WIPO

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Genetic Resources and the Patent System:

Perspectives on Disclosure Requirements in Patent Applications from the Rx Pharmaceutical Industry

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Overall viewpoints

- **Support the principles of A/BS**
  - (a) Access to be granted on mutually agreed terms
  - (b) and subject to prior informed consent
  - (c) Realistic benefit sharing to be promoted
- **Role of Intellectual Property**
  - (a) Without IPRs – nothing to share with biodiversity rich countries
  - (b) Without predictable and transparent ownership – no investment in biotechnology

Disclosure Requirements in Patent Applications

- **Purpose given by some parties**

  to fulfill the obligations of the CBD in relation to access to GR and benefit sharing which could arise from the commercialization of a drug based on those resources

- **Global R&D Pharma Industry Perspectives**

  (a) effectiveness

  (b) practical difficulties

  (c) adverse consequences

Effectiveness

(a) Need to **properly define** the subject matter based on CBD provisions

(b) No **clear data** on the scale of "bio-prospecting" activities on which to draw sound policies

(c) **Relevance** of GR to the industry: misperception on prevalence and negative impact driving down interest

Properly Defining the Subject Matter: What Does the CBD say?

(a) Limited to Genetic Resources defined as "any material of plant, animal, microbial or other origin containing **functional units of heredity**" and that are "of **actual or potential value**" (articles 1-2)

(b) GR restricted to "**those provided by Parties that are countries of origin of such resources or that have acquired the GR in accordance with the CBD**" (article 15.3)

(c) Exclusion of material from **human origin**
(CBD COP Decision II/11 and para. 9 of the Bonn Guidelines)

(d) Exclusion of GR obtained before **December 1993**
(non-retroactivity principle)

Relevance of Genetic Resources to the Global R&D Pharmaceutical Industry

- Downward trend seen in using naturally occurring biotech despite potential value
- 1980's: heightened interest in drug discovery enabled by access to naturally occurring GR
- 2004: bio-pharma moving away from reliance upon naturally occurring GR towards high-throughput screening of synthetic compounds with known profiles (combinatorial chemistry)

Practical difficulties

- **Capacity to innovate requires a predictable regulatory environment conducive to innovation**

(1) Increased uncertainties and risks:

- country of origin or immediate source? And what if the GR can be identically found in several countries?
- nexus between invention and naturally occurring material
- sanctions

(2) Increased bureaucratization of A/BS obligations

Practical Difficulties (contd)

B. R&D process implications

- Inventive step: to develop commercially worthless samples of naturally occurring materials into commercially valuable products and services
- Remuneration in relation to involvement in the innovation process

Adverse Consequences

(a) deter further public and private interests in access and use

(b) thereby extinguish any potential benefits that countries providing access could claim

(c) compromise overall benefits of biotech for society at large

(d) negatively impact future prospects for those DCs trying to establish biotech hubs for development

Conclusions

- Need for clarity: national laws on A/BS to be enacted
- Exploration of the viability of other « enforcement » mechanisms outside the patent system (other areas of law)
- Self-regulatory tools as means to ensure compliance with benefit sharing standards
- Effective framework for partnerships in an effort to provide mutual benefits

Merck – INBio Agreement

- Concluded in 1991 with the National Biodiversity Institute of Costa Rica (renewed in 1994 and 1996)
- INBio provided:
  - (i) access to biodiversity resources
  - (ii) exclusive rights to study the samples
  - (iii) proprietary rights for any innovative product
- Merck agreed to pay research costs ($1mio) and % royalties – used towards conservation of biodiversity
- Capacity building (technological equipment)