



Implications of access and benefit-sharing (ABS) frameworks for collection and utilisation of marine genetic resources (MGR)

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With thanks to Oonagh McMeel

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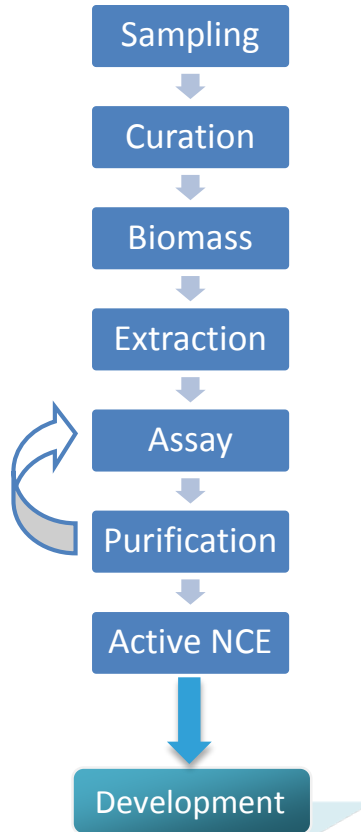
Visiting Professor in Marine Biotechnology at University of Tromsø, Norway

Co-Author of ESF Marine Board Position Paper “Marine Biotechnology – A New Vision and Strategy for Europe”

Scientific Leader, PharmaSea EU FP7 Consortium

Chair of the Advisory Panel of Policy and Legal Experts – aiming to provide clear recommendations and ready-to-use solutions to address critical policy and legal barriers which impede the access and sustainable use of MGR for European biotechnological research, development and commercialisation

The Marine Bioprospecting Process



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, MGRs are not mined.

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

Marine Biotechnology Products on the Market



Vent Polymerase

Origin: Vent bacterium

Production: Recombinant



Prialt for pain

Origin: Phillippino cone snail

Production: Recombinant



ω -3 polyunsaturated fatty acids
for heart disease Source: Fish

Production: Fish



Halaven for cancer

Origin: Japanese deep water sponge

Production: Chemical synthesis

Current Good Practice in Cruise Planning

Application

- Cruise path/stations/equipment.



Award

- Clarification for feasibility/equipment availability.
- Check MPAs not entered.

After Cruise

- Data is logged with central agency – cruise report
- Sample list/locations collected/location stored
- Environmental data/images and video



Access is difficult to monitor and control

Need to ensure notification, reporting and recording of sampling activities in ABNJ

Refer to sampling protocols developed (eg Interridge)

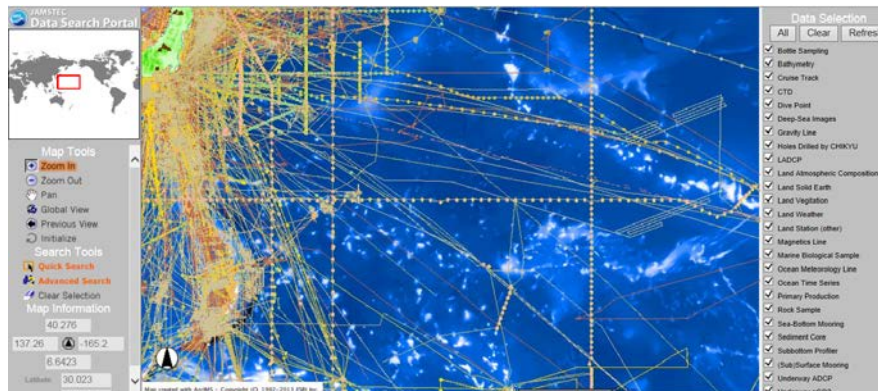
Good Practice for Cruise Data and Samples

Metadata may include

- | Location
- | Depth
- | Temperature
- | Salinity
- | pH
- | Oxygen content
- | Seafloor conditions

Sample storage

- | Ambient temperature
- | Cooler (4°C)
- | Freezer (-20°C)
- | -80°C Freezer
- | Liquid nitrogen (-196°C)
- | Formaldehyde
- | Ethanol
- | DNA/RNA preservation liquids



Needs standardisation

Notification Requirements

Options:

