Geneva Pharma Forum
WIPO Geneva

Technical Briefing on Biopharmaceutical Innovation: The Value of Legal Certainty

“The Industry’s Perspective”

Andrew Jenner
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The Current Challenge

• “Our industry is taking too long, we’re spending too much, and we’re producing far too little… Ironically, the crisis in our innovation model comes at a time when we have vastly more scientific knowledge and data than ever before… In the face of diminishing results, we can’t simply perform the same old rituals and hope for a different outcome.”

The case for research and new medications was compelling he said, but with the age of austerity upon us this isn’t enough – drugs have to make their way to patients faster and cheaper. Not only should pharma become more networked, global and entrepreneurial, it needs to be matched with regulations that support an environment of innovation.”

• “Even as we rebuild our R&D engine, we must build an environment where pharmaceutical innovation can thrive.”

John Lechleiter (CEO Eli Lilly) 10 February 2011
Risk Factors: Chemical

- Pharma Activity
- Safety & Efficacy
- Approval
- Patent Invalidity
- Market Potential
Risk Factors: Natural

- Pharma Activity
- Risk of Supply
- Safety & Efficacy
- Approval
- Patent Invalidity
- Market Potential
- Bio-Piracy Claims

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Chemical vs. Natural Product R&D: Assessing Risk Factors

STANDARD PRODUCT RESEARCH

✓ Pharmacological Activity
✓ Safety & Efficacy
✓ Challenges of R&D process
✓ Patent Invalidity
✓ Market Potential

NATURAL PRODUCT RESEARCH

✓ Pharmacological Activity
✓ Reliability of Supply
✓ Safety & Efficacy: Longer, more complex R&D
✓ Stricter Regulatory Approval Process
✓ Patent Invalidity
✓ Claims of Bio-piracy & Misappropriation
✓ Market Potential
TK in the Public Domain?

Time (t)

TK Holder 1

Researcher 1

Researcher 2

BioTech with Venture Capital

Researcher 5 uses R1 & R2

Large Biotech Company 1

TK Holder 2

Researcher 3

Researcher 4

TK Holder 3
Conclusions

• Industry is keen to fulfill obligations under the CBD
• Legal certainty is a vital component for the research and development of natural products
Thank you

For more information

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Industry Examples

INBio
Instituto Nacional de Biodiversidad

MSD

Lilly
INBio created 1989 as a private, non-profit public interest institution

Mission: to conserve biodiversity
  • (1966 – 1989 Estimated 28% Forrest Lost)

Collecting and Taxonomically identifying well over 500,000 wild land species

Clear ABS laws established
INBio/Merck & Co. Agreement

- Collaborative research agreement
- Merck agreed to up front fee for plant, insect and soil samples
- Merck also agreed to royalties on any drug developed from the samples
- Merck had exclusive right to evaluate 10,000 samples
- INBio was able to enter into other agreements but could only share Merck samples if given permission.
• Monetary Benefits - $1 Million
• Technology transfer - equipment donation worth over $135,000
• Merck sent two natural product chemists to set up extractions labs and train scientists
• INBio scientists visited Merck’s labs
Lilly/INBio Collaboration Agreement

- Research Collaboration from 1999-2000
- Collection of extracts from plant samples by INBio
- Payment for each individual extract received, with possibility of milestones and royalties
- Technology transfer
  - Provided extraction procedure still in use today
  - Exchange of scientists
- Dispute resolution mechanism
Industry Examples

Cameroon & Lilly

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Lilly Experience in Cameroon

• A research scientist in Cameroon contacted Lilly to engage in a natural products collaboration (2007)

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

• Research scientist was 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 more than one year, Lilly closed its files on this potential collaboration

• No collaboration therefore no access, no benefit-sharing, no technology transfer, no new medicines
Lessons Learnt

• Clear and useable ABS laws
• Single Point of Contact
• Creating the right environment for mutually beneficial collaboration