Access and Benefit Sharing: A university and Small Company Perspective

Ad Hoc Working Group Meeting on Access and Benefit Sharing
Cali Colombia

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About BIO

- Trade association with more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 states.
- Vast majority are small, emerging companies with little revenue and no marketed products
  - » Health care,
  - » Agricultural,
  - » Industrial, and environmental biotechnology products

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Topics

- Universities and Companies in Innovation
- Academic Technology Transfer
- Source and/or Origin
- Prior Informed Consent (PIC)
- Access and Benefit Sharing Arrangements (ABS)
- Challenges

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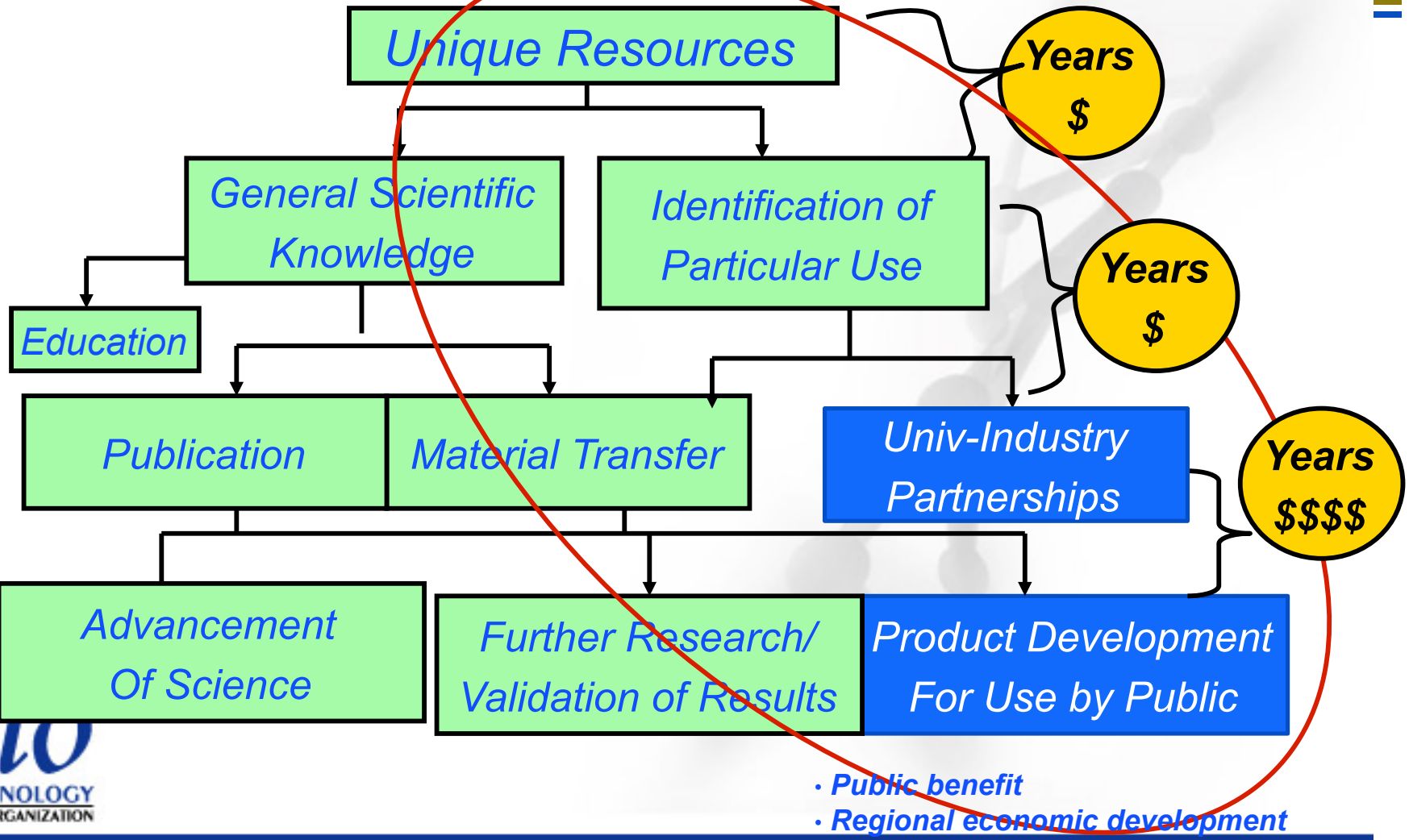
Access to Unique Resources
Incentives for Research Universities



