Exploration of access and benefit sharing models: The common domain model.

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With thanks to Thomas Vanagt, Arianna Brogiato, Harriet Harden-Davies & Hiroko Muraki Gottlieb
Why use marine genetic resources?

- Offers advantage over comparable terrestrial resource:
  - Superior performance
  - Better economics
- Unprecedented activity in particular application:
  - Enzymes: new reactivity/new biotransformation
  - Small molecules: novel chemical structures & new mechanism of action
  - Materials: new properties

Vent Polymerase
for DNA amplification
Origin: Vent bacterium

Halaven for cancer
Origin: Japanese sponge
Marine Bioprospecting suggests that the MGR are mined to generate product – this is not true for most examples.

The MGR are used as inspiration to generate a product which is made by other means.

For this reason the words “marine biodiscovery” are used which suggest that it is the inspiration that is important and that the resource is not mined.
Biodiscovery from BBNJ

Sampling in ABNJ

MGR

Chemistry

Product

Bioassay

Elements of good practice already exist at all stages of the marine biodiscovery pipeline
Notification & Reporting Requirements

Application
- Cruise plan

Award
- Feasibility
- Checks

After Cruise
- Cruise report

- Starts with marine scientific research

Where to report data?
- Nagoya Protocol clearing-house
- New clearing house linked to NP
- A new international organisation

NP already requires evidence that collection did not come from area under national jurisdiction
Impact of Sampling

• Volume of a 1 m long core 15 cm Ø = 20 liters
• Estimate 5 cores sampled at same time = 100 liters
• Total sampling points recorded = 100,000*
• Total volume = 10,000,000 liters = 10,000 m³
• Equivalent to 150 x 40 foot shipping containers (66 m³ each)
• Equivalent to a layer 32 picometers (32 x 10⁻¹² m) thick covering ABNJ
• 32 picometers is equivalent to radius of Helium atom

*Ward Appeltans, OBIS
Benefit Sharing

- Must be multilateral compared to bilateral for Nagoya Protocol
- In most cases most important benefits from use of MGR are non-monetary.
- Non-monetary benefits may include:
  - Scientific exchanges/training
  - Technology transfer
  - Capacity building (infrastructure)
  - Enhanced reputation
  - Increased number/quality of scientific publications
  - Biodiversity conservation
  - Valuable regional resources developed (knowledge, samples, data)
- Non-monetary benefits still cost money – however they are upfront compared to royalties
Is a Public Domain Approach Possible?

- Public domain approach may be used when:
  - There is no desire/need to control access
  - There is more than enough of a resource for all to utilise
- Precedents in biology/software/semiconductors
- Low cost – commensurate with size of problem
Public Domain Approach

• Benefits will accrue where MGR are used
• All should be able to benefit from discoveries
• This approach will lead to greater innovation, transparency and openness
• Access for landlocked & developing countries
• Make sure all can benefit and can exploit - requires capacity building to ensure fairness
IUCN Matrix: Public Domain

• Create a multilateral/pool system based on the public domain approach facilitating international access to and scientific research on MGR from ABNJ as well as associated raw data

• Fair and equitable sharing of non-monetary benefits, in particular by putting samples of MGR collected in ABNJ as well as associated data in the public domain as soon as possible (use embargo period)

• Share further non-monetary benefits by facilitating international collaboration, technology transfer and capacity-building

• Fair and equitable sharing of monetary benefits in case of commercialisation
How to Achieve a Public Domain Approach

• Samples and related data to be put in public domain
• Sharing through international networks of biorepositories and international networks of databases creating common pools
• Sub-samples stored in centralized biorepositories at national or international level
The Idea

MGR samples and raw data

Commercialisation (not just IP filing but use of IP)

Share samples and data
The Idea:

- Share MGR and associated data from BBNJ, upholding freedom of MSR in ABNJ
- If resulting work on these MGR is commercialised, apply for IP protection

However:

- UNCLOS Article 244 provides that the results of MSR should be shared. Propose that this includes raw data and samples, but not intellectual knowledge development.
- Part XIV provides that marine technology should be transferred to developing States.

But:

- Allow IP derived from inventions based on raw data/samples to be used by all in their respective markets thus sharing results (meeting requirements under Part XIII MSR and Part XIV marine technology transfer).
- Focussing on socially beneficial uses is also a non-monetary benefit from MGR - contributes to addressing big societal problems.
- Requires capacity building to ensure fairness.
Where is the transition from basic research to research with commercial intent? (when does actual value become apparent?)

