

Managing Biological Materials (“Bioproperty”): Research & Technology Transfer

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Bioproperty: Management & Technology Transfer

- ❑ Bioproperty defined
- ❑ Why access and tech transfer of bioproperty is important
- ❑ The fundamental basis of bioproperty ownership and control
- ❑ Regulatory gates
- ❑ Access and technology transfer

Bioproperty Defined

- ❑ “Bio”

- ❑ all tangible, non-human*, wild and domestic organisms (individuals and groups), their parts, progeny, and by-products

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- ❑ “property”

- ❑ the right to own and control

* human cell lines, tissues, organs, etc. can also be bioproperty but typically have other issues

Why is Bioproperty Important?

- ❑ Tangible biological materials are an integral part of biotechnology and other technologies in the life sciences
 - ❑ Bioproperty is the lifeblood of technological development
 - ❑ Bioproperty *per se* can have significant financial value
 - ❑ It is a key component of technology transfer and commercialization
 - ❑ It is the subject of national and international policy and law

Bioproperty is Tangible Property

- ❑ Legally, it is fundamentally different than intangible property
 - ❑ Such as intellectual property
- ❑ It falls under personal property law
 - ❑ Most legal systems treat it similarly; law, custom and practice)
- ❑ It can be bought, sold, traded, etc.

Bioproperty Has a Very Long History

Domesticated

- ❑ Livestock
- ❑ Field crops
- ❑ Bee hives

Wildlife

- ❑ Royal rights over game
- ❑ Fish & game as a public commons
- ❑ Jurisdictional “tug of war” over rights in wildlife
- ❑ Federal species and international treaties (CITES, Marine Mammals, Migratory Birds)
- ❑ Convention on Biodiversity

Modern Biology

- ❑ Cell lines
- ❑ DNA, genetic materials
- ❑ Genetically-engineered plants and animals

Examples of Bioproperty

- ❑ Crops in a field
- ❑ Seeds in a bag
- ❑ Animals in a flock
- ❑ An animal listed as an “Endangered Species”
- ❑ A collection of germplasm
 - ❑ Sperm bank, seed repository, research mice)
- ❑ Cell line in test tubes / petri dish
- ❑ DNA
- ❑ A game animal – free-ranging vs. caught

Bioproperty = Personal Property

- ❑ The law presumes that the possessor of personal property is the owner
 - ❑ Unless.....
 - ❑ The property has been bailed to a bailee
 - ❑ Or, it has been:
 - ❑ Lost
 - ❑ Mislaid
 - ❑ Stolen

Bioproperty

- ❑ Tangible biological material
 - ❑ Plants, parts, seeds, tissues, DNA, etc)
- ❑ Possessor is considered owner unless:
 - ❑ Bailment has transferred right to possess or...
 - ❑ It has been stolen
 - ❑ Requires physical management and bailments (MTA)
- ❑ Can be licensed, sold, traded, gifted, etc
- ❑ It can become public domain if not careful

Bioproperty = Personal Property

- ❑ Although bailment rules apply.....
- ❑ Government laws and regulations can supercede bailment rules
 - ❑ Examples:
 - ❑ Animal & plant health
 - ❑ Animal cruelty laws
 - ❑ Human health & safety
 - ❑ International wildlife treaties

What is a Bailment?

- ❑ A legal contract between an owner of personal tangible) property and another party
 - ❑ Which allows....
 - ❑ Transfer of the right to possess
 - ❑ With no transfer of ownership
 - ❑ The contract can be written or implied
 - ❑ In widespread use in society and commerce
- ❑ The tangible property counterpart to a license agreement for intangible property
 - ❑ Transfers the right to use
 - ❑ Without transferring ownership

A Bailment is the Transfer.....

- ❑ Of the right of possession to tangible property
 - ❑ By the owner
 - ❑ The “bailor”
 - ❑ To a recipient
 - ❑ The “bailee”
 - ❑ Who gets the right to use it
- ❑ with no transfer of ownership
 - ❑ The Bailor still owns it

Bailments in Life Sciences R&D

- ❑ Breeders exchanging crop lines
- ❑ Providing a cell line to a colleague
- ❑ Conducting a necropsy on a valuable animal
- ❑ Providing a cloned gene to another laboratory for research-only purposes
- ❑ Conducting field trials on a contract basis

Regulatory “Gates” for International Access and Technology Transfer

- ❑ Environmental, Health & Safety laws
 - ❑ Transboundary transport permits
 - ❑ Quarantines
 - ❑ Dangerous organism protocols
- ❑ National Biodiversity Laws

International and National Biodiversity Laws

- ❑ Convention on Biological Diversity (CBD)
 - ❑ Signatories recognize the rights of states to assert sovereignty over their biodiversity
 - ❑ Effective December 29, 1993
 - ❑ Ratified by 196 countries
- ❑ Some countries have a national biodiversity law
 - ❑ e.g., India
- ❑ Others do not
 - ❑ e.g., U.S.

