

University Research/Technology Transfer

IP Issues Associated with Genetic Resources and Natural Product Development

Pacific Science Intercongress, Tahiti
6 March 2009

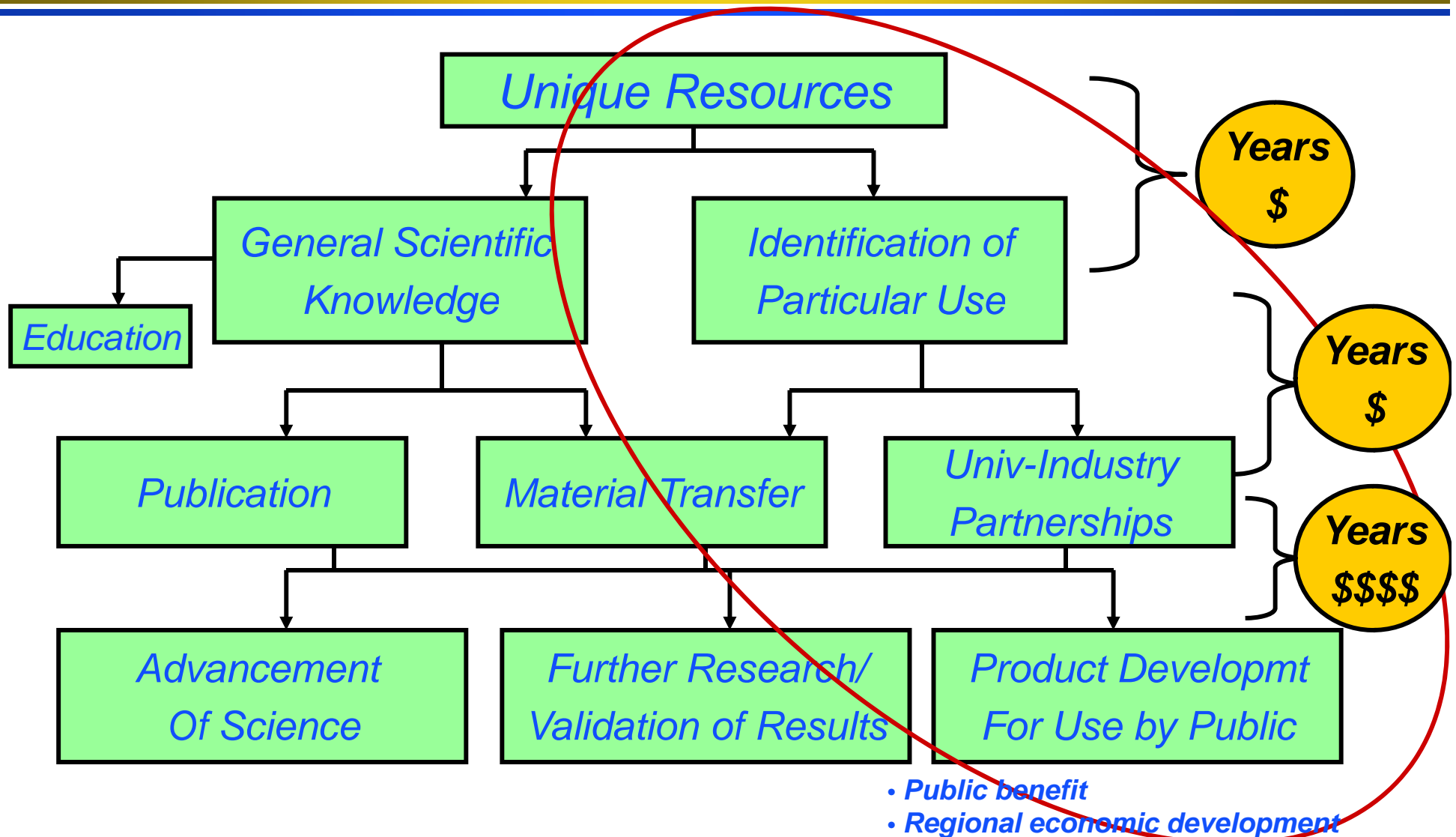
Janna Tom, Office of Technology Transfer
University of California
Janna.Tom@ucop.edu