Using the Nagoya Protocol clearing-house mechanism

Setting up a new ABS clearing-house mechanism for ABNJ linked to Nagoya Protocol clearing-house

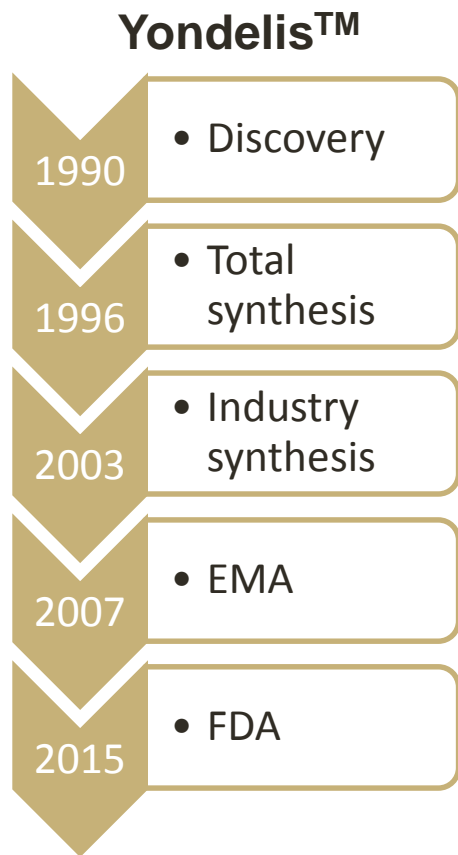
An international organisation with a mandate to grant access and monitor access

Note that the Nagoya Protocol already requires evidence that collection did not come from area under national jurisdiction

Benefit Sharing

- Must be multilateral compared to bilateral for Nagoya Protocol
- In many 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

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.

*Tufts Study http://csdd.tufts.edu/news/complete_story/cost_study_press_event_webcast

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
 - Biology - open data resources (also BioBricks)
 - Software – open source software can be used to make a profit
 - Semiconductor industry – all contributors get right to exploit
- Low cost – commensurate with size of problem
- Benefits will accrue locally on exploitation (exploiter patents & profits – percentage should go to common pool)
- All should be able to benefit from discoveries
- This approach will lead to greater innovation, transparency and openness
- Requires capacity building to ensure fairness
- Access for landlocked & developing countries
- Make sure all can benefit and can exploit

Benefit Sharing Suggestion 1 – 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 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 (consider having 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 commercial research

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

Monetary benefits: The public domain approach would translate into an obligation to share monetary benefits in case of commercial utilization

Benefit Sharing Suggestion 2 – Like CBD/NP

Develop a basic benefit-sharing provision (as done under CBD):

Comprising general principles and obligations aiming at:

Fair and equitable sharing of monetary and non-monetary benefits arising from the utilization of MGR from ABNJ

Facilitation of MSR on MGR from ABNJ through access to *ex situ* MGR from ABNJ and related MSR results/data

Promotion of collaboration in MSR on MGR from ABNJ

Commercial Research

Suggestion 1: Upfront Payment

Access to MGR from ABNJ (i.e. sampling of in situ MGR and access to ex situ MGR as well as related data) for commercial purposes shall trigger an appropriate access fee to be paid by the user to a multilateral fund.

Suggestion 2: Mandatory Milestone Payments

Appropriate milestone payments shall be made by the researcher to a multilateral fund in case of commercialization (see use of terms):

Royalty payments after product based on in situ or ex situ MGR from ABNJ or related data is put on the market.

Exclusivity fee in case of protection of samples and/or data (e.g. through IPR), i.e. when in situ and ex situ MGR from ABNJ as well as associated data is not put in the public domain.