Example: Thailand

Committed to preserving its unique natural heritage, Thailand became a party to the Convention on Biological Diversity in 2004. In furtherance of this commitment, the National Reform Plan in Natural Resources and Environment was published in the Government Gazette on 4 April 2018 to align with Thailand's 20-year National Strategy (2018–2037), providing governmental guidelines to move forward with Thailand's development while balancing concerns about the sustainability of its natural resources. The NRP prescribes that action must be taken towards a comprehensive domestic biodiversity law by 2020.....

.....While Thailand is not a party to the Nagoya Protocol on ABS (a supplementary agreement to the CBD), the Draft BD Act would adopt its legal framework to ensure effective implementation and the fair and equitable sharing of genetic resources and associated benefits.....

Nagoya Protocol Countries

Albania, Belarus, Benin, Bhutan, Botswana, Burkina Faso, Burundi, Comoros, Côte D'Ivoire, Denmark, Egypt, Ethiopia, European Union, Fiji, Gabon, Gambia, Guatemala, Guinea Bissau, Guyana, Honduras, Hungary, India, Indonesia, Jordan, Kenya, Lao People's Democratic Republic, Madagascar, Mauritius, Mexico, the Federated States of Micronesia, Mongolia, Mozambique, Myanmar, Namibia, Niger, Norway, Panama, Peru, Rwanda, Samoa, the Seychelles, South Africa, Spain, Sudan, Switzerland, the Syrian Arab Republic, Tajikistan, Uganda, Uruguay, Vanuatu, and Vietnam

International Bioproperty Access and Technology Transfer

- ❑ Determine the necessity of bioproperty transfer
- ❑ Make sure ownership is clear and true
- ❑ Consider the need for Material Transfer Agreements
 - ❑ Bailment contract)
- ❑ Understand and properly execute the export and import regulations for the bioproperty
- ❑ Be aware of any laws that constrain the shipment of bioproperty outside the country

International Bioproperty Access and Technology Transfer

- ❑ Conduct these in parallel:
 - ❑ Execute regulatory necessities
 - ❑ MTA in place, if necessary
 - ❑ Negotiate terms for possession and use
- ❑ Remember to manage:
 - ❑ Intangible IP.....

and

 - ❑ tangible bioproperty
 - ❑ in parallel and jointly, where appropriate

Bioproperty Management by Individual Researchers

- ❑ Keep good records of their property
- ❑ Label their property appropriately
- ❑ Take proper steps to restrict access to property by others
- ❑ Actively protect against “pirates”
- ❑ **ALWAYS** require a signed bailment (MTA)
 - ❑ Prior to providing physical possession
 - ❑ Keep a record of the bailment
- ❑ Require an MTA to bring any bioproperty into the lab

Bioproperty Management by Organizations

- ❑ Keep good records of all biomaterials
- ❑ Allow physical possession by others only with a written bailment
 - ❑ i.e., An Material Transfer Agreement
- ❑ Who owns inventions made using the bioproperty?
 - ❑ The “but for” clause
 - ❑ Who owns (and / or has rights in) clonal progeny?
 - ❑ Who owns (and / or has rights in) derivatives?

Bioproperty Licensing

- ❑ Requires tight control of possession & use prior to licensing
 - ❑ Some bioproperty cannot feasibly be licensed
 - ❑ If it is the item of commerce, it will become public domain
 - ❑ Because it reproduces
- ❑ Works well when the bioproperty is used in manufacture of a product
- ❑ When appropriate, bundle the bioproperty and IP in the license grant and royalty provisions:
 - ❑ Tiered royalty on use of bioproperty and IP
 - ❑ Bioproperty-use royalty after IP expiration
 - ❑ Must step down if IP is a patent

Bioproperty Licensing

- ❑ Determine if bioproperty is part of the technology
 - ❑ If so, bundle it with the IP in the license agreement
 - ❑ Make sure you are the clear owner
 - ❑ Be sure it has not been made publicly available
 - ❑ E.g., Through actions of your researcher
 - ❑ Consider the value of the bioproperty to the licensee
 - ❑ And factor that into the negotiation
- ❑ Include a bailment-type clause in the license agreement that extends your ownership / control