- When research is initiated?
- When organism is found to be active?
- When active pure compound is identified?
- When NDA is filed?
- On patent filing?
- Actual Commercialisation (IP licencing/development)

Organism

Active compound

Extract & Purify

Cycle of purification and bioassay

NCE/NDA

Marketed drug

Commercialisation
Precedents That Can Be Used For Inspiration
Open Source
We promote an innovation paradigm that focuses on a distinction between the tools of innovation and the products.
We promote licenses that couple rights with responsibilities to foster efficient development, improvement, sharing and use of technology.

Open Science
We create and share new biological enabling technologies and platforms that can be used to deliver innovations.
We develop new licensing and distributive collaboration mechanisms that have resonance with the open source software movement, but are tailored for biological innovation.

Open Society
We enhance the transparency, accessibility and capability to use all the tools of science, whether patented, open access or public domain.
BioBricks

Users Contribute Genes to BioBricks

Genes Incorporated in Product

Accessed by Multiple Users

Improvements Contributed Back

BioBricks Parts
BioBricks

- **Mission Statement:** “The BioBricks Foundation’s mission is to ensure that the engineering of biology is conducted in an open and ethical manner to benefit all people and the planet. We believe fundamental scientific knowledge belongs to all of us and must be freely available for ethical, open innovation. This is a new paradigm”

- Relies on adoption of standards.
- Uses a legal framework that enables the accrual of an open collection of functional genetic elements encoding standard biological parts.
- Exacts a promise not to assert any property rights against others under certain conditions of use.
- Supports the development of an open shared platform that both academics and industry can use, while still allowing proprietary systems to be built on this open platform (cf Open Source software)
- Patent the product not the parts?
BioBricks Public Agreement: The User agrees that if the User commercializes or otherwise distributes the Materials in either their original form or a modified form, the User will attribute the use of the BioBrick Public Agreements by using reasonable efforts to conspicuously include the logo in all packaging or product inserts, publications, and grant-related materials. In order to ensure the quality and integrity of the Foundation’s activities, the Foundation owns that logo and all goodwill derived from its use.

Due Diligence: The User will also respect the valid property rights of others in the Materials and determine if User’s use of the Materials violates any intellectual property rights.

Socially Beneficial Uses: The User will refrain from using the Materials in connection with any intentionally harmful or unsafe uses.
Open Source Drug Discovery

Contributors/ Users: Materials / Ideas
Facilities/ Capabilities

Assays: Neglected Disease focused

Compounds

Design/ Redesign

Data

Data Analysis

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• Driving force is neglected diseases such as TB
• OSDD enables sharing of data for collaborative research for drug discovery, information, including but not limited to, ideas, articles, papers and other literary work, data, software, applications, notes, results of experiments, patented inventions, confidential information and other materials submitted by the users
• Use of ‘click-wrap’ licence requiring users to agree that they will not file product patent applications where they rely on open source data
• Use of microcredits for contributions
• NCEs developed by OSDD will be taken up for clinical trial in a non-exclusive manner by participation of multiple companies with majority funding from OSDD
Open Source Drug Discovery

- Anyone is free to contribute or use OSDD community property but with the obligation that all improvements and value additions are contributed back to the community
- Requires credit given to the works of others
- Use a business model where drugs are made available at affordable prices through market based competition without the exclusivity of IPR, leading to competitive pricing
- Data standards agreed at the outset
- **Licence**: “You assign to OSDD the worldwide royalty free non exclusive licence on any information submitted by you to Protected Collective Information for the sole purpose of the use of OSDD members for furthering the Vision and Mission and for that purpose only”
- “In the event of your acquiring any intellectual property rights by making improvements or modifications on any part of the Protected Collective Information, you shall grant an unencumbered worldwide non exclusive right to the OSDD for use of such rights for further research in furtherance of its Vision and Mission.”
Additional Ideas

- Can a sponsor be found to manage IT infrastructure for MGR from ABNJ (a major IT provider helped OSDD)?
- Alternatively can we develop open source database solutions?
- Involve the Schmidt Ocean Foundation with their focus on open data
- Tap into existing sharing networks, many exist besides OSDD, BioBricks, Open Source Software, gene databanks, sample repositories.
- If multiple actors contribute to the development of a product from BBNJ how can we share credit and benefits – use idea of microcredits?
- If milestones or royalties arise from the use of MGR from ABNJ can a common percentage flow back to a common pool, the percentage depending on the market?
“The research leading to these results has received funding from the European Union's Seventh Framework Programme (FP7/2007-2013 under grant agreement n° 312184)”