

**Sub-Regional Experts Meeting in Asia on Intangible Cultural Heritage:
Safeguarding and Inventory-Making Methodologies**
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TRADITIONAL KNOWLEDGE DIGITAL LIBRARY

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CONTENTS

- I. INTRODUCTION
- II. PROBLEM DIMENSIONS IN THE INDIAN SCENARIO: SCALE OF MISAPPROPRIATION OF DISCLOSED TK
- III. HORIZONTAL INTEGRATION INTO IPO PRIOR ART SEARCH SYSTEMS
- IV. CURRENT STATUS OF TKDL
- V. TKDL: TOOL FOR ACTIVE RESEARCH
- VI. STRATEGY FOR PREVENTING ABUSE AND MISAPPROPRIATION OF TKDL
- VII. REGIONAL INITIATIVES
- VIII. CONCLUSIONS

ANNEX:

- I. FORMULATION TRANSCRIBED FROM ANCIENT AYURVEDIC TEXT
- II. FORMULATION TRANSCRIBED FROM ANCIENT UNANI TEXT
- III. ACCESS AGREEMENT
- IV. OVERVIEW OF INDIAN SYSTEMS OF MEDICINE

I INTRODUCTION

1. The grant of wrong patents linked to traditional medicines, which is either based on what is already a part of the traditional knowledge of the developing world, or a minor variation thereof, has been causing a great concern to the developing world. The origin of Traditional Knowledge Digital Library (TKDL) goes back to the legal battle waged by Council of Scientific and Industrial Research (CSIR) from India for re-examination of patent No. US 5 401 504, which was granted for the wound healing properties of turmeric filed by two US based Indians. In a landmark decision, United States Patent and Trademark Office (US PTO) revoked this patent after ascertaining that there was no novelty, the innovation having been used in India for centuries. This was the first time that a patent based on the traditional knowledge of a developing country was challenged successfully and US PTO revoked the patent. The case of the revocation of the patent granted to W.R. Grace Company and US Department of Agriculture on Neem (EPO patent No. 436 257) by European Patent Office, again on the same grounds of its use having been known in India, is another example.

2. Following these experiences of wrongful patenting, TKDL project was formally established in June 2001 through a memorandum of understanding between Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) (erstwhile Department of Indian Systems of Medicine and Homoeopathy, ISM&H) and National Institute of Science Communication And Information Resources (NISCAIR) (erstwhile National Institute of Science Communication, NISCOM) in order to prevent further misappropriation of disclosed Traditional Knowledge (TK) through similar wrong patents in the future.

3. The first presentation on TKDL was made at international level during third session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in June 2002. Details are present in document WIPO/GRTKF/IC/3/6, paragraphs 38 to 42.

4. TK documentation lacked a classification system. Therefore, a modern classification system based on the structure of International Patent Classification (IPC) was evolved. This has been established for Ayurveda and Unani and has been named as Traditional Knowledge Resource Classification (TKRC). The concepts of TKRC were presented at the committee of experts meeting of IPC Union in February 2001, which constituted a WIPO-TK Task Force comprising United States Patent and Trademark Office, European Patent Office, China, Japan and India to further study the possibility of linking and/or integrating TKRC developed by India with IPC. Subsequently, the Task Force in February 2002 recognized the need of having more detailed level of classification relating to medicinal plants and recommended for adding a subclass A61. In February 2003 the Committee of Experts recommended:

- inclusion of 200 subgroups on TK against earlier single subgroup on medicinal plants (A61K 35/78);
- linking of TKRC to IPC, and continuation of work on biodiversity, TK and TCE.

Subsequently, in the Thirty fifth meeting of committee of experts of IPC Union held in October 2004, as a result of the presentation made on TKDL and concordance table between IPC and TKRC, a decision was taken to link IPC with TKRC which will be posted at the WIPO website. This is likely to have significant impact on the system of search and

examination while granting patents in the area of traditional knowledge whereby the possibilities of grant of wrong TK patents shall get significantly reduced.