Topics

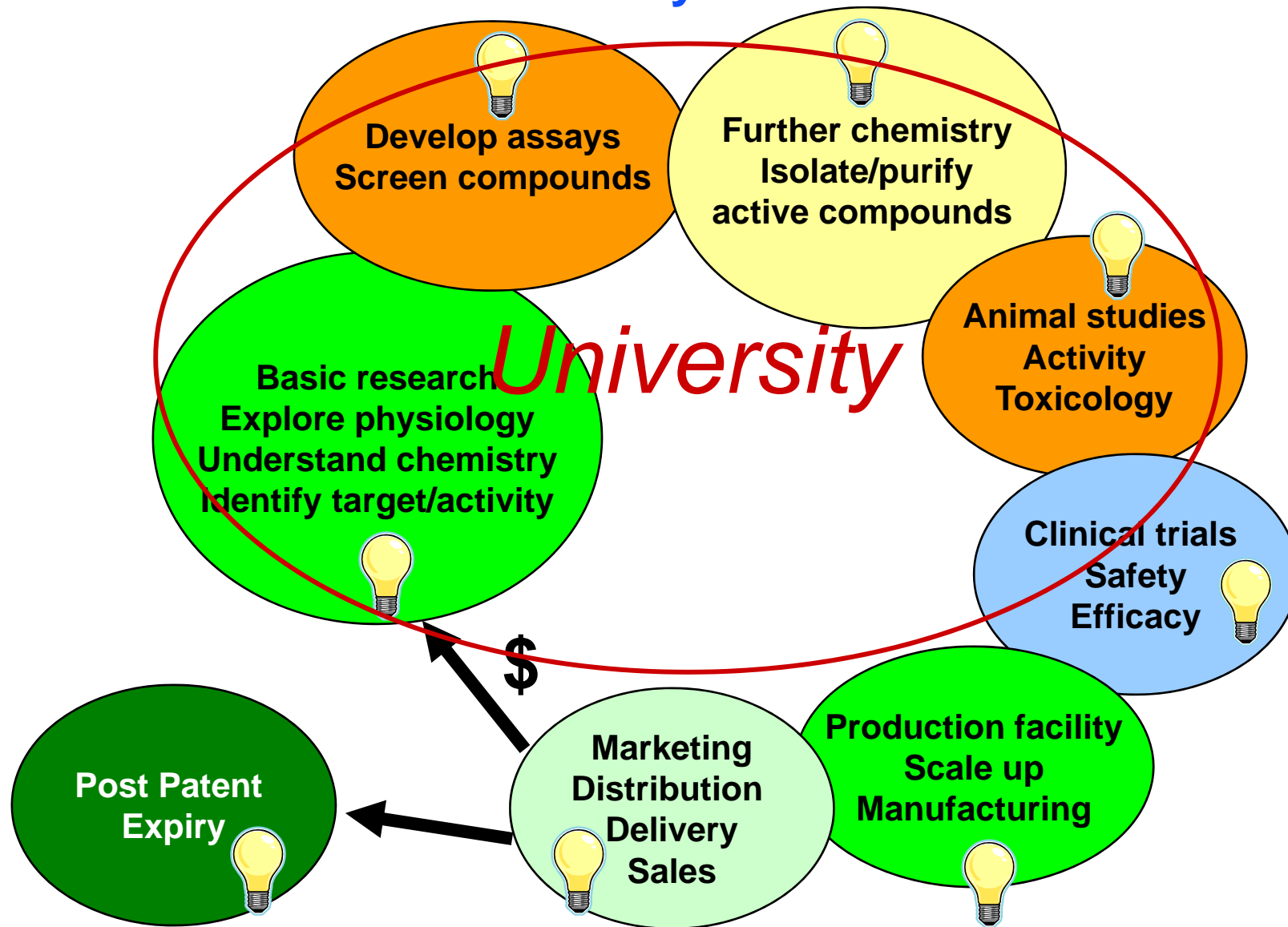
- Research University's Role in the Innovation Ecosystem
- Academic Technology Transfer
- Source and/or Origin
- Prior Informed Consent (PIC)
- Access and Benefit Sharing Arrangements (ABS)
- Challenges

