WIPO Seminar on IP and Genetic resources:

Disclosure Requirements relating to Genetic Resources and Associated Traditional Knowledge

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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.

Complex natural products R&D

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.

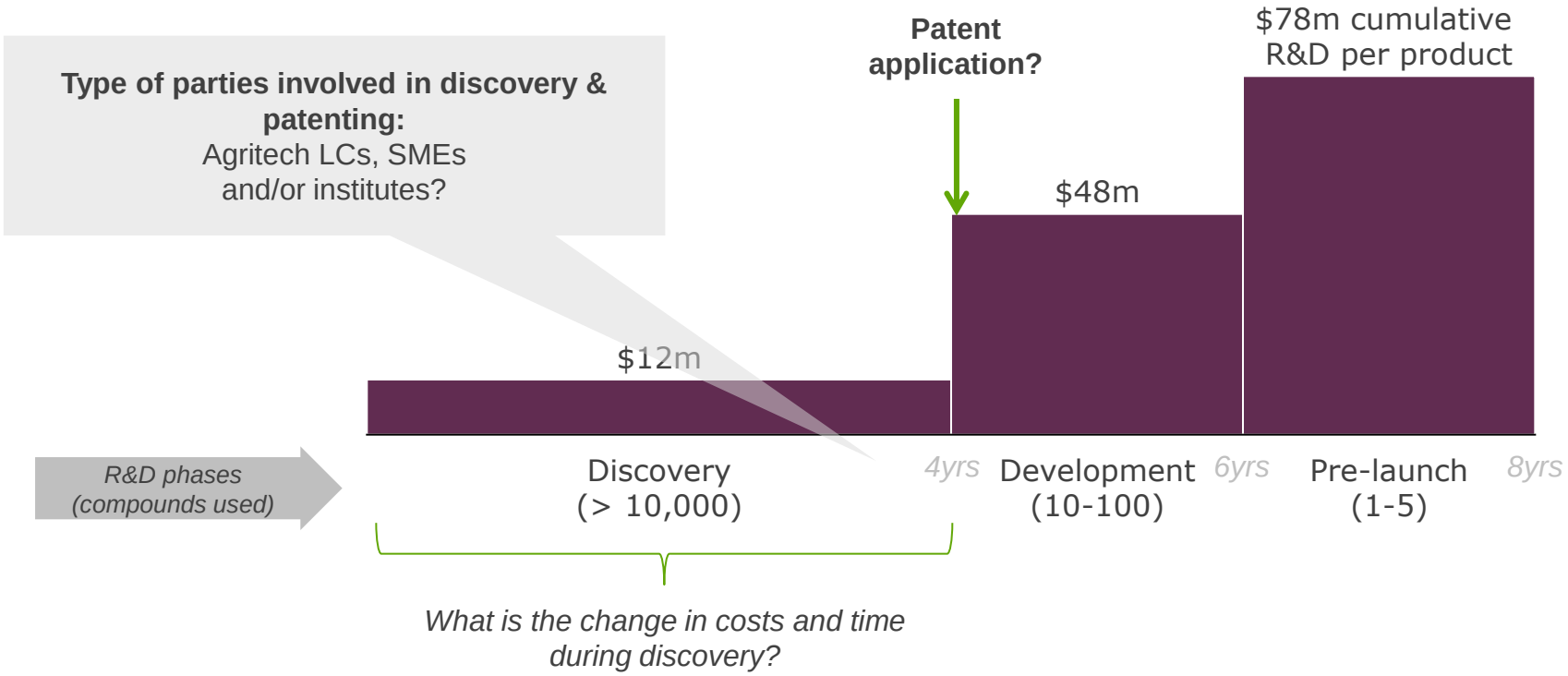
Patent system

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



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.