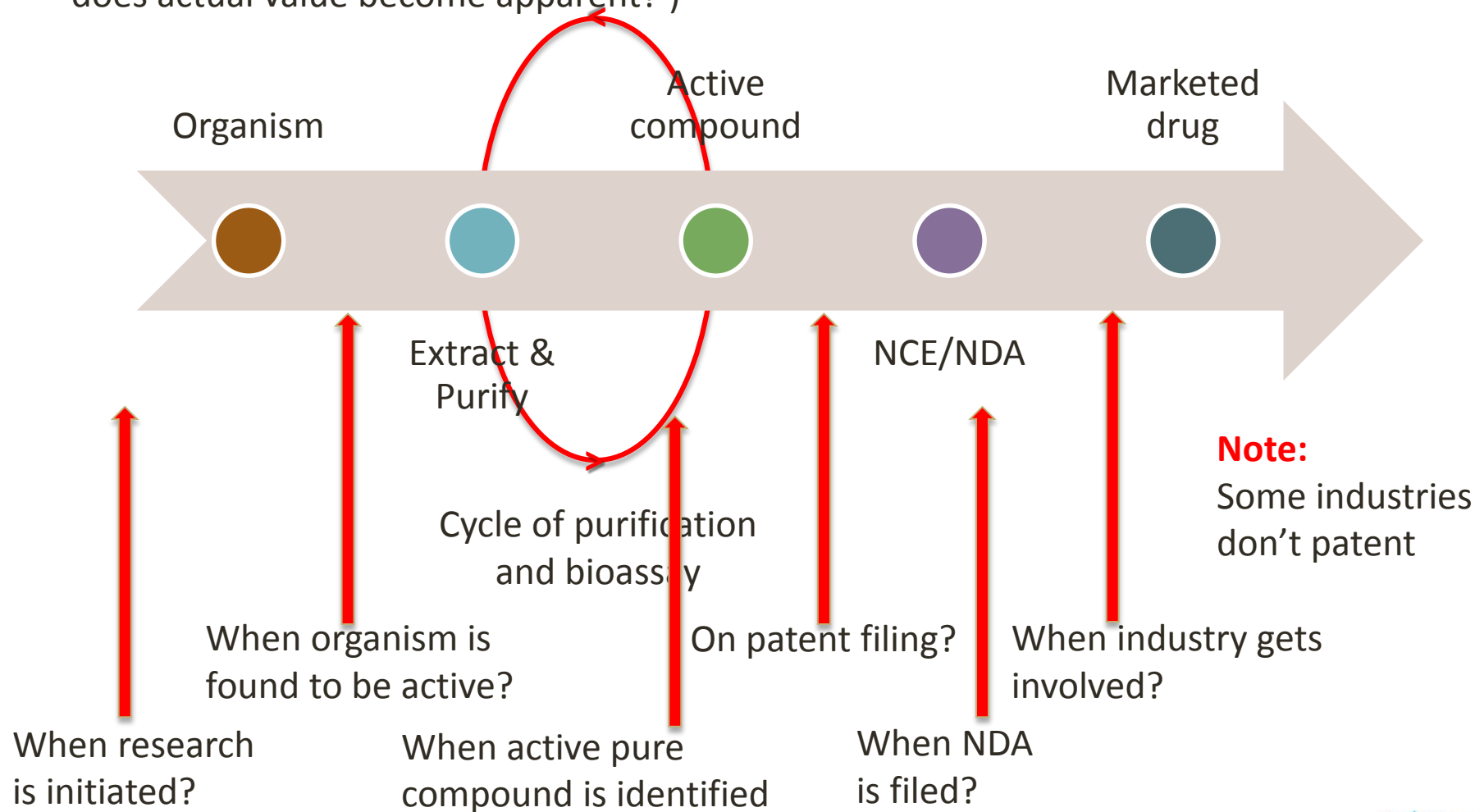
Commercial Research

Suggestion 3: (Mixture of Suggestions 1/2) Mandatory upfront payments as well as mandatory milestone payments in case of commercial research.

Suggestion 4: Mixture of voluntary and mandatory payments from research institutions, commercial end-users, governments and others into an endowment fund for marine scientific research in ABNJ

When does commercial intent become apparent?

Where is the transition from basic research to research with commercial intent? (when does actual value become apparent?)



