

Genetic Resources and the Patent System: Perspective on Disclosure Requirement in Patent Applications

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The Problem

- Grant of questionable patents to products based on genetic resources
 - Inadequate search and examination system followed in grant of patents for products based on genetic resources
 - No prior art search for traditional knowledge associated with genetic resources
 - No effective examination to finding out obviousness or inventive step considering traditional knowledge
- Prior informed consent and benefit sharing

Prior art search

- Grant of patents only to new products or processes
 - Search for prior publication of the new knowledge disclosed in the patent application
 - Search on published documents
 - Patent applications filed earlier
 - Other publications on the subject – scientific journals, books etc.
 - Search conducted with the minimum documentation available with patent offices based on domestic capabilities
 - Prescribed minimum documentation for international searching authority recognized under PCT

Prior art search

- Genetic resources and prior publication
 - The traditional knowledge associated with genetic resources are with local and indigenous communities
 - Documented and oral knowledge
 - Documented in local languages based on the terminology and teaching of local communities – “The Teaching of TK”
 - Published or unpublished documents
 - These documents do not form part of the documentation of patent offices in most of the countries
 - In many cases there is lack of equivalent scientific analysis and study of this knowledge base
 - Oral disclosure not treated as prior art in many countries
 - Results in inadequate prior art search

Examination

- Test of obviousness to ensure that patents are granted to inventions having sufficient inventive faculty
 - “person having ordinary skill in the art”
 - Different standards used by patent offices of countries to find out obviousness
 - Who is the person having ordinary skill in the art in case of traditional knowledge?

Examination

- *In re Berg*, 320 F.3d 1310 (2003)
 - “As persons of scientific competence in the fields in which they work, examiners and administrative patent judges of the Board of Patent Appeals are responsible for making findings, **informed by their scientific knowledge**, as to the meaning of prior art reference to persons of ordinary skill in the art and the motivation those references would provide to such persons. Absent legal error or contrary factual evidence, those findings can establish a prima facie case of obviousness”
- Are patent examiners persons of ordinary skill in the art in case of traditional knowledge associated with genetic resources?
- Lack of teaching in TK results in poor quality of examination

Disclosure Requirement

- Disclosure requirement in the patent application
 - Full and complete disclosure of the information necessary to establish novelty and non obviousness
 - Enable the persons skilled in the art to practice the invention
 - There is no express obligation to provide detailed information about the genetic resources and associated traditional knowledge that too undisclosed and undocumented information
 - The present disclosure requirement inadequate in case of GR and associated traditional knowledge

The Indian Experience

- Patent (Amendment) Act 2002
- TK is not an invention
 - “an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components” – are not inventions for grant of patents (Section 3 (p)).

The Indian Experience

- Obligation to disclose
- Disclose the source and geographical origin of the biological material in the complete specification, when used in an invention (Section 10(4)(D))
- Prior art – Anticipation – oral knowledge
 - That the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere

The Indian Experience

- Grounds of opposition and revocation
 - that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention
 - Anticipated by oral or documentary knowledge (Sections 25(1)(j) & (k) and 64(1)(p) & (q))

The Indian Experience

- The Protection of Plant Varieties and Farmers' Rights Act 2001
 - Disclosure in the application full details of the prior art of TK including location (section 18(e))
 - Evidence of prior informed consent (section 18(h))
 - Take prior informed consent in case of use of essentially derived varieties - Section 43

The Indian Experience

- The Biological Diversity Act, 2002
 - Prior informed consent for use of TK associated with genetic resources from the National Biodiversity Authority by the foreigners
 - Prior informed consent from the NBA before grant of patent protection for the invention based on genetic resources of India
 - Sharing of benefits with the community

The Challenges

- Maintain the credibility of the patent system
- Prevent issue of questionable patents in case of new products based on genetic resources
 - Introduce additional disclosure requirements in case of genetic resources
 - Disclosure of the source and geographical origin of the genetic resources
 - Disclosure of the full published and oral information regarding the traditional knowledge associated with genetic resources
 - Disclosure of the details of the holder of the information

The Challenges

- Recognize documents relating to traditional knowledge for prior art search
- Recognize holder of traditional knowledge as the person having ordinary skill in the art
- Create new institutional arrangements in patent offices of the countries rich with genetic resources for prior art search and examination
 - Creation of traditional knowledge documentation
 - Pool of experts in traditional knowledge including TK holders to assist examination of the patent application
- Patent offices of foreign countries to seek assistance from these institutions for prior art search and examination in case of patent applications based on genetic resources