II PROBLEM DIMENSIONS IN THE INDIAN SCENARIO: SCALE OF MISAPPROPRIATION OF DISCLOSED TK

Background to TKDL

5. As indicated by the Indian experience, defensive and positive protection of TK should be fully integrated within a national TK protection and documentation policy. TKDL has an important function in each of these aspects.

Tool for defensive protection

6. Patent examiners use available resources for searching the appropriate non-patent literature sources, when considering the patentability of any claimed subject matter. Patent literature, however, is usually wholly contained in several distinctive databases and can be more easily searched and retrieved whereas non-patent literature *prior art* may be scattered diversely. Therefore, TKDL serves as a more easily accessible non-patent literature database that deals with traditional knowledge subject matter.

Tool for active research

7. It has potential to act as a bridge between modern science, modern medicines and Traditional Knowledge, and can be used for international advanced research based on information on Traditional Knowledge for developing novel drugs. In fact, there are several examples where intensive research on TK has successfully led to creation of drugs.

Complementarity with positive protection

8. Defensive protection of disclosed TK through TKDL is only the first step within a comprehensive TK protection policy of India. Defensive measures must be supplemented by positive measures, such as benefit sharing, in order to provide adequate protection for TK holders. Therefore, it was concluded at national and regional levels, that a positive legal protection framework should complement TKDL systems, in order to safeguard the interests of TK holders. At national and regional levels, work is under way for *sui generis* protection frameworks, which will protect TK, whether disclosed or undisclosed, against misappropriation in form of commercial use without benefit sharing, etc. Since biopiracy studies have shown that most misappropriation of Indian TK occurs outside the region, use of TKDL is being internationalised and need for *sui generis* protection also need to be extended to international level.

Features and functionalities of TKDL

Bridge between TK as prior art and patent examiners

9. TKDL database acts as a bridge between ancient traditional knowledge in the original languages (which may be in Hindi, Sanskrit, Urdu, Persian, Arabic, Tamil, etc.) and a patent examiner at a global level, since the database will provide information on modern as well as local names in a language and format understandable to patent examiners. The gap on lack of *prior art* knowledge is minimized. The database has sufficient details on definitions, principles, and concepts to minimize the possibility of getting accepted minor /insignificant modifications as novelty.

Traditional Knowledge Resource Classification (TKRC)

10. Traditional Knowledge documentation lacked a classification system. Therefore, a modern classification based on the structure of International Patent Classification (IPC) was evolved. This has been attempted for Ayurveda and has been named as Traditional Knowledge Resource Classification (TKRC). It was essential to seek international recognition to this innovative effort. Therefore, linkages have been established with IPC Union at World Intellectual Property Organization (WIPO) Geneva as mentioned in introduction.

Knowledge conversion

11. Documented Knowledge available in local language i.e. Sanskrit, Hindi, Arabic, Persian, Urdu, Tamil etc. is transcribed into TKRC symbols by Experts. The Patent Examiner helps the Experts for preparation of a concordance between TKRC and IPC, which is then a part of the software. The converted version of all the TKRC symbols is thereafter ported in the database. The knowledge available in local language can be presently converted in five international languages i.e. English, German, French, Japanese and Spanish. The converted version of the formulation is easily understood by a layman.

12. TKDL software with its associated classification system i.e., TKRC converts the available documented Knowledge into multiple languages. It may be noted that the software does not do transliteration rather it does knowledge based conversion, where data abstracted once is converted into several languages by using state of the art technology such as Unicode, XML and Metadata methodology. Software also converts traditional terminology into modern terminology, for example *Kumari* (local name) to *Aloe barbadensis Mill.*, *Masurika* (Sanskrit name of a disease) to small pox etc.

