Mare Geneticum – Building Blocks Towards a Pragmatic Solution for ABS in ABNJ

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The Benefits of Bioprospecting

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
**Pharmaceutical Products**

**Yondelis**
- Cancer treatment
- Origin: Seasquirt
- Location: Caribbean Mangroves
- Production: Semisynthesis
- Owner: PharmaMar

**Prialt**
- Intractable pain
- Origin: Cone snail
- Location: Philippines
- Production: Recombinant
- Owner: Neurex/Elan

**Non-Pharmaceutical Products**

**Vent Polymerase**
- DNA amplification
- Origin: Vent bacterium
- Location: Naples, Italy
- Production: Recombinant
- Owner: New England Biolabs

**Ventuzeane**
- Cosmetic screening infra-red rays
- Origin: Vent bacterium
- Location: Unknown
- Production: Fermentation
- Owner: Sederma (Croda)

**Fuelzyme**
- Enzyme used in biodiesel production
- Origin: Deep sea bacterium
- Location: Unknown
- Production: Recombinant
- Owner: Verenium (BASF)

**Brominated Furanones**
- Anti biofilm agents
- Origin: Red seaweed
- Location: Australia
- Production: Synthesis
- Owner: Unilever
The Biodiscovery Pipeline

Sampling in ABNJ

Universities

Large companies

Universities and SME’s

Scientific knowledge & data

Commercial

‘Potential’ value

Actual value

Thomas Vanagt
Case study: Halaven

Current sales
Ca US$ 350 M pa
(Usual Royalty Rates are 1-3%)

Laboratory tests and clinical trials
2010: approval by US FDA

Pre 1986: Screening
Isolation & Structure

1996: Synthesis

2001: Derivative synthesis

Bioprospecting
The Marine Pharmaceutical Pipeline

Mainly derived from shallow reef dwelling organisms

Mainly anti-cancer with a few analgesics and antivirals

Mainly start-ups at early stage with large pharma at late stage

http://marinepharmacology.midwestern.edu/
Mare Geneticum

**Balanced benefit sharing must consider:**
- Size and timing of benefits accrued by user(s)
- Cost and burden of benefit-sharing to the user
- Burden of benefit-sharing to the regulator – institutional cost
- Who are the beneficiaries?
- How many beneficiaries are there?
- Impact of benefit-sharing on the beneficiary
- Timing of the transaction

**Requirements:**
- Inclusivity of developing states
- Facilitated access for the scientific community
- Legal certainty, predictability and stability for industry
- Enforceability for the regulator
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**Access:**
Online notification system: OPEN

Free but conditional access

Embargo period

**Benefit-Sharing:**
Mandatory deposit of material in biorepositories

Mandatory sharing of meta data and raw data (including GSD)

Possibility of extending embargo period in return for a fee

If monetary benefits are requested: at the point of commercialization, and not negotiated
Biodiscovery Pipeline and Benefit-sharing

Sampling in ABNJ

Scientific knowledge & data

Deposit in biorepository
Sharing of metadata

Commercial

Embargo period (fee)

Monetary BS?

Thomas Vanagt
BUT: The Biodiscovery Pipeline is Discontinuous

- **Sampling**
  - *In situ*

- **Bioresource Repository**
  - *Ex situ*

- **Chemistry**

- **Genetic Sequence Data**
  - *In silico*

- **Biological screening Functional testing**

- **Product**

Each step may take a significant period. In addition, there may be periods of inactivity/waiting for a variety of reasons.
Sample and data management from origin to exploitation is possible
Already part of good scientific practice but needs standards & improved data infrastructure

Source: OpenNAPIS, White Point Systems
Real World Example

Example 1 sample of sediment

- 100 new microbes (10 used)
- Each microbe grown in 4 different media
- Each one gives 8 fractions
- Each fraction tested in 10 assays

Total 3596 datapoints – for 1 sample & Genetic Sequence Data
Network Analysis of PharmaSea Dataset (150,000 datapoints) shows complexity of data.
Obligatory Prior Electronic Notification (OPEN)

Sampling
- In situ

Submit OPEN
- Obtain Unique Identifier

Bioresource Repository
- (Ex situ)

Update OPEN
- (Location, metadata, species etc)
- Share Materials

Researchers accessing material provided with Unique Identifier

Genetic Sequence Data
- (In silico)

Chemistry

Share Data

Biological screening
- Functional testing

Unique Identifier Needed for Publication/IP

Product
Build on Science
Good Practice

Data Must Be:
Findable
Accessible
Interoperable
Reusable

Muriel Rabone
Natural History Museum, London
IT Solutions (e.g. Blockchain)

Build on existing data infrastructure (Data Curation Essential)

But: Human Compliance main issue

Feasibility Study?

Marine Science
Collections/Curation
Marine Bioprospecting
Computing Science
Behavioural Science
Law/Policy

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