

Complementary Measures for the Protection of TK: The U.S. Perspective



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Overview

- Joint Recommendation on Genetic Resources and Associated Traditional Knowledge, WIPO/GRTKF/IC/32/6
 - Prevention of Erroneous Grant of Patents
 - Databases
 - Training of Patent Examiners
 - Opposition Measures in U.S.
 - Post Grant Review
 - Inter Partes Review
 - Supporting Measures
 - Voluntary Codes of Conduct
 - Contracts
- Joint Recommendation on the Use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated with Genetic Resources, WIPO/GRTKF/IC/32/7



Joint Recommendation on Genetic Resources and Associated Traditional Knowledge, WIPO/GRTKF/IC/32/6, by Canada, Japan, the Republic of Korea and the U.S.



Erroneous Grant of Patents

- Preventing Erroneous Grant of Patents:
 - Providing legal, policy and administrative measures
 - Databases:
 - Member States should encourage, as appropriate, the creation, exchange and dissemination of, and access to, databases of and/or regarding GR and TK associated with GR
 - In U.S., examiners have access to various databases (e.g., Traditional Knowledge Digital Library)
 - Training of Examiners: In U.S., examiners in related technology centers (i.e., biotechnology) are trained in searching TK databases



Opposition Measures in U.S.

- Member States should provide legal, policy or administrative measures, in accordance with national law, to allow third parties to dispute the validity of a patent, by submitting prior art, with regard to inventions that include TK associated with GR.
- U.S. has instituted various post grant procedures under the America Invents Act (AIA).



Opposition Measures in U.S.

U.S. Opposition Procedures under AIA

- **Post Grant Review** – Trial proceeding conducted at the Board of Appeals to review the patentability of one or more claims in a patent on any ground that could be raised under § 282(b)(2) or (3) of the AIA.
- ***Inter Partes Review*** – Review conducted by the Board at request of third party, who has not previously filed lawsuit challenging the patent's validity, and has not been served with a complaint alleging infringement of the patent more than 1 year prior (exception for joinder).



Supplementary Measures

- Encourage, as appropriate, the development and use of voluntary codes of conduct and guidelines regarding the protection of the use of TK associated with GR.
- Facilitate, as appropriate, the creation, exchange and dissemination of, and access to, databases of and/or regarding TK associated with GR with a view towards preventing the erroneous grant of patents and supporting opposition measures.



Supplementary Measures

- Voluntary Codes of Conduct (VCCs)
- WIPO members should encourage use of VCCs
- Definition VCC: Voluntary framework that sets basic guidelines of behavior between users and providers of TK in a way that benefits both.



Supplementary Measures

- Typical Scope of VCC:
 - Commitment to follow international, national and local research policies; and
 - Benefit sharing and fair compensation (PICs and MTAs)
 - Designation of who is authorized to sign PICs and MTAs
 - Collaboration with indigenous groups on product development and technology transfer



Supplementary Measures

- Examples of VCCs.:
 - Principles for the Conduct of Research in the Arctic by University of Alaska Fairbanks
 - Food and Agricultural Organization (UN) *International Code of Conduct for Plant Germplasm Collecting and Transfer*;
 - Guidelines for BIO Members Engaging in Bioprospecting by Biotechnology Innovation Organization; and
 - Code of Conduct and Standards of Practice of the International Society of Ethnobiology.



Supplementary Measures

- Contracts
 - WIPO members encouraged to implement contractual measures.
 - Cooperative Research and Development Agreement (CRADA) developed by Yellowstone National Park. As an example, Yellowstone and Diversa Corporation entered into a benefit sharing arrangement using a CRADA in 1999. The agreement allowed Diversa to study the wolves of Yellowstone and develop a DNA pedigree. Yellowstone was able to use this knowledge to gain a better understanding of the wolves and implement conservation measures.



Supplementary Measures

- U.S. National Park Service has additional agreements for collecting research materials from national parks.
 - Basic Research and Educational Purposes: Research Permit
 - Field work, specimen collection: Scientific Research and Collecting Permit
- Material Transfer Agreements: Allows for the transfer of materials between institutions



Joint Recommendation on the Use of Databases

Joint Recommendation on the Use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated with Genetic Resources, WIPO/GRTKF/IGC32/7, by Canada, Japan, the Republic of Korea and the U.S.



Databases

- Each participating WIPO member state will, as it deems necessary, collect information on non-secret TK associated with GR within its territory and store this information in its database.
- By accessing the WIPO portal site and entering a search formula, examiners can obtain search results derived from the databases of all participating WIPO member states. Information can be used in making determinations on novelty and non-obviousness.



Continued Discussions on Databases/Portal

- Q&As Document WIPO/GRTKF/IC/27/inf/11
- Future Work Section of the Joint Recommendation on Databases on pg 4 of the Annex
- Thoughts on Logistical Issues, GR/Tka matching project, and interoperability