

Guidebook of IP/Technology Transfer

Track 1

Entry-level Tech Transfer Professional

Topic 1.7.6

Bioproperty and Other Tangible Property in Technology Transfer

Managing Biological Materials
“Bioproperty”:
Research & Technology Transfer

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

“property”

the right to own and control

*(human cell lines, tissues, organs 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 physical possessor of tangible, personal property is the owner unless.....

The property has been “bailed” (physically transferred) to a “bailee” (the recipient) 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 physically possess...
.....with no transfer of
ownership

The contract can be written or implied

In widespread use in society and commerce

A Bailment

is the transfer.....

of *the right of possession*

to tangible property

by the owner (“bailor”)

to a recipient (“bailee”)

with *no transfer of ownership*

Bailments

in life science 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

Common Examples of Bailments in everyday life

- Leaving a car with a mechanic for repair
- Giving your clothes to a laundry, to be cleaned
- Letting your neighbor borrow your lawn-mower
- A painter gives a gallery paintings for an art-show

Bioproperty and the MTA

MTA = Material Transfer Agreement

- A written bailment in which the owner of tangible material transfers right of possession to a recipient, but not ownership
- Typically used when materials shared for research use
- MTAs typically prohibit transfer of materials by recipient to a 3rd party
- MTAs usually restrict commercial use
(that may include inventing/patenting)

Bioproperty and the MTA

MTA = Material Transfer Agreement

- Typically don't allow commercial use or sale
- May be terminated by owner at any time, if term not expressly described.... or
terminated at the end of the defined term
- Disposition of the materials defined in the MTA
destroy, or return
- Often a necessary precursor to an eventual license
agreement
- MTAs should accompany any transfers of bioproperty
into/out of a research institution or company

Regulatory “Gates” for international access and technology transfer

- Environmental, Health & Safety laws
transboundary transport permits
quarantines
dangerous organism protocols
- National Biodiversity Laws

National Biodiversity Laws

Convention on Biodiversity (CBD)

(signatories recognize the rights of states to assert sovereignty over their biodiversity)

Some countries have a national biodiversity law (e.g., India), others do not (e.g., U.S.)

National Biodiversity Laws:

Some have evolved

The Philippines story:

Philippine law started out as extremely restrictive – even prohibiting legitimate research and bioprospecting. Realizing the need for a reasonable approach, later legislation provide a more rational and regulated process

Nagoya Protocol implementation:

[the Protocol stipulates ethical and regulated access to bioresources of a signatory country and shared benefits by rightful “owners” of such resources]

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 & 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 & 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 an Individual

- Keep good records of your property
- Label your 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 an Organization:

Interaction with third parties

- Keep good records of all biomaterials
- Allow physical possession by others only with a written bailment (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)
- 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 & IP
 - bioproperty-use royalty after IP expiration

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 publically available 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

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Thank you