Open Science, Open Data & Nagoya Protocol

Legal certainty in uncertain times

Philippe Desmeth
BCCM International Cooperation Manager
MOSAICC, MOSAICS & TRUST Coordinator
WFCC Past President 2010-2017
OUTLINE

Nagoya Protocol - The Spirit and the Letter
Essence of Science - Cumulative Research
Economics of Science - Creation of Knowledge
Benefit Sharing - Scientific Data Sharing
Communication - Facts, figures and explanation
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3 Objectives

1. **Conservation** of biological diversity
2. **Sustainable use** of its components
3. Fair and equitable **benefit sharing**
PARADIGM SHIFT

to sovereign rights (CBD article 15)

[...the authority to determine access...] (CBD article 15.1)

[...to create conditions to facilitate access...] CBD art. (15.2)
1 Objective  
**fair and equitable sharing of the benefits**  
arising out the utilization of genetic resources  

thereby contributing to the  
1. conservation of biological diversity  
2. sustainable use of its components
NAGOYA PROTOCOL

ABS - Access and Benefit Sharing

Access to Genetic Resources

Quid pro Quo

Fair and Equitable Benefit Sharing arising from their Utilization
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Striking a balance - Law in support of Responsible Science
THE ESSENCE OF SCIENCE

If I have seen further, it is by standing on the shoulders of giants

Letter dated 1676

Isaac Newton
(1642–1727)

CUMULATIVE RESEARCH
MOLECULAR STRUCTURE OF NUCLEIC ACIDS

A Structure for Deoxyribose Nucleic Acid

We wish to suggest a structure for the solid of deoxyribose nucleic acid (D.N.A.) which has novel features which are of biological interest.

A structure for nucleic acid was proposed by Pauling and his collaborators in a series of publications in 1953. In this structure three intertwined chains are near the fibre axis, and the chains lie side by side with identical bases. Each base pair must be a purine and pyrimidine for bonding to occur. The structure is made as follows: purine position 1; purine position 6 to

J. D. WATSON

F. H. C. CRICK

It is found that only specific pairs of
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KNOWLEDGE IS AN ECONOMIC ASSET

From sciences to economic production

The Bioeconomy to 2030
DESIGNING A POLICY AGENDA

Main Findings and Policy Conclusions

Francis Bacon
(1561–1626)
KNOWLEDGE BASED BIO-ECONOMY

From renewable biological resources to sustainable products and services
KNOWLEDGE BASED BIO-ECONOMY

Internet based
KNOWLEDGE BASED BIO-
ECONOMY

Culture Collections
Socio-economic agents
Material Expertise & Data Providers

Public
Research Infrastructures

Industry

Socio-economic outputs

Networks

COOPERATION - COMMUNICATION

Collections

Internet based

Public

Private

FUNDING

New technologies

Knowledge

Data / Metadata

Microorganisms

IT

Biological diversity
COLLECTIONS ARE SOLUTION PROVIDERS

MED: Material-Expertise-Data

Micro-biological Resources

Data (raw & processed data)

Expertise Services & After sales
Collections’ mission

To provide for

Fit for Purpose Material-Expertise-Data

Scientific & technical adequacy

Legal Certainty

Biological Resources

Data

Services + after sales

To provide for Scientific & technical adequacy

Legal Certainty

To provide for Scientific & technical adequacy

Legal Certainty
STAKEHOLDERS  I.E. ECONOMIC AGENTS

Biologists  R&D

Lawyers  Contracts

Officials  Authorization

Civil Society  Consent

In situ
Ex situ facilities
Biosafety, biosecurity
ABS

Civil society
Local communities, NGO
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CONTROVERSIAL DEVELOPMENTS

Should the Nagoya Protocol rule the access to Digital Sequence Information on Genetic Resources?

Legal Certainty requires
- applicable laws, applying rules in the real work setting
- clear delineation, scope of the law

Scientific progress requires
- Open science - Open Access to Data
CONTROVERSIAL DEVELOPMENTS

WORLD FEDERATION FOR CULTURE COLLECTION

- Open access to DSI for the advancement of life sciences
- Accurate identification of strains is paramount for cumulative research
- Benefit sharing rights to be acknowledged,
- Ethical use of DSI at all times,
- Subject to sovereign rights and abide by the laws of relevant jurisdiction
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Communication - Facts, figures and explanation
Scientific community must explain

- The actual working of Up- and Downstream research
- The role of science in achieving the CBD objectives
SCIENTISTS’ MESSAGE