Access to Unique Resources

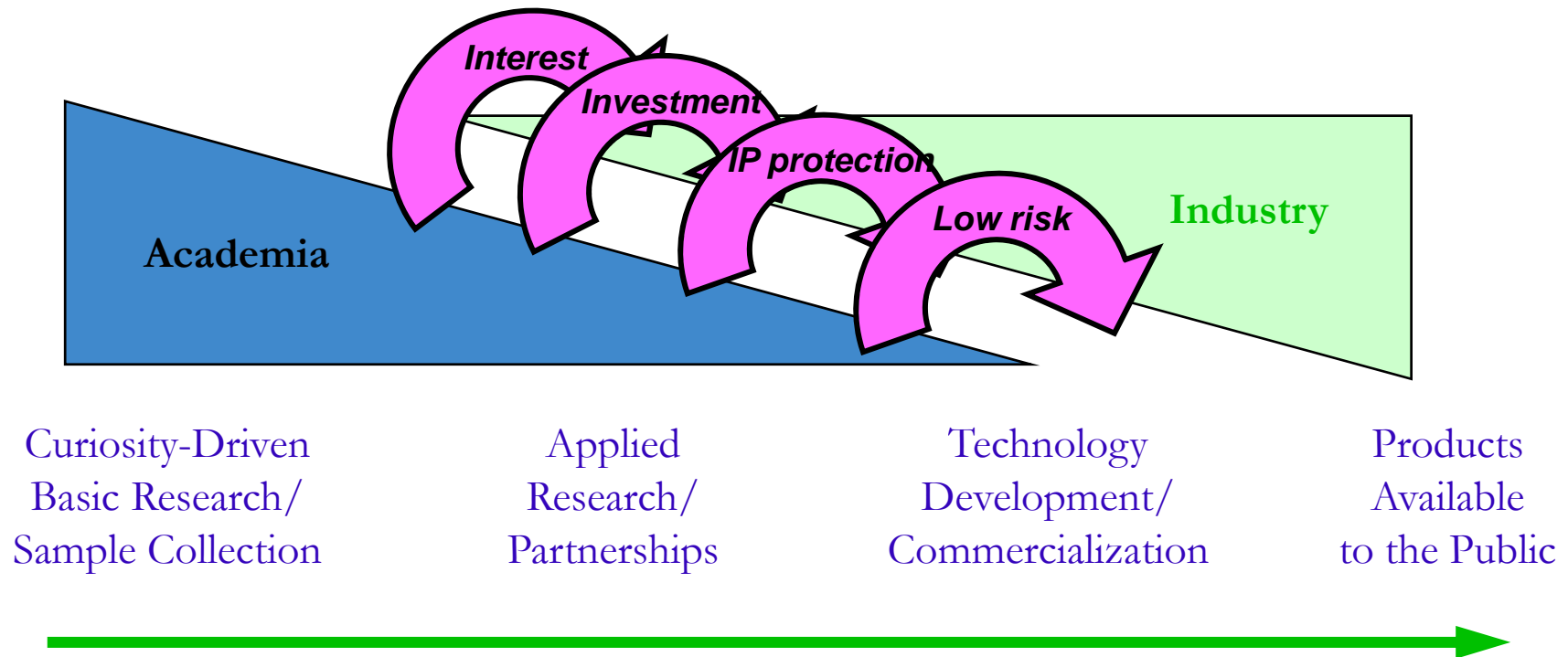
Incentives for Research Universities



Elements of the Healthcare Biotechnology Innovation Ecosystem



Incentives Needed for Technology Transfer



From Basic Research to Products on Shelves

Genetic Resources/Natural Products

Impact on Technology Transfer

- Industry often needs patent protection and legal certainty to justify investment of effort/resources into developing a product, esp. healthcare products.
- Non-compliance with national laws (or proposed international requirements) re: access and benefit sharing may preclude or invalidate a patent.
- Industry partners may avoid sponsoring research on or licensing/developing patented technology whose collection holds too much uncertainty.
- Non-compliance could lead to accusations of biopiracy!
 - ❖ *A product may not get developed for public use.*

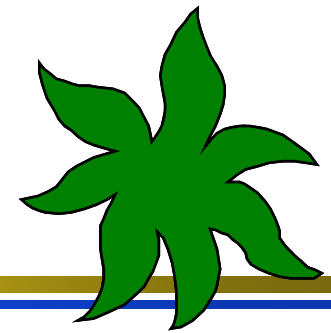
Potential Authorities That May Affect Sample Collection

- 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).

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 ensuring advancement of science and preserving opportunity for further public benefit through development of products that can alleviate human suffering and enhance daily living.
- Three main elements to consider.

1. Documentation of Source and Origin



- At the time of collection, researchers must identify the source and origin and maintain accurate laboratory documentation. Try to trace back to the true origin, but at least document the source where acquired.
- While proposals are still being discussed in the international arena, unclear what will be required later when a patent application is filed. Document as much as possible.
- A certification process from local, regional or government officials to document the origin or compliance is being considered. Use it if available.
- This could be coupled with the Prior Informed Consent.

2. Prior Informed Consent (PIC)

- Researcher or university must obtain *prior* informed consent *in writing* from custodial community or provider country.
- Even if obtain PIC from authority, may need to collect PIC from stakeholders within community, e.g. individual farmers or landowners.
- Obtain in writing; seek use for research and educational purposes, as well as potential future commercialization; can be coupled with Access and Benefit Sharing Agreement.

3. Access and Benefit Sharing (ABS) Arrangements

- University 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.

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).

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

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!

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>

Thank you

Janna Tom, Office of Technology Transfer
University of California
Janna.Tom@ucop.edu
510-587-6059