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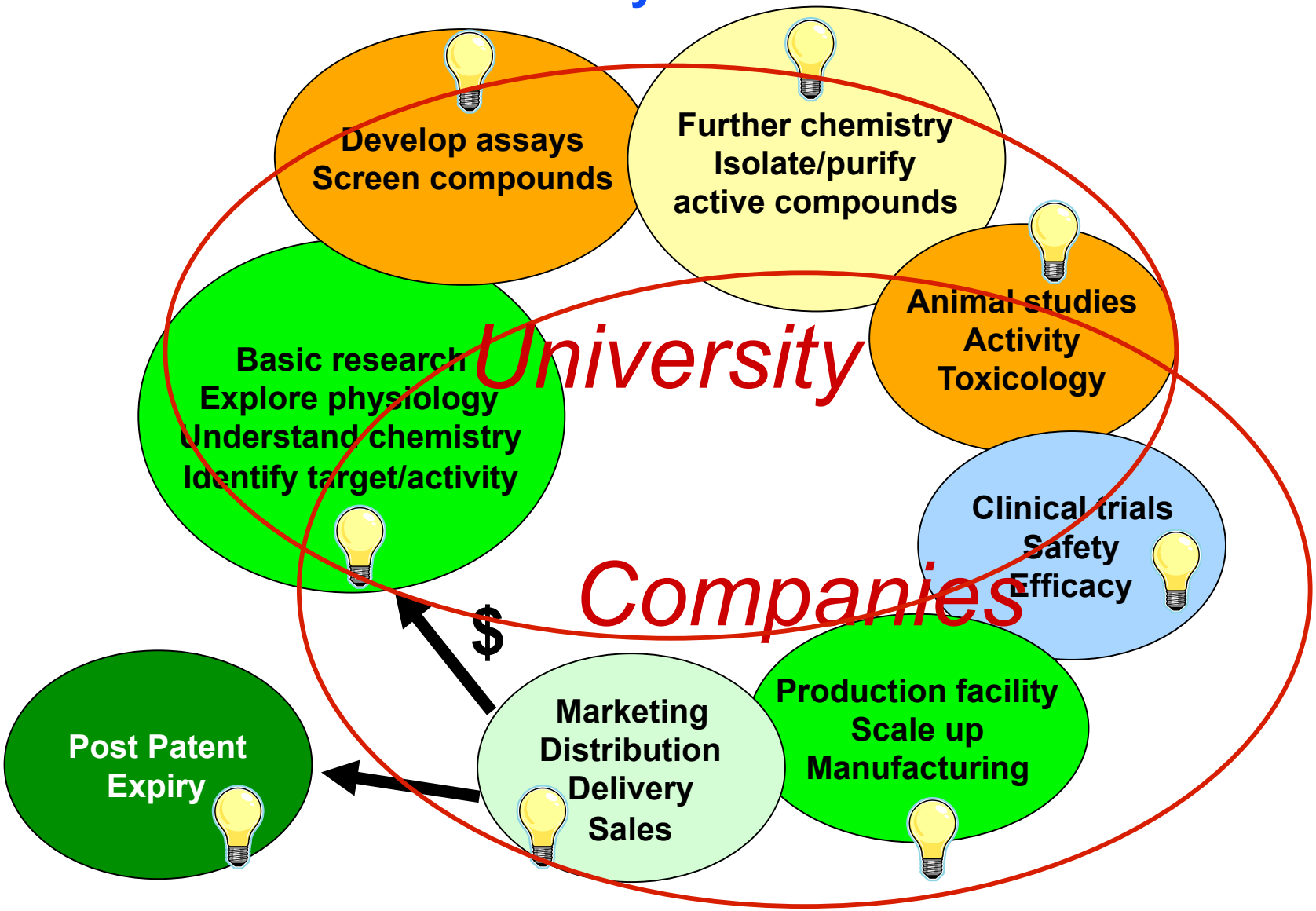
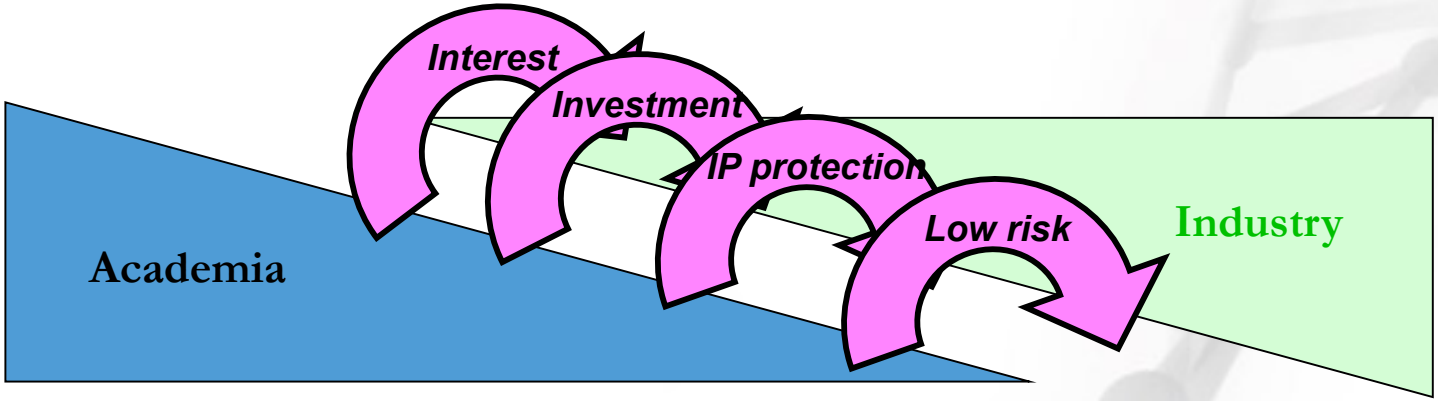
- *Public benefit*
- *Regional economic development*