• Promote open science and open data access
• Present hard facts and oppose subjective statements
• Popularize science in the CBD context, show examples
• Integrate the opinion of same-minded stakeholders
• Propose solutions

STRIKING A BALANCE : LAW in support of RESPONSIBLE SCIENCE
PREREQUISITES to Fair and Equitable Benefit Sharing

Convention on Biological Diversity

Utilization

Conservation

Benefit Sharing

NAGOYA PROTOCOL
STRIKING THE RIGHT BALANCE

Many scientific upstream research are non-monetary multi-lateral benefit sharing mechanisms that effectively implement the CBD and Nagoya Protocol.
GCM 2.0 Whole Genome Sequencing of 10 000 type and reference strains

GCM 2.0 Collaborative Research Agreement:

[...] Sequences and associated information will be
- posted to public available databases (Genbank/EMBL/ DDBJ/GCM) and
- used for free for non-commercial use. [...]

GCM 2.0 Contributes to the CBD objectives

CBD Article 7. Identification and Monitoring
Each Contracting Party shall, [...] Identify components of biological diversity

Nagoya Protocol Annex - [...] Non-monetary benefits [...] (a) sharing of research and development results (k) Access to scientific information [...], including biological inventories and taxonomic studies;
Conclusions

MAKE IT WORK

Optimal access to material
=> Law(s) facilitating *ex situ* preservation of biological material

Optimal access to data
=> Data easily accessible
=> Consolidation of non monetary benefit-sharing systems

Optimal legal definitions
Blending Science, Law and Ethics for Sustainable Bio-economy
=> How to help building jurisprudence beforehand?
=> Adapt the legislative frame to the R&I working: switch from static to dynamic R&I model
Conclusions

ENLARGE THE PLATFORM

- Universities and Public research institutions
- Scientific societies
- Scientific journals
- Other stakeholders
Coordinated efforts
Cooperation between networks
Consistent legal policies
Communication
DIALOGUE & COLLABORATION

World Intellectual Property Organization

World Health Organization

United Nations Educational, Scientific & Cultural Organization

Convention on Biological Diversity

International Standards Organization
Conclusions

SHOWCASE OPEN DATA MODELS

Examples

- GCM 2.0 => 10 000 Whole Genome Sequences in 5 years
  - Genomic data made publicly available
  - Growing partnership from all continents
  - Capacity building

- GenBank, EMBL-EBI, DDBJ

Communication towards other stakeholders

- CBD & Nagoya Protocol meetings, submissions
STRIKING THE RIGHT BALANCE WITH FACTS

Accuracy & Precision

Subjectivity

Objectivity
Message distortion
“Frankenvirus”, “Biopirates”, etc
SCIENTIFIC PUBLICATION ≠ GENERAL MEDIA
PROACTIVE STRATEGY

December 1993  CBD comes into force

MOSAICC (1999)  Basic procedures
Standard contract (Material Transfer Agreement)

April 2002  Bonn Guidelines

MOSAICS (2005)  Global Hazard Identification
Yeast Global Catalogue of Microorganisms

October 2014  Nagoya Protocol comes into force

The Global Catalogue of Microorganisms
Linkage with ABS Clearing House (ABSCH)
Updated Model contracts MTA & MDA
Specific procedures (basic research, emergencies, regularization)

Facilitating Access & legitimate use
Operating Nagoya Protocol in Microbiology

TRUST - TRansparent Users-friendly System of Transfer

Two parts system

Administrative Guidelines, Documents & Procedures
= Legal processing (MOSAICCC based)

Global Catalogue of Microorganisms (GCM)
= Technical processing
Global Strategy supported by ICT infrastructure

Global Directory & ID System
- CCINFO: Culture Collections Information Network for culture collections in the world.
- 763 collections from 76 countries

Global Catalogue of Microorganisms
- Global Catalogue of strains - Access
- 125 catalogues from 47 countries

Data Mining - R&D developments
- Analyzer of Bio-resource Citations
  - ABC is a platform that could support the researchers on the citations among papers, patent, genome, nucleotide sequences.

NP art 22 Capacity
NP art 23 Technology Transfer, Collaboration & Cooperation

Supporting Uses & QMS processes
Linking the ABS Clearing House and user sector databases

Operating Nagoya Protocol in Microbiology

MOSAICC Guidelines
TRUST System
GCM
GCM 2.0

Optimize information flow => maximise legal certainty => E-TRUST
What does a nice girl do?

She seeks the advices of her Tech Transfer office.

She listens to her Tech Transfer office!

“To Kill a Mockingbird” Harper Lee
Thank you