WIPO Seminar on IP and Genetic resources:

Disclosure Requirements relating to Genetic Resources and Associated Traditional Knowledge

Geneva, May 27, 2016

Dominic Muyldermans
Senior legal consultant, CropLife International
Key elements re disclosure

Not needed & already covered

• **Not needed**: ABS compliance covered by specific ABS laws;
• **Not wanted**: questions re legality;
• **Already covered** by the patent system:
  • To the extent needed for the enablement condition;
  • To avoid granting of erroneous patents.
• **Economic cost-benefit analysis** shows an increase of transaction costs and an undermining of innovation incentive.
Use of genetic resources

• **Complex R&D 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.**
ABS Compliance

Not needed: ABS specific compliance rules

• ABS Regulatory context has fundamentally changed since 2000:
  • Nagoya Protocol requiring countries of use to implement an effective compliance system;
  • Implementing regulations specifically addressing compliance:
    • EU Regulation (patent offices not retained as check points);
    • National laws.
• WIPO IGC discussions started when there were no ABS regulatory frameworks;
• Effective ABS compliance rules and tools exist, cfr EU due diligence system re compliance, as referred to in WIPO IGC discussion text.
ABS & the patent system

**Not wanted:** issues of legality re patent system

- **No interference *per se*** between patent law and ABS:
  - No conflict between the public ABS rights and private patent rights;
  - Complementary nature of obligations.

- **Disclosure obligations raise questions of compliance with the principles of patent law:**
  - Numerous clausus of patentability requirements;
  - Incompatibility with the prohibition of discrimination:
    - Products resulting from natural product research which are/cannot be patented;
    - Other technologies.
  - Incompatibility with the reasonableness requirement:
    - It goes beyond what is required re the patent;
    - Risk of interference creates legal uncertainty.
Patent system

**Already covered in the patent system (1)**

- **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 (GR);
  - Patent: obligation of complete disclosure to comply with the enablement condition under patent law (Invention):
    - Limited to what is required for a person skilled in the art to practice the invention;
    - Often mandatory deposit of material.

- **Continuing the confusion:**
  - Undermines the effectiveness of the patent system;
  - Does not enhance compliance *re* ABS;
  - Undermines the value of GR.
Patent system

Already covered in the patent system (2)

- Key aim: avoiding the erroneous granting of patents;
- No patent on the GR as such;
- Defensive protection of GR and TK is ensured by the patent system;
- To be further enabled by facilitating instruments:
  - Databases;
  - Guidances of the patent offices.
- For erroneously granted patents, ABS disclosure is useless;
- Consistency in the application of the disclosure obligation is ensured by safeguarding the necessary relationship between the invention and the GR.
Cost-benefit analysis

Green biotech R&D process

Type of parties involved in discovery & patenting:
Agritech LCs, SMEs and/or institutes?

R&D phases (compounds used)

Discovery (> 10,000) 4yrs
Development (10-100) 6yrs
Pre-launch (1-5) 8yrs

What is the change in costs and time during discovery?

Patent application?

$12m

$48m

$78m cumulative R&D per product
Cost benefit analysis

Higher transaction costs (1)

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

➢ higher transaction costs – lower incentive for natural product research – less benefits to be shared.
Cost benefit analysis

Higher transaction costs (2)

• Administrative burden and uncertainty for natural research products that are patented;

• Higher transactions costs early in the R&D process, independent and remote from final product creating benefits:
  • Patent applications on a diversity of research results, probably never resulting in final product;
  • Institutions and SMEs conducting early natural product research, independent from companies developing and commercialising final product.
  ➢ High transaction costs for the value chain, and no added value for more effective benefit sharing or ABS compliance re final product.

• Economic study to provide data on cost-benefit analysis, focusing on megadiverse countries with a disclosure obligation.
Cost benefit analysis

Negative effects on all stakeholders

Provider

Less use of GRs and related benefits

Strict DOO requirements in IP system

User

Higher costs R&D

R&D delay

Lower ROI GR-based innovation, Lower incentive for GR-based innovation

Consumer

Less use of GRs and related benefits

(-)

Strict DOO requirements in IP system

(-)

Lower ROI GR-based innovation, Lower incentive for GR-based innovation

(-)
Example of Ogura case, rapeseed increasing technology in France:
Seed producers’ benefits would have decreased with at least 46% and break-even point delayed with 3-5 years.
Thank you
doninic.muyldermans@croplife.org