Examples of Ayurveda and Unani formulation

13. The example of one of the Ayurveda formulation and its transcription into five international languages in patent application format is given at Annex.1 and an example of Unani formulation is at Annex.2

III HORIZONTAL INTEGRATION INTO IPO PRIOR ART SEARCH SYSTEMS

14. The primary objective of creation of the TKDL database is the defensive protection and prevention of misappropriation of the disclosed TK existing in India. The purpose of creating the database will be achieved only when the database gets integrated with the international intellectual property office activity of search and examination of the prior art search systems. On the other hand, it is also essential to ensure that this database is only used for search purposes and must not act as an easily available tool for enhancing bio-piracy. In view of the above, an access agreement has been prepared which gives the obligations on part of the database provider and user, and needs to be signed by both the parties for access to database. The access agreement is placed at Annex.3

Training of IPO staff

15. The usage of the database by the patent examiners at the international patent offices may be done rapidly by either the IPC symbols, the TKRC symbols or by using the search engine where simple and advanced search using boolean search are possible. Since the TKDL database will be used for the first time by the international patent offices, if any difficulties are encountered, a short-term (web based) training or even exclusive training programs based on request will be imparted to the patent examiners for a meaningful utilization of the database in search and examination process

Technical support

16. The technical support will be extended by NISCAIR, in case required by the patent offices. Assistance in patent search on TK will be made by horizontal integration of TK experts from NISCAIR with the examiners of patent offices.

Access 24/7

17. The TKDL database having secured access will be available at its website, which will be provided 24/7 access.

IV CURRENT STATUS OF TKDL

TKDL project team framework

18. TKDL integrates multidisciplinary skills in Traditional Knowledge, classification expertise, International Patent Classification, Information Technology, language experts in French, German, Spanish and Japanese. Therefore, project team represents above skill set.

19. The IT Experts create the software, provide the software support system and develop the portal. The TK Experts identify the formulations, enter the formulations, edit and verify the formulations. Patent examiners are responsible for finding out the appropriate IPC codes and hence develop a concordance between the IPC and the TKRC for integration of the appropriate IPC codes for each of the formulations. Scientists validate the scientific names of the plants, which appear in the formulations. Technical Officers carry out the scanning of formulations from the original texts for integrating these in the database, which appear along with the formulations. Eminent TK Experts who are retired TK Experts verify and validate each of the formulations that has been included in the TKDL database.

TKDL available ready for access

20. Indian Systems of medicine - Ayurveda and Unani – 57000 and 48000 medicinal formulations are available for access and search for prior art i.e. 10 million A4 size pages are ready for access on the website in five international languages English, French, Spanish, German and Japanese along with the references, scanned original formulations and illustrations on most of the bio- and mineral resources used in the formulations.

TKDL under progress

21. Ayurveda 2100 and Unani 29000 medicinal formulations are being transcribed i.e. 21 million pages will be available for access by December 2006. TKDL on Siddha system of Medicine has also been initiated and TKRC is being made. Transcription of 10000 Siddha formulations will be initiated from January 2006.

Likely date of completion

22. The project on TKDL Ayurveda, Unani and Siddha are likely to be completed by December 2006 when the data will be included in the portal.

V TKDL: TOOL FOR ACTIVE RESEARCH

Brief introduction of ISM

23. Documentation of TK in India has focused to date on the codified Indian Systems of Medicine with a view to break language barriers between the original languages in which these systems are codified and the patent examiners. The Indian Systems of Medicine consist

of Ayurveda, Yoga, Unani, Siddha and Naturopathy. These systems are indigenous and have over the years become a part of Indian tradition. Ayurveda and Unani system of medicine *are* the oldest systems of medicine in the world, which are still popular and practiced in the Indian sub-continent and other parts of the world. They deal with both the preventive and curative aspects of life. The texts or knowledge of these systems is in various languages such as Ayurveda in Sanskrit and Unani medicine in Arabic /Persian /Urdu. For details please see Annex. 4.

