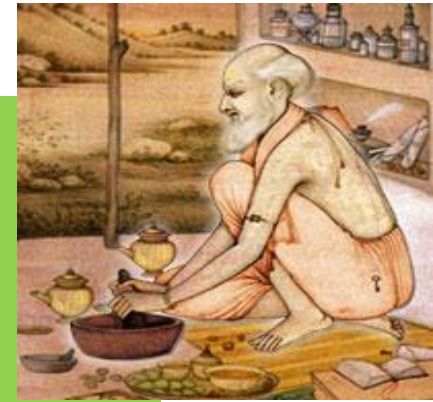


Brainstorming Session on Guidelines for Processing Patent Applications Relating to Traditional Knowledge And Biological Material



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Traditional Knowledge (WIPO)



“Traditional knowledge” or “TK” may be considered as:

- (a) knowledge, know how, skills, innovations or practices;*
- (b) that are passed between generations;*
- (c) in a traditional context; and*
- (d) that form part of the traditional lifestyle of indigenous and local communities who act as their guardian or custodian.*



Section 2(c) of Biodiversity Act “Biological Resources”



*"biological resources" means plants, animals and micro-organisms or parts thereof, their genetic material and by-products (**excluding value added products**) with actual or potential use or value, but does not include human genetic material;*



Section 2(p) of Biodiversity Act "Value Added Products"



“Value added products” means products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form.



Value Added Product



Value added product implies products containing portions/extracts of plants and animals in unrecognisable and physically inseparable form.

For example: Chyawanprash, Isabghol, Pudina Hara, Turmeric creams etc.

- FAQs

The Biological Diversity Act, 2002





- Traditional Knowledge (TK) has been incorporated in TKDL.
- TK which has been disclosed in Ayurveda, Unani and Siddha systems of medicine.
- Sec. 3(p) of the Patents Act, 1970 ‘in effect’ not Patentable.
- Need to be distinguished from invention which may have a TK base but have substantial ‘*value addition*’, meeting patentability criteria of Novelty and Inventive Step.



- Isolation of ‘Vinblastine’ and ‘Vincristine’ from *Vinca Rosea* or Artemisinin from *Artemisia Annua* / Qinghaosu (200 BC) could not be treated as TK or subject of biodiversity.
- *Vinca Rosea* used to be cultivated extensively for extraction
- *Artemisia Annua* cultivated extensively globally for extraction of Artemisinin.





Indian example Safed Musli (*Chlorophytum Borivilianum*) is extensively cultivated and is presently available in the range of 10:1 with regard to availability of cultivated plant vis-à-vis demand for extract / commercial product.





- Characterization of herbs with isolation of marker compounds and study of isolated ingredients for newer diseases (not reported in TKDL) are also being objected to.
- Extensive value addition such as 'drug discovery' (NCE) are also being objected to.





- Biodiversity Act which is repeatedly quoted in the guidelines is extremely deficient in provisions for sustainable development and utilization with equitable benefit sharing.
- While TK or biological resources may be in public domain, it is not fair to say that “*patent relating to TK does not qualify as an invention under section 2(1)(j) of the Patents Act, 1970*”



- Interpretation of Sections 3 (b), (c), (d), (e), (f), (h), (i), (j) and (e) of the Patents Act, 1970 ignoring patentability criteria of Novelty and Inventive Step.
- Sec 6 of the Biodiversity Act refers to biological resources requiring prior permission for grant of patent.
- Biological Resources in its definition excludes 'value added product' (*a well intended exclusion which should be considered during examination of patent applications*)



BD-IPR Agreements



Year wise status of applications	Agreement signed by the Applicant with NBA	Cleared	Applications pending for want of information from the Applicant	Closed Applications
2006-2007	0	0	-	-
2007-2008	11	222	-	-
2008-2009	21	35	-	-
2009-2010	9	16	-	-
2010-2011	4	9	-	-
2011-2012	6	39	-	-
2012-2013	3	22	-	-
Total	54	343*	113	22

* CSIR is yet to execute the Agreements in respect of 231 applications cleared by the NBA.



BD-IPR Agreements



- Agreement and percent of royalty and terms thereof are highly deficient and impracticable.
- The agreement fails to provide exemption for value added use of
 - Biological waste
 - Wholly sustainable self-cultivated and self-harvested material for in-house captive use.



Guidelines Issued By Indian Patent Office



- **Guiding Principle 1:** Extends to isolation of chemical / extracts and industrial application thereof.
- **Guiding Principle 2:** Combination and composition not reported in TKDL are also being cited as not patentable.
- **Guiding Principle 3:** Presumption of obviousness should not be a bar to patentability.



Guidelines Issued By Indian Patent Office



- **Guiding Principle 4:** Discovering the Optimum or Workable Ranges of Traditionally known ingredients by Routine experimentation is not inventive.
- **Guiding Principle 5:** Presumption of obviousness should not be a bar to patentability.
- **Guiding Principle 6:** Presumption of synergy should be avoided.



Guidelines Issued By IPO



- **Para 17:** Source and geographical origin of the biological material – Commercially available product such as well-known fruits and vegetables are also being subject to Biodiversity permissions.
- Ex: Discarded / Bio-waste / Seeds of fruit
- There is no BD or TKDL related issues in pursuing research on naturally and commercially available bio-waste, which in no way affects biodiversity or sustainability.



Circular No. 1 of 2012 by CGPDTM



“Exemption to medicinal plants from the provisions of the Biological Diversity Act, 2002 given by the notification issued by the [Ministry of Environment and forests Notification dated 26th October 2009](#) is available only if they are traded as commodities and the said provisions are very much applicable if the biological resources are used as ingredients for medicine. As such, any interpretation by the Controllers/Examiners of the Office of CGPDTM to see this as an exemption from the Biological Diversity Act would be wrong.

Controllers/Examiners are directed to ensure strict compliance with the aforesaid order and approval of NBA should be sought for any biological resources derived from India and used in an invention for which patent application is filed.”



HC seeks MoEF reply to PIL on Biodiversity Act



- Karnataka High court has asked the Ministry Of Environment And Forests to respond in 6 weeks to a PIL challenging Section 40 of the Biodiversity Act, 2002.
- The petitioners claimed that the MoEFs' 26 October 2009 notification listing 190 plants as Normally Traded Commodities (NTC) includes at least 18 critically endangered plants.
- They said Section 40 of the Biodiversity Act, 2002 allows such unfettered trade in India's biological wealth through an unchannelized power to label something as a Normally Traded Commodity, paving the way for rampant bio piracy.

Source: http://articles.timesofindia.indiatimes.com/2013-01-25/bangalore/36547430_1_recruitment-scam-biodiversity-act-pil



Applications related to Traditional Knowledge, Food & Pharmaceuticals



- The list is compiled without application of mind and purely by word check of TK name and terminologies.
- The sweeping and broad guidelines of listing increases the work of the patent applicants /inventors as well as that of the Patent Office.



Personal Opinion



- Patentability criteria should be applied to all TK based applications justly, by treating TK as prior art.
- Encouragement of sustainable development and protection of IP, further based on indigenous system, will help in improved benefit sharing opportunities on a practically viable model, beneficial to all stakeholders.



Personal Opinion



- The TK list as published on the website of the Patent Office ought to be responded to, by the Industry and professionals, sensibly and scientifically.

