Implications of Access and Benefit Sharing Frameworks for Collections and Utilisation of Marine Genetic Resources

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With thanks to Oonagh McMeel and Thomas Vanagt
PharmaSea

>110,000 screening events
>700 active dereplicated extracts

Active, non toxic, novel chemistry

45% From existing partner collections
55% New samples from cold/hot/deep habitats

At 30 Months:
13,689 Strains
>14,000 Active Extracts
>80 Active Compounds
1 Drug Lead
2 Drug Leads

Microorganisms → Extracts → Molecular Leads → Scale Up

Screening
Microbial Library
Extract Library
Molecular Families
The PharmaSea Pipeline

Sampling in ABNJ → MGR → Chemistry

Product

Bioassay

% PTZ-induced activity vs time (min)

- PTZ
- VHC
- PS-243 - 100µg/ml
- PS-243 - 50µg/ml
- PS-243 - 25µg/ml
PharmaSea is Working at the Science/Policy Interface

Create Science/Policy Interface

MGR Practitioners
Research / Industry

Awareness Raising

Inform Policy

Legal Experts & Policy Makers
EC (DG MARE & DG ENV), UNDOALOS, CBD Secretariat, CIESM, ISA, CMS Secretariat

Share best practice

Marine Genetic Resources and the Nagoya Protocol
Preparing the Marine Scientific Community

Natural Product Reports

Welcome

The PharmaSea MGR User Toolkit will support the lawful and sustainable use of marine genetic resources (MGR) within European maritime biotechnology.

Marine biotechnology may often depend on access to marine organisms, collectively termed marine genetic resources (MGR). Scientists, familiar with the potential challenges of collecting MGR samples in the marine environment, are often less aware of the legal and policy frameworks governing access to MGR. The applicable regime governing MGR sampling and utilization varies depending on where in the marine environment the sample originates. For example, the Nayarit Collective Access Agreement may apply to marine samples from Arctic collections depending on the applicable laws in the State from where the samples were originally sourced.
United Nations Convention on Laws of the Sea (UNCLOS)

**UNCLOS:** ‘peaceful uses of the seas and oceans, the equitable and efficient utilization of their resources, the conservation of their living resources, and the study, protection and preservation of the marine environment’

**BUT:** No mention of ‘Marine Genetic Resources’ UNCLOS Part XI only applies to “resources” defined as non-living, mineral resources

**Conflicting Elements:**

**Freedom of the High Seas:** Freedom to conduct Marine Scientific Research – requires sharing of results

**Common Heritage of Mankind:** No state shall claim sovereignty over any part of the area or its resources (incompatible with IP protection?). Implies equitable sharing of benefits?
UNCLOS Definitions

Scale of Rights

- **Sovereign Territory**
  - **Territorial Sea** Baseline
  - **Contiguous Zone**
  - **Exclusive Economic Zone**
  - **Continental Shelf**
  - **The High Seas**
  - **The Area**

- **Sovereign rights to the water column and continental shelf**
- **Sovereign rights to the continental shelf**
- **No national rights**

1 nautical mile (M) = 1852m
UNCLOS Relationships to Other Bodies

- **UNCLOS**: UN Convention on the Law of the Sea
- **UNGA**: UN General Assembly
- **UNEP**: UN Environment Programme
  - **CMS**: Convention on Migratory Species
  - **CBD**: Convention on Biological Diversity
  - **RSCs**: Regional Seas Conventions
- **FAO**: UN Food & Agriculture Org.
- **RFMOs**: Regional Fisheries Management Orgs.
- **UNESCO**: UN Education, Science & Cultural Org.
  - **[WHC]**: World Heritage Convention (not currently applied in the high seas)
- **IOC**: Intergovernmental Oceanographic Commission
- **UNFSA**: UN Straddling Fish Stocks Agreement
- **Part XI**: Part XI Agreement
  - **UNSAF**: UN Non-Self-sustaining Fishing
- **IMO**: International Maritime Organization
  - **ISA**: International Seabed Authority
  - **MARPOL**: London Convention & Protocol (dumping)
- **LC/LP**: London Convention & Protocol
The Process so Far