Monitoring and Compliance

Suggestion 1. To support ABS implementation, the agreement could include obligations for all Contracting Parties to:

Monitor sample and data flows throughout the whole chain of utilization (R&D)

Take appropriate and effective legislative measures to ensure compliance with ABS obligations under the agreement

Address situations of non-compliance (sanctions)

All to be further concretized and developed at national level

Monitoring and Compliance

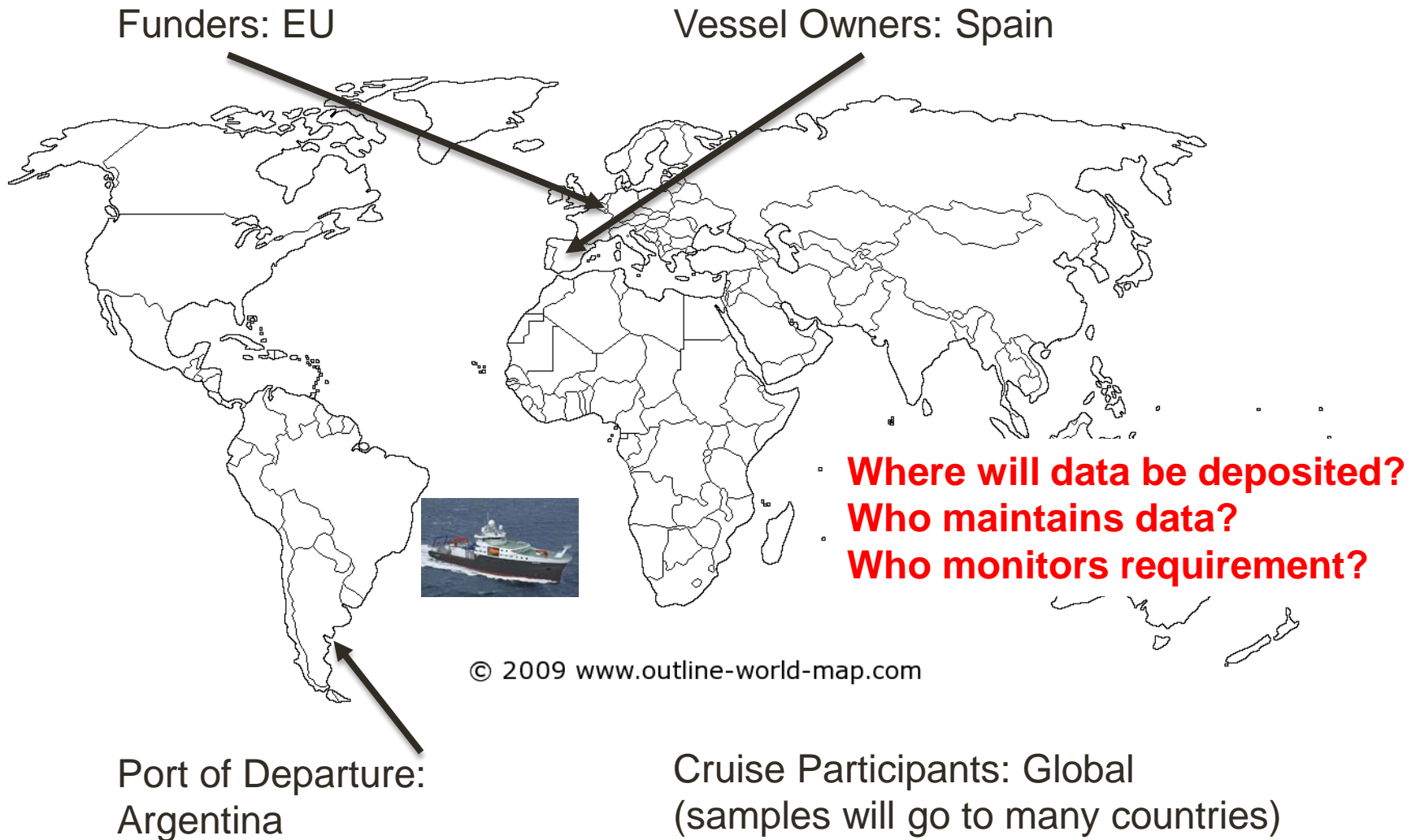
Suggestion 2. As suggestion 1, but specifying:

