

WIPO Seminar on IP and Genetic resources, traditional knowledge and traditional cultural expressions:

**National experiences with disclosure requirements related to
genetic resources and associated traditional knowledge.**

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Context of ABS compliance measures

- WIPO IGC discussions started when there were no ABS regulatory frameworks;
- ABS Regulatory context has fundamentally changed since 2000:
 - Nagoya Protocol;
 - Implementing regulations specifically addressing compliance:
 - EU Regulation;
 - Patent offices assessed, but not retained;
 - National laws.
- Effective ABS compliance rules and tools exist, cfr due diligence system re compliance, as referred to in WIPO IGC discussion text.

Disclosure requirement in **patent law**

- Fundamental confusion between aim of disclosure *re* ABS and disclosure in a patent application:
 - ABS: enable the collection and transfer of relevant data to assess compliance with relevant ABS laws;
 - Patent: comply with the enablement condition under patent law. (cfr interpretation of (non)disclosure data)
- For erroneously granted patents, ABS disclosure is useless;
- Continuing the confusion:
 - Undermines the effectiveness of the patent system;
 - Does not enhance compliance *re* ABS;
 - Does not foster the protection of biological diversity (CBD).
- ABS issues to be decided in relevant legal instruments
on ABS.

Key elements re disclosure

Use of genetic resources (1)

- Complex development process:
 - Access to a multitude of genetic resources;
 - Very long timespan and complex interactions;
 - Involvement of different entities in value chain; initial access and eventual patent very far apart.
- Direct link between invention and accessed genetic resource difficult or impossible to establish, or non-existent;
- Many innovations are not protected by a patent.
- Compliant use of genetic resources and transfer of relevant data in applicable ABS frameworks.

Key elements re disclosure

Use of genetic resources (2)

- Industry experience:
 - Additional administration;
 - Additional complexity; and
 - Legal uncertainty:
 - through R&D process to develop an innovative product;
 - Undermining the patent at the end of the R&D process, undermines the basis for the initial investment;
 - Fundamentally impacting R&D and invested resources;
 - Risks are made intangible and create a barrier for investments.
 - BUT: no added value in ABS compliance.

Thank you
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