Responsible Use of Biodiversity - an industry perspective

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International Regime in context

- International Regime on ABS is one element of CBD activities
- IR is not the only international agreement which addresses ABS
- IR issues addressed in other fora – eg: disclosure, TK – may be elements of the regime
- Expertise on these issue often lies outside CBD
- Purpose, nature and scope all remain difficult
- Examples of complex issues

Traditional Knowledge

- Scope of IR – TK associated with Genetic resources
- Objective of IR in relation to TK
- Underlying questions
  - Relevance of existing IP "tools" to protection of IR
  - Potential of improved management of TK
  - Interface of national and customary law
- What can expect IR to achieve?

Disclosure obligations in the patent system

- There are many practical issues that have not been addressed
  - Current proposals fail to adequately define the scope of an obligation in a way that provides adequate user security
  - Creates risk of huge legal and commercial uncertainties for users – will they lose patents, will they be subject to substantial penalties outside the patent system?
- They will achieve no CBD-based policy objective
  - Main objective of demandeurs - to prevent "bad patents"
    - There is no basis for supposing this will be achieved. Most "bad patents" commonly cited in fact disclosed origin
  - Objectives of others e.g. EU – to help track use of genetic resources and facilitate benefit sharing. Will not achieve these objectives as
    - not needed to monitor activities of those who abide by obligations and agreements
    - cannot be effective against "biopirates"
    - addresses only the uses of GRs that are innovative, not the vast majority of uses
- So there are no benefits and they deter development of GRs and creation and sharing of benefits

The International Regime Working Group mandate

Decision VII/19D "to elaborate and negotiate an international regime

- on access to genetic resources and benefit sharing
- with the aim of adopting an instrument/instruments
- to effectively implement the provisions of Article 15 and Article 8(j) of the Convention and the three objectives of the Convention"

Article 1. Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Article 15 provides the principles for access

- Governments
  - have the authority to determine access to GRs
  - are obliged to create conditions to facilitate access to GRs for environmentally sound reasons
  - Should take measures with the aim of fair and equitable sharing of benefits arising from the commercial and other utilisation of GRs with providers
- Access is to be subject to PIC and on mutually agreed terms

Potential Users of Genetic Resources

- Academia/ex situ collections/public research bodies
- Various industries
  - Food and food processing (without conflicting with FAO-IT)
  - Horticulture, including seeds
  - Cosmetics
  - Wine and spirits
  - Industrial chemicals
  - Biotech and pharma
  - Large and small

Uses of GRs – or materials made from them – by the pharmaceutical industry

- As starting point in developing active compound
- As elements of vaccines
- As inactive parts of final product
- As a tool in the research process
- As a tool in the production process

Suggestions

- Without economic activity, there are no benefits to share, hence regime must be facilitative
- The diversity of uses between and within sectors suggests a highly flexible regime
- Three key contributions from business are to
  - Provide support tools
  - Transact business in a sustainable and responsible way
  - Support best practice

Provide support tools

- Codes of conduct
- Arbitration/dispute settlement procedures
- Model clauses

What we need from the regime……

- Recognition of these tools
- Legal certainty
- Appropriate level of regulation, enabling business to take place

Transact business in a sustainable and responsible way

- A range of monetary and non-monetary benefits
- Adaptation to the immediate needs of Emerging/developing country partners

What we need from the regime…..

- Recognition of different types of benefits
- Avoid penalisation of the compliant
- The ability to contract in a flexible way

Commitment to implementation and address problems

- Support for introduction of national regimes (key building block of the IR)
- Case studies of effective partnerships

What we need from the regime…

- Fact-based and proportionate approach to contentious issues
- Focus on building national capacity
- Partnership-based approach

What is the problem to be solved by the international regime?

- The IR is not a substitute for adequate national systems.
- The IR may be useful for
  - filling the gaps
  - building capacity for implementation of national regimes and negotiation of MAT
  - monitoring progress towards achievement of CBD objectives
- If there is current non-fulfilment of ABS objectives, it is possible that some of the problems may lie in national regimes (where they exist)
- An evidence-based gap analysis is vital to establishing what is wrong and what needs to be done to fulfil ABS objectives. This may take time

Conclusions

- Regime must respect and reflect CBD, not rewrite or contradict
- Provider flexibility and user friendliness are key to any international ABS regime that can be effective in achieving CBD objectives
- Scope, substance and security must all be right if access is to be facilitated and benefits to be created
- The regime should guide not prescribe
- Gap analysis should identify where national laws and MAT are not sufficient
- The costs and benefits of regulation must be considered in the light of how they would operate in practice
- Proposals for disclosure obligations in patents should not be pursued
- Industry should be involved in all stages of the development of the regime.