List of checkpoints that need to be established at national level

Port State measures

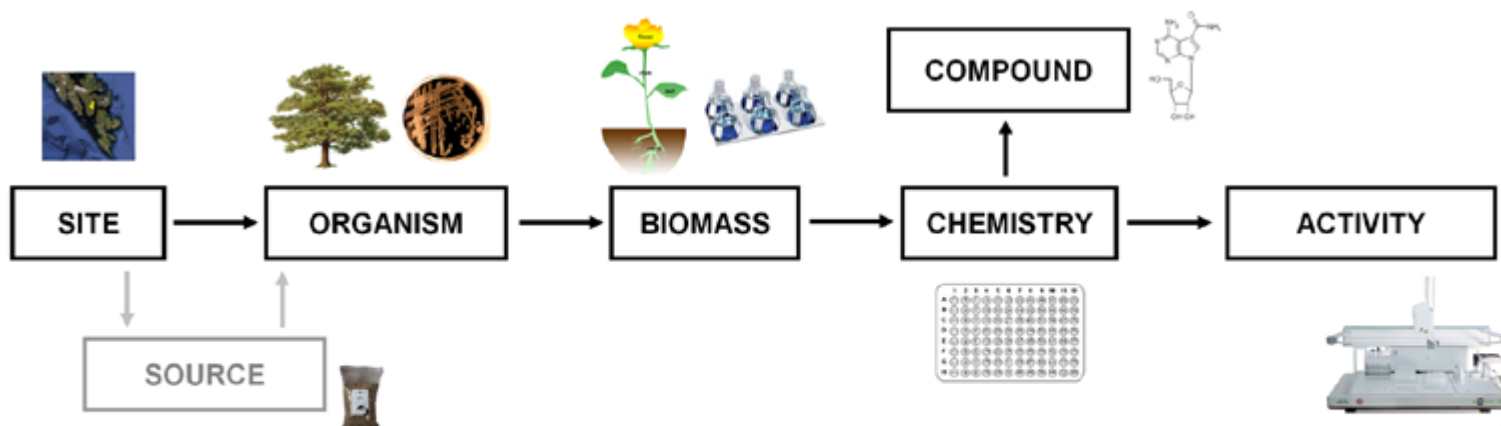
Sanctions in case of non-compliance

Flag State Problem



Monitoring Sample and Data Flows

Possible to track sample from origin to exploitation
(but better databases are needed)