Elements of the Healthcare Biotechnology Innovation Ecosystem



Incentives Needed for Technology Transfer



Curiosity-Driven Basic Research/ Sample Collection

Applied Research/ Partnerships

Technology Development/ Commercialization

Products Available to the Public

From Basic Research to Products on Shelves

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What can Countries do?

- Easy one-stop shopping
  - » Focal point or Liaison Office
  - » Where to get paperwork
  - » Catalogue resources and develop a simple exchange program
  - » Create network within country to create alliances
    - – Researcher to researcher connections
    - – Educate in country researcher about the process

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Benefits to Countries

- Beef up University curriculum on a particular topic
  - » Visiting professors, exchange program
  - » Seminars at universities
  - » Data and information exchange
  - » Sharing of techniques (two way street)
  - » In country training to ensure that knowledge is shared throughout the country

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University Country partnerships

- Develop and build infrastructure
  - » UC's BioCode project http://moorea.berkeley.edu/
    - – UC with French Polynesian government collects specimens and will maintain in a repository with a database that notes the specimen's unique identifiers and will be shared for research purposes.
    - – Access for commercial purposes must be approved by French Polynesian Government

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Country Efforts

- Sarawak Biodiversity Center
  - The center created technical jobs locally, catalogued biological and genetic resources, Catalogue of Traditional Knowledge
  - Created a material transfer agreements and research regulations
  - Partnered with companies
  - Awareness programs
- Early this year SWINBURNE University of Technology Sarawak Campus (SUTS) and the Sarawak Biodiversity Centre (SBC) are collaborating in biotechnology under a Memorandum of Understanding (MoU), to develop discoveries with potential commercial value from Sarawak's rich biodiversity. http://www.theborneopost.com/?p=5171

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Industry Considerations for Investment

- Industry often needs patent protection and legal certainty to justify investment of effort/resources into developing a product, esp. healthcare products.
- Ability to comply with national laws (or proposed international requirements) re: access and benefit sharing may preclude or invalidate a patent.
- Partnership opportunities to sponsor research or license/ develop patented technology-- uncertainty with the GR is a disincentive.
- Accusations in poorly developed national systems could lead to accusations of biopiracy!
  - *A product may not get developed for public use.*

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Potential Authorities That May Affect Sample Collection

- Individual national laws
- Other international discussions (e.g. proposed mandatory patent disclosure requirements in WIPO)
- Convention on Biological Diversity (current negotiations until 2010)
- Regional/community desires and customary laws
- "Samples" include natural products (e.g. plants), genetic resources (e.g. DNA samples, saliva swabs) or traditional knowledge (e.g. herbal medicines and know-how).

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An Eye Toward the Future: Ensuring Collection Allows Public Benefit

- Goal: balance needs, desires and laws of the source community in fair and equitable manner while promoting sustainable development utilizing genetic resources.