Golden triangle of modern science, modern medicine and TK

24. TKDL database breaks the language and format barriers. Hence, TKDL database is a valuable tool for carrying out advanced research for identifying novel drugs through the route of reverse pharmacology. This is possible by the integration of Traditional Knowledge with Modern Medicine and Modern Science. In fact, CSIR, India has new drugs developed using the concept of Golden Triangle. To give, one example, the drug Asmon has been developed by Indian Institute of Chemical Biology, Kolkata for the treatment of Bronchial Asthma. Simultaneously, based on Indian TK TKDL is likely to serve as a valuable tool for carrying out advanced research. Indian system of medicine has well system of traditional medicines i.e. Ayurveda, Unani, Siddha. These system have been practised since origin of creation while documented knowledge dates back to more than 1000 BC, 400 BC,----- respectively and are quite proven. However, all these systems though a part of Indian system of medicine have existed independently. TKDL is a mechanism, which can validate these systems against each other. Thus likely to enhance active research potential based on TK through reverse pharmacology by order of magnitude.

Active research program

25. There is a scope for active research programmes based on TKDL database. As per the policy of the country, the information collected in TKDL can become the basis for development of new pharmaceutical products, which can bring major health care benefits to wide populations in India and abroad.

VI STRATEGY FOR PREVENTING ABUSE AND MISAPPROPRIATION OF TKDL

Access mechanism

26. TKDL is a proprietary database and shall be available for patent offices for preventing misappropriation and for collaborative research.

Patent Offices: Non-disclosure agreement

27. Access to patent offices will be provided freely. However, the access to Patent offices will be based signing of an Access Agreement on non-disclosure, i.e., there will not be any third party disclosure unless it is essential for search purposes. In view of the above, an access agreement has been prepared and is placed at Annex.3.

User Obligations

28. The user obligations are:

- The User shall not disclose any information of TKDL contents to third party unless it is necessary for patent search and examination.
- The User shall use TKDL information only for patent search and examination.
- The User shall provide related information to Provider as and when TKDL is utilized for prior art searches.

- The User shall give feedback on enhancing the features and functionality of TKDL to provider in case considered necessary.

Access for collaborative Research

29. Access to the TKDL database shall be provided on the basis of a bilateral agreement, which shall include non-disclosure and non-complete clauses. The income generation model will be based on well-established principles of Access and Benefit Sharing (ABS). The ABS model may be based on one or more of the following list of non-exhaustive conditions.

30. Collaborative Research and Development and /or Marketing / Commercialization. Joint Ownership and Licensing of Intellectual Property Rights of the products to be created based on the contents of the TKDL, which may include a lump sum initial payment and payment of periodic royalties based on mutually agreed basis, such as agreed percentage of gross turn over of the product(s) concerned.

31. Transfer of technologies including the categories:

- technologies for conservation
- technologies for biotechnological research
- technologies for duplicating the biotechnological inventions
- laboratory techniques
- technologies for selection and screening of samples, but not limited to these technological options alone.

Any other terms and condition that may be found to be mutually beneficial.

VII REGIONAL INITIATIVES

32. The activities with respect to creation of TKDL were initiated in March 2002, when the Governing Board approved the creation of SAARC Task Force on Traditional Knowledge. Nominations for TK Experts were requested from the SAARC Member Countries in October 2002. Fifty-six nominations were received from Member Countries.

Workshop on 'Creation of TKDL for SAARC Countries'

33. A two-day workshop on 'Creation of TKDL for SAARC Countries' was held on 27 and 28 December 2004 at Kamal Mahal Hall of Maurya Sheraton, New Delhi. Eleven delegates from SAARC Member Countries, viz., Bangladesh, Bhutan, India, Maldives, Nepal and Sri Lanka attended the workshop. The workshop was organized by SAARC Documentation centre in collaboration with National Institute of Science Communication and Information Resources (NISCAIR), Council of Scientific and Industrial Research and Department of Secondary and Higher Education, Ministry of Human Resource Development, India.

34. The international resource persons, Mr Mikhail Makarov, Head, International Patent Classification (IPC) Division and Mr Shakeel Bhatti, Global Intellectual Property Issue Division from World Intellectual Property Organization participated in the workshop.