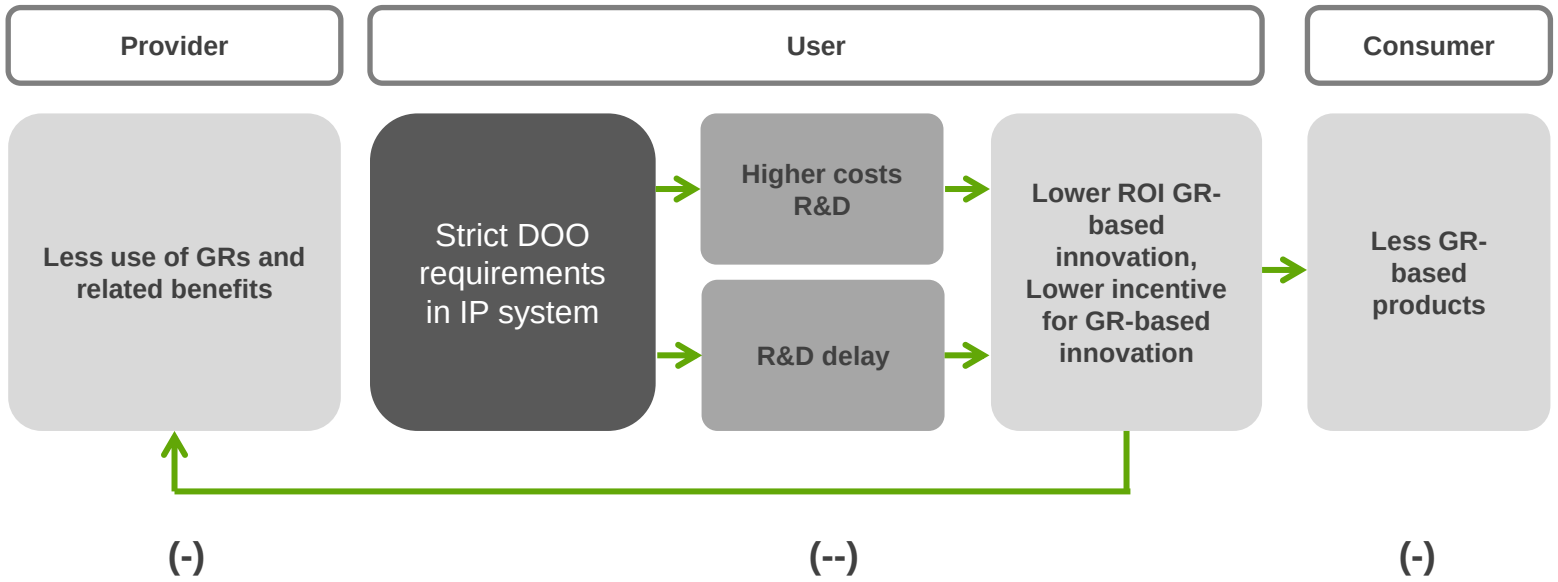
Cost benefit analysis

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.

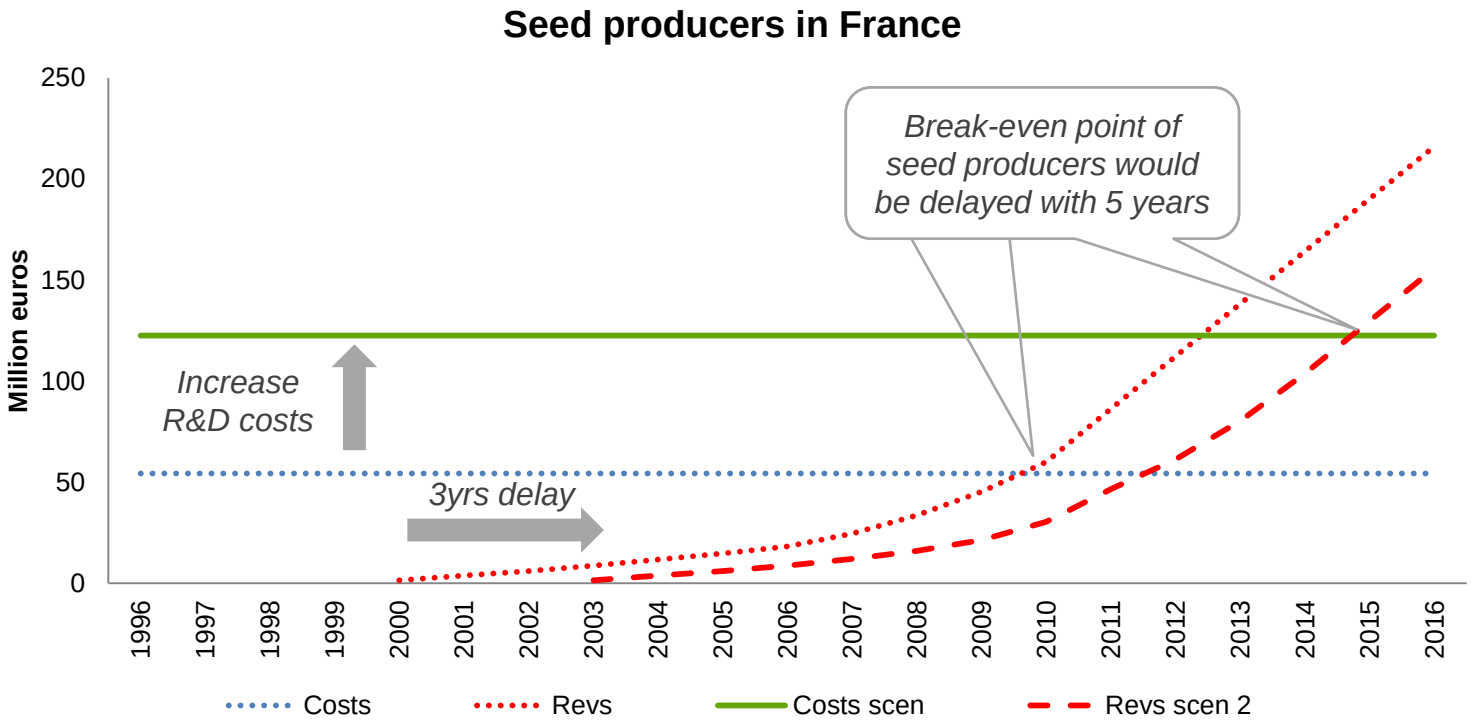
Cost benefit analysis

Negative effects on all stakeholders



Cost benefit analysis

Reasonable break-even point undermined



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

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