Lilly Recent History in Natural Products Research

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Answers That Matter.
Today’s Discussion

• Lilly history with natural product research

• Recent experiences

• Use of contracts to manage Acess Benefit Sharing (ABS), technology transfer, and conservation/sustainable use of GR/TK

• Requirements for Successful ABS Contracts
Natural Products Research at Lilly

- Natural Products research at Lilly dates back to founding of the company, in 1876 and ended in the early 1990s.

- New techniques, such as combinatorial chemistry, led to use of synthetic organic chemistry in research and development of new compounds.

- Passage of the CBD and lack of national laws implementing the objectives of the CBD, including mechanisms for ABS, created challenges/ambiguities.
Historic Breakthroughs Lead to Inaccurate Charges of “Biopiracy”

Decades of research on rosy periwinkle plant, by Lilly and others, led to historic discovery of vinca alkaloids for treatment of cancer, in 1961.

FACTS:

- Rosy periwinkle is found throughout the world, and plants used by Lilly were commercially grown in Texas, United States.
- Original research efforts were for treatment of diabetes, not cancer.
- Scientific research, not TK, led to development for cancer indication.
- Products launched 30 years before CBD.
- Risk-intensive research, combined with inappropriate claims of biopiracy, discourage natural products research.
A Successful ABS Agreement:
Lilly-INBio Collaboration Agreement

- Research Collaboration from 1999-2000
- Collection of extracts from plant samples by INBio
- Testing for human and animal health and agriculture
- Payment for each individual extract received, with possibility of milestones and royalties
- Technology transfer
  - Visiting scientists from INBio to Lilly
  - Perpetual rights to use Lilly proprietary plant extraction procedure
- Dispute resolution mechanism
National ABS Strategy: Recent Lilly Experience in Cameroon

• A research scientist in Cameroon contacted Lilly to engage in a natural products collaboration

• Lilly informed the scientist that transfer of GR without authorization is a violation of Cameroon national law

• Research scientist is unable to obtain authorization from relevant ministries
  – Authorization forms were later found to be from the wrong ministry
  – Lilly letter to CBD Focal Point in Cameroon to resolve the deficiencies
  – After over one year, Lilly closed its files on this potential collaboration

• No collaboration = no access, no benefit-sharing, no technology transfer, no new medicines
Contracts: A Practical Solution

• Legal mechanism for access and prior informed consent
  – Contracts provide legal certainty to the user and to the provider
    • Document access when it occurs
    • Establish benefit-sharing up front, at the time of access
  – May result in benefit sharing even if the research is unsuccessful
    • License Fees
    • Milestones/Royalties
    • Technology transfer
The Basis for Contracts: The Convention on Biological Diversity

- Article 15(4): Access [to genetic resources], where granted, shall be on mutually agreed terms.

- Article 15(7): Parties shall implement measures to ensure fair and equitable sharing of benefits arising from use of genetic resources. Benefit-sharing shall be upon mutually agreed terms.

- Article 16(3): Parties shall take measures to provide access to and transfer of technology, on mutually agreed terms.

- Article 19(2): Access to results and benefits arising from biotechnologies based on genetic resources shall be on mutually agreed terms.
The Basis for Contracts: The Bonn Guidelines

- Para. 13: National Focal Point – “to inform applicants for access to genetic resources on procedures for acquiring prior informed consent and mutually agreed terms.”

- Para. 14: Competent National Authority – responsible for advising on entering into mutually agreed terms; monitoring and evaluation of ABS agreements; implementation and enforcement of ABS agreements.

- Para. 42-45: Lists basic requirements for mutually agreed terms and typical mutually agreed terms to be included in agreements.

- Appendix I: Suggested Elements for Material Transfer Agreements
Conclusions

• Management of ABS via contracts can be effective, with the appropriate national policies in place.

• Implementation of these national policies is less burdensome than other proposals, such as patent disclosure or certificates.

• Use of patent disclosure is an unsuccessful attempt to shift the burden of implementing ABS policies
  – Increases uncertainties for patent applicants and patent examiners
  – Fails to achieve the intended compliance goals
THANK YOU