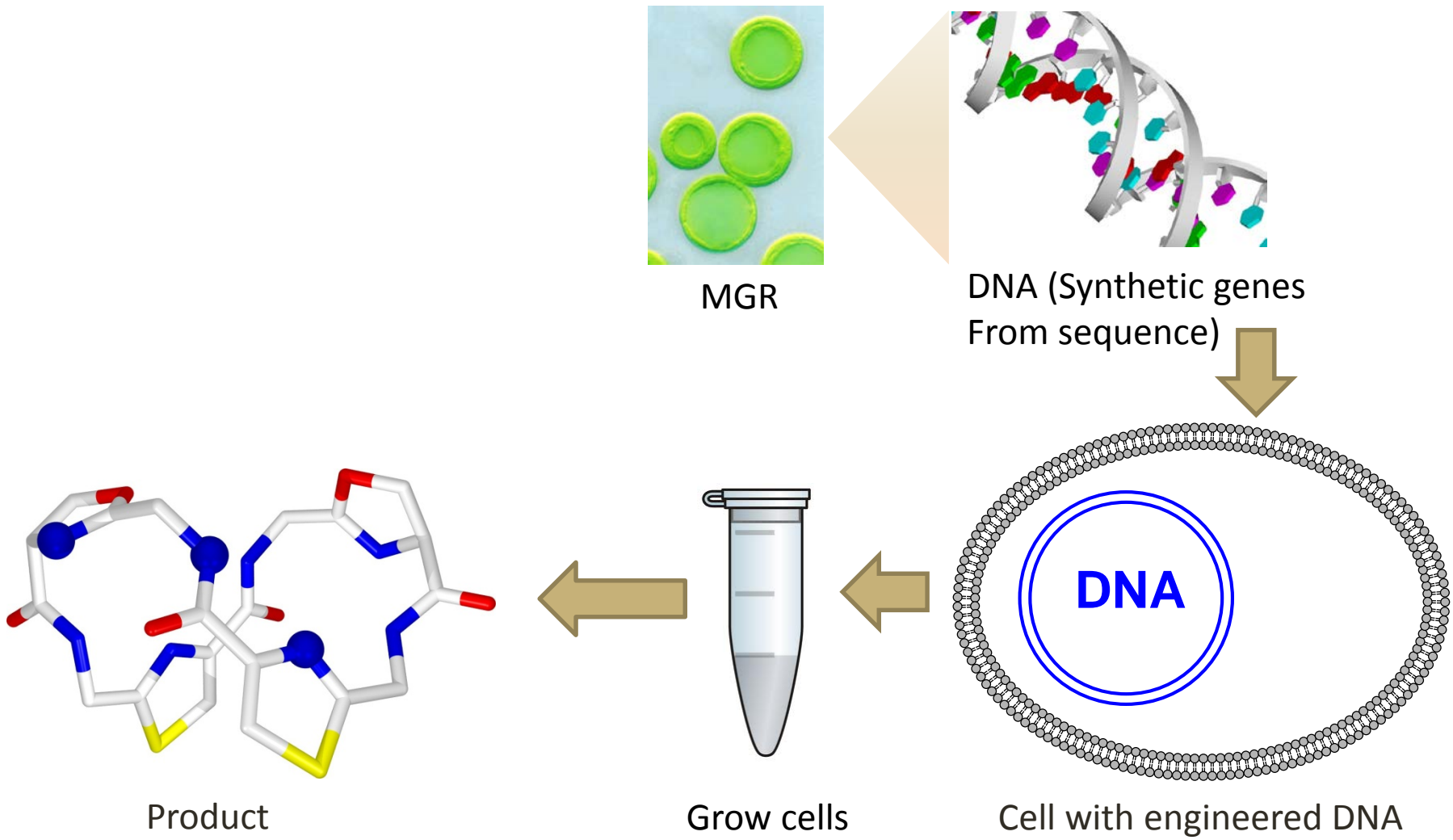
OpenNAPIS™
Functional Design

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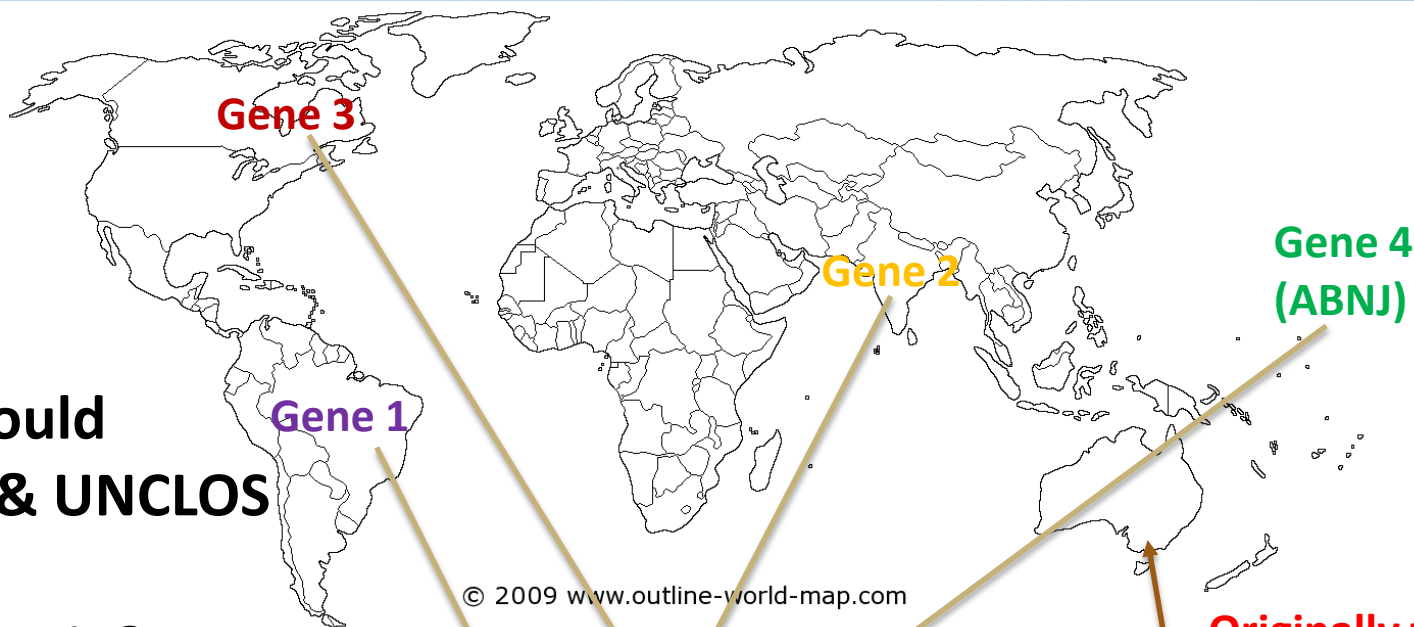
Science is Moving Very Quickly

