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

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

Non-Pharmaceutical Products

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

**Venuceane**
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

Universities and SME’s

Large companies

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

2001: Derivative synthesis

1996: Synthesis

Pre 1986: Screening
Isolation & Structure

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/
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
Mare Geneticum

**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

Sharing of MGR data

Embargo period (fee)

Monetary BS?

Thomas