventions would not be commercialized and there shall be no sharing of economic benefits in the absence of an environment conducive to grant of patents. Such a scenario would be a loss for both, the consumer as well as the holder of the resource or invention, for neither would be gaining anything. Hence, it is the need of the hour to present a system which would provide for industrial development without compromising the rights of indigenous people.

It is good that the IPO proposes to publish a list of all patent applications granted on or after 1st July 2012 on its website. While such precautionary steps and guidelines may be intended at protecting the Indian TK, the IPO should try to remove the ambiguity and ensure proper harnessing of TK.

In short, the new guidelines may not encourage innovations

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and actually turn out to be deterrent for discovery and development of novel pharmaceutical and nutraceutical substances by industries and scientists. We hope that IPO will take serious cognizance of experts' opinions and make suitable modifications to ensure innovations are encouraged, promoted, respected not discouraged.

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Editorial Note

J-AIM has successfully completed timely publication of 3 volumes and 12 issues during last three years. The number and quality of submissions has considerably increased from 146 in year 2010 to 361 in 2012 with average acceptance rate of 14%. Although, 86% of the manuscripts have been rejected, we have given sufficient opportunities to authors to revise and improve their manuscripts. As a policy, J-AIM considers this as a capacity building exercise to encourage and train budding authors to acquire necessary skills and discipline of scientific publishing. In this process, the role of Editorial Board members and Reviewers is of paramount importance. I personally wish to thank each one of them for sparing valuable time and patience to review the submissions.

As a policy, J-AIM has decided to undertake annual revision of all sections of the Editorial Board and also offer an opportunity for our reviewers to support the journal activities as a member of the 'Editorial Review Board' (ERB). The ERB Members are expected to complete a timely review of at least 60 % of the assigned manuscripts. ERB members are also expected to submit or recommend at least one manuscript to the journal every year. The revision of the ERB is based on the overall performance of the reviewers. J-AIM has completed the process of revision of the ERB for the year 2013- 14. The revised list of Senior Editors and Editorial Advisory Board will be published on line and in print version of J-AIM. We trust that all the members of various sections of Editorial Board will kindly consent and continue to help guide us.

We thank all reviewers who may not be formally included in the Editorial Review Board but have worked diligently towards enhancing the quality of articles published in J-AIM. The efforts of these reviewers are acknowledged in the first issue of every year.

After I returned to University of Pune in October 2012, the Editorial Office is functioning from the Interdisciplinary School of Health Sciences, University of Pune. I wish to thank the Vice Chancellor Dr W.N. Gade for allowing and encouraging J-AIM activities in the University campus.

J-AIM deeply appreciates support from the members of Editorial Board who are volunteering services purely in honorary capacity. To improve efficiency and processes, I-AIM has now revised the operational structure. Eminent Ayurveda scholar G G Gangadharan will be the new Executive Editor along with Girish Tillu and Vivek Sanker as Associate Editors. I-AIM has also designated young scholars as sectional Assistant Editors. This includes Kishor Patwardhan (Theoretical), Namyata Pathak (General), Sriranjini S.J. (Clinical), Supriya Bhalerao (Experimental) and Vinay Mahajan (Statistics). I wish to place on record my appreciation to the outgoing Associate Editor Shrivathsa B who sincerely worked to ensure timely publication of J-AIM for the last three years.

J-AIM wishes to thank all the authors for preferring J-AIM for submissions of their valuable work. On behalf of the Editorial Board I wish to assure them that J-AIM would continue to offer transparent, efficient and ethical processes thorough critical yet constructive peer review system.

Lastly, I also wish to thank the entire team of Medknow which is now part of Wolters Kluwer Health for technical support and timely publications.

I am sure J-AIM will continue to progress and emerge as one of the top sought and cited scientific Journal in the field of health. Let's continue to work for this goal together.

Bhushan Patwardhan
Editor-in-Chief