1982
- **UNCLOS** Excludes marine genetic resources, but allows freedom of marine scientific research

1996
- “The Deepest of Ironies” by Lyle Glowka raises this issue

2000s
- “Ad-hoc open ended working group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction”
The Process so Far

2015
• Decision to “develop an international legally-binding instrument under UNCLOS”

2016
• Preparatory Committee (4 x 2 week sessions) open to all UN member states and observers to develop elements of a draft text for an implementing agreement.

2017-
• Intergovernmental conference, to consider the recommendations of the preparatory committee on the elements and to elaborate the text of an international legally-binding instrument
The Package Deal

Conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction, in particular, together and as a whole:

• marine genetic resources
• sharing of benefits
• area-based management tools
• marine protected areas
• environmental impact assessments
• capacity building and the transfer of marine technology
Definitions

**Bioprospecting (Oxford English Dictionary):** “the search for plant and animal species from which medicinal drugs and other commercially valuable compounds can be obtained.”

**Bioprospecting** is the discovery of compounds and associated ideas from genetic resources to develop novel biomedicines, biomedical research tools, antifoulants, catalysts, nutraceuticals, cosmeceuticals, etc. **Unlike seabed mining, marine genetic resources are not mined.**

**Marine Genetic Resources:** Term has no meaning to biologists and is not defined in UNCLOS but is taken to mean the Nagoya Equivalent: “Marine genetic material” means any material of plant, animal, microbial or other origin, **found in the marine environment**, containing functional units of heredity ; “Marine genetic resources” means **marine** genetic material of actual or potential value”
An International Instrument on Conservation and Sustainable Use of Biodiversity in Marine Areas beyond National Jurisdiction

Matrix of Suggestions

16 December 2015
Input into the Process – Before and During the PrepCom

Recommendations for the elements of a draft text of an international legally binding instrument on MGRs

United States Mission to the United Nations

[Image]

IUCN Intervention on MGRs for Informal WG

Thank you Mr. Facilitator. We would also like to congratulate you on your appointment.

Speaking from the scientific perspective, we would like to add a few points to the discussion for your consideration. We believe that the provisions of the Agreement on marine genetic resources should be informed by science and scientific practice so that they can be more realistically implemented.
Differing Opinions

**USA, Norway and others:** Freedom of the high seas is paramount

**G77 & China:** common heritage of mankind applies

**EU:** seeking pragmatic solutions
PharmaSea Advice to Policy Makers at the UN

Early 2014 – APPLE meeting on biodiversity beyond national jurisdiction

June 2014 – Side event at the UN Ad-Hoc Open Ended Working Group on BBNJ, UN, NY

November 2015 – Tarrytown NY, presentation of the IUCN matrix to members of the IA Preparatory Committee (PrepCom)

February 2016 – Centre for International Law, Singapore, BBNJ workshop

March 2016 – Ugandan UN Mission, NY, advice on BBNJ to African Union

March 2016 – Advice to G77 on BBNJ

April 2016 – Advice to Peru, Chile and Ecuador at Peruvian UN Mission

April 2016 – Side event at PrepCom on the Science and Business of Marine Genetic Resources

April 2016 – IUCN/PharmaSea Workshop at NYU Law School on Challenges and Options for Addressing Marine Genetic Resources in Areas Beyond National Jurisdiction
PharmaSea at the UN – Side Events

Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction
Examples of Scientific Advice Provided

• Diversity of marine genetic resources
• Current good practice in marine bioprospecting
• Examples of successful exploitation of marine genetic resources
• Realistic benefit scenarios
• Traceability
• Benefit sharing scenarios
• Capacity building ideas
• Scientific advances that might affect implementing agreement
Marine Genetic Resource Diversity

Animal Diversity

Of the major divisions of animal life ~20 have no representatives on land.