- Gene sequencing is now inexpensive and extremely rapid
 - Sequence whole genomes/metagenomes very quickly
- Bioinformatics is making huge advances
 - Genome mining to find enzymes/compounds
 - Understanding of how to express these compounds in alternative hosts
- Low cost gene synthesis is a game-changer
 - No longer need genetic resource, only sequence
 - Sequences can be optimised to express in alternative host
 - Genes can be easily combined
 - Genes may be modified and origins hard to trace
- **But:** current databases don't always indicate origin of materials.
- **An UNCLOS implementing agreement developed over the next few years would need to be flexible enough to deal with rapid scientific progress**

Synthetic Biology – From Genes to Products

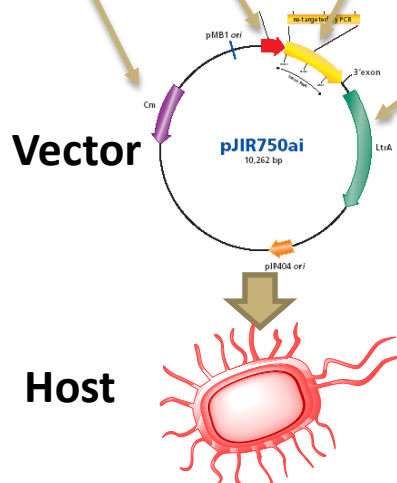


Possible Scenario

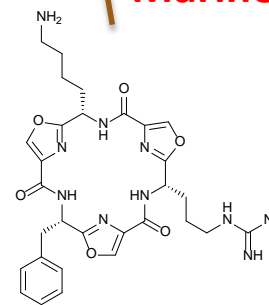


What would Nagoya & UNCLOS do with this scenario?

Vector and host may have associated IP rights



Originally found in Australian EEZ Marine organism



Known bioactive compound

Nagoya-O-Meter

Nagoya-like regime

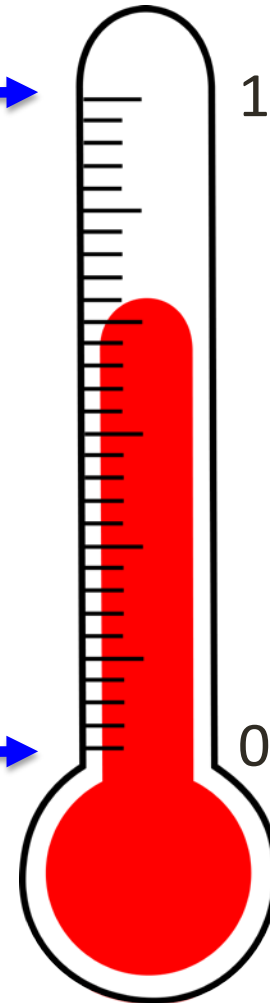


100% Nagoya

Public Domain Model



0% Nagoya



Questions for Discussion

- How can we make sure MSR on MGR is not impeded?
- How will the process be monitored/policed and by whom?
- Who will collect monetary benefits and who will distribute funds and how?
- 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 an IA flexible enough to cope with scientific progress?
- Is a public domain model acceptable to the parties?
 - At what scale does the collection of BBNJ occur?
 - Will adapting current good practice be sufficient as monitoring tool?
 - Is it possible/desirable to control the flow of data, much of which is open access?
 - How can we be sure that all can utilise and benefit from MGR from ABNJ?
 - How can we ensure capacity building so all can truly benefit?

PHARMASEA



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