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Benefit Sharing

- Specifying the cost of a specimen is not always possible
- Royalties and milestones should be made clear up front
- The ability to export of specimens is desirable
- Upfront, transparent benefit sharing schemes. The partner must know who all the beneficiaries are.
- Some benefits could be monetary but could also include job creation, knowledge sharing, research infrastructure building,
  - A country may benefit from a new hospital or a new university.. Sometimes these are more useful than monetary compensation.

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What Researchers Should do..

- At the time of collection, researchers must identify the source and origin and maintain accurate laboratory documentation.
- If available go through the certification process from local, regional or government officials to document the origin or compliance is being considered.
- Researcher or university must obtain *prior* informed consent *in writing* from custodial community or provider country.
- Obtain in writing; seek use for research and educational purposes, as well as potential future commercialization

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3. Access and Benefit Sharing (ABS) Arrangements

- University and company officials should execute *in advance* an access and benefit sharing arrangement with custodial community or provider country.
- If ABS agreement is limited to non-commercial research, may need to renegotiate for commercial research later. Identify when it crosses the line.
- Consider short term and long term benefits.
- Short term benefits could include seminars, research collaboration, material transfer, equipment, etc.
- Long term benefits could include royalty-sharing or access to resulting products.

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Some Types of ABS Arrangements

- Education and Training, e.g. seminars at local universities, exchange programs, enhance curriculum.
- Capacity Building, e.g. research collaborations and grants, knowledge transfer, training farmers/researchers of new techniques.
- Infrastructure Needs, e.g. research equipment left for continued local use.
- Royalty-Sharing, e.g. portion of net royalties.
- Access to Resulting Product, e.g. at lower cost (must balance with licensee's needs).

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An Example: UCB/Samoa ABS Arrangement

- Access
  - Access to Samoa for research purposes
  - Importation w/o tax/duty of research equipment
  - Exportation of living material/genetic collection of *mamala* tree (destroyed at end of research)
- Benefit Sharing
  - Acknowledge intellectual contributions of Samoa
  - Obtain PIC of villages or other landowners
  - Name genes/gene products to show Samoa connection
  - Try to protect discoveries w/potential commercial value (no obligation to file patent applications)
  - License for public benefit, inc. low cost therapies in developing world
  - Annual report to Samoan Prime Minister
  - Share net revenue; given to nonprofit foundation for distribution:
    - *50% to Samoan Government*
    - *33% to Village #1*
    - *2% each to Villages #2 & #3 (total = 4%)*
    - *8% to other villages*
    - *2% each to lineal descendants of Healers #1 & #2 (total = 4%) and*
    - *1% to nonprofit foundation*

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Some Future Challenges

- Researchers may be unable to document source/ origin for materials collected in the past or for resources acquired through public domain. ABS obligations unclear.
- Unknown origin – is documenting the source enough?
- At what point does non-commercial research blend into commercial research?
- Clarity on national focal point and national authority to address PIC/ABS promotes efficiency/compliance.
- Many national laws with similar requirements are already instituted in certain countries – not all are the same!

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Some Future Challenges, *cont.*

- Proposal to allow provider country to file for patent apps may not be effective in securing protection.
- Lack of awareness of related country laws/rules or proposed patent disclosure requirements may hinder a university's ability to ensure development of a resulting technology for the public benefit.
- International discussions are on-going; current research is in limbo.
- Ideal would be common international rules for contract-based system that allows flexibility to clarify:
  - National focal point/authority for PIC and ABS arrangements
  - Expectations and obligations of the stakeholders (provider and user)
  - Enforcement
- Universities must balance PIC/ABS issues with obligations to third party sponsors of research

Some Resources

- World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)
  - http://www.wipo.int/tk/en/
  - Click on Genetic Resources in left sidebar to find portal to Disclosure Requirement proposals submitted by various countries.
- Convention on Biological Diversity (CBD) International treaty that focuses on conservation of biodiversity, its sustainable use, and assurance of fair and equitable benefit arising from use of genetic resources
  - http://www.cbd.int/
  - 2010 Biodiversity Targets: http://www.cbd.int/2010-target/about.shtml
- Biotechnology Industry Organization (BIO)
  - Some background information: http://www.bio.org/ip/international/
  - Bioprospecting Guidelines
    Cover memo http://www.bio.org/ip/international/200507memo.asp
    Guidelines: http://www.bio.org/ip/international/200507guide.asp
- Access and Benefit Sharing Alliance (ABSA)
  - http://www.abialliance.com/version02/html/main.html

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Thank you

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