Microbial Diversity

There is no clear estimate of marine microbial diversity or its economic value.
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
- Onus on flag state/vessel operator?

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

Trawling impact ranges from 0.005 to 0.009 km²

Gravity coring leaves a 10cm diameter hole that close within 1 h.

Mega coring in a typical cruise will impact ~0.5m² of seafloor

Removing 0.5m² of seafloor in ABNJ = 0.19cm² of Yellowstone national park
Non-Pharma MGR Derived Products on the Market

Vent Polymerase – for DNA amplification
Origin: Vent bacterium (Naples, Italy)
Production: Recombinant
Owner: New England Biolabs

Fuelzyme – Enzyme used in biodiesel production
Origin: Deep sea bacterium (location unknown)
Production: Recombinant
Owner: Verenium (BASF)

Cosmetic screening infra-red rays
Origin: Vent bacterium (location unknown)
Production: Bacterial culture
Owner: Sederma (Croda)

Anti biofilm agents
Origin: Red seaweed
Production: Chemical Synthesis
Owner: XXXXXX
Real Benefit Scenario

- Cost in 2014 to bring drug to market US$2,558 M* - >70% Clinical trials
- Typical industry royalties on natural products developed into drugs is 1-3%
- Halaven (Eisai), derived from a Japanese sponge makes US$200 M per year – in principle yielding US$ 2-6 M pa.
- Currently 7 approved marine drugs – total royalties would be US$ 10-50 M.
- Blockbuster drug (> US$ 1 Bn pa income) would yield US$10-30 M pa
- Currently 7 approved marine drugs come from ~28,000 discovered marine compounds (1 in 4000 chance) – none are ‘blockbusters’
- All examples were discovered pre-CBD – not clear if actual royalties are being paid
- Other markets – nutraceuticals/cosmeceuticals, lower risk, quicker to market, lower investment and lower returns.

Benefit Sharing

- Multilateral NOT Bilateral
- Most important benefits are non-monetary.

Public domain approach

- Low cost
- Benefits will accrue locally
- All should be able to benefit from discoveries
- **Requires capacity building to ensure fairness**
- This approach will lead to greater innovation, transparency and openness
Monitoring Sample and Data Flows

Sampling in ABNJ → MGR → Chemistry → Bioassay → Product

Possible to track sample from origin to exploitation (needs better databases)
Tracking Samples can be Tricky

Vent Polymerase
For DNA amplification
Synthetic Biology - Nightmare Scenario

Vector and host may have associated IP rights

Gene 1
Originally found in Australian EEZ Marine organism

Gene 2
Gene 3
Gene 4 (ABNJ)

Known bioactive compound
How You Can get Involved

• Contact your national delegation to the UN
  • Contact permanent mission to the UN in NY
  • Many are requesting advice but don’t know who to ask
• Contact relevant Ministry in your Country
• Contact EU policy maker at DG-MARE representing your country in the EU Delegation to the UN
• Work with PharmaSea on developing networks and contacts
• Work with the IUCN on developing networks and contacts
• Through the European Science Foundation Marine Board
• Through EMBRC
• Through the Deep Ocean Stewardship Initiative
• Please get involved – this will affect you!
Issues for Our Community

• Provide reliable scientific and other evidence to ensure marine scientific research on marine genetic resources is not impeded.

• Definitions (e.g. Marine Genetic Resources)

• Highlighting and agreeing on elements of good practice.

• Reporting and notification procedures: how will it be monitored/policed and by whom?

• Traceability becomes an issue as benefits may take a long time to be realised. Who will trace this?

• How can we manage expectations for financial returns?

• Can we make sure an implementing agreement is flexible enough to cope with scientific progress?

• Light touch regulation which does not impose high bureaucratic burden is preferable.
Nagoya-O-Meter

Overly restrictive regime can damage progress of products (Australian example)
“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)”