35. The key issues that were discussed include creation of draft Legal and Policy Frameworks for TK protection in SAARC Countries and developing a Technical Framework for Creation of TKDL for SAARC Countries that have emerged as the major recommendations of the workshop.

Salient features of the Draft Technical Framework for setting up of TKDL for SAARC

Countries

36. Draft Technical Framework for setting up of TKDL for SAARC Countries has the following features:

- The preamble deals with the need for creation of TKDL for SAARC Countries, which is severely felt due to the large number of cases on misappropriation of traditional knowledge, particularly, in the SAARC countries.
- The areas of traditional knowledge have been identified which include traditional medicines, biodiversity and genetic resources; traditional foods; oral, communities, tribal knowledge; traditional architecture and construction technologies; traditional agricultural and farmers' knowledge; and traditional cultural expressions.
- The objectives of creation of TKDL identified are:
 - prevention of misappropriation of TK;
 - using TKDL database as valuable tools for carrying out advanced research;
 - use of traditional knowledge for commercial purpose under prior informed consent and access and benefit sharing agreements.
- The different activities that have been identified for the creation of TKDL includes:
 - creation of TKRC, which may be for both codified and non codified knowledge and also for Components of Biodiversity Digital Library for the SAARC countries;
 - identifications of deliverables, time frame and milestones for the TKDL project;
 - use of TKDL toolkit and adopting of technical specifications of standards for the database creation and documentation of the traditional knowledge information wherein the different methods for documenting TK have been enlisted.
- The resource and infrastructure for the creation of TK has also been identified. The details of IT infrastructure required have been classified under five types and the approximate cost for each type of IT infrastructure has been given. It has been recommended that the work may be initiated with type one IT infrastructure, which can further grow with the increase in data volume and workload.
- The skilled manpower requirements for carrying out the collection of data and preparing the database have also been classified under three types. The monthly wages for these experts have been also suggested. It has also been recommended that the manpower requirement that may be deputed for the work initially may be of the type 1 category that can be stepped up depending on the need.
- It has been recommended that the space requirement may be created by the National Focal Point institute along with identification of the coordinator who will oversee the creation of the Digital Library.
- The budget provisions for the type 1 specifications may be provided by the SDC, whereas expenditure towards the subject expert team, creation of space and other miscellaneous expenditure may be met by the SAARC Member States.
- The SAARC Member States, which create the Database, will be the owners of the database. The database may be made available to patent examiners against non-

disclosure agreement for search and examination purposes only. However, a demo version of that database may be made available freely for showcasing of the databases similar to the demo CD that has been created for TKDL Ayurveda.

- A format for sending the proposal has also been provided for submitting the project proposal to SDC.
- It has been suggested that the SAARC Member States may submit the proposal of creation the TKDL to SDC by April 2005 which will be placed before the Governing Board Members for examination, which will further be sent to SAARC Secretariat for approval by the SAARC programming committee and the standing committee. It will further be placed before the Council of Ministers. After the formal approval of SAARC Secretariat the project may be initiated.

Recommendations of the workshop were adopted unanimously by SAARC-IPR Working Group.

VIII CONCLUSIONS

- Documentation of TK is essential for preservation, protection & wealth creation of TK.
- Requirement of documentation are different for disclosed and undisclosed TK.
- Before initiating documentation of TK it is necessary to evolve appropriate classification scheme for structuring TK.
- Traditional Knowledge Resource Classification created by India has got wider international acceptance and has become a basis for enhancing international patent classification for medicinal plants.
- TKDL has been a successful model resulting in creation of several new technologies
- Access to database such as TKDL need be regulated as per national requirements and policies.
- Access conditions need be different for collaborative research and prior art search.
- TK databases are vital resource for creating new IPR and new drug development.
- For protection of TK (positive and defensive) internationally accepted legally binding framework is essential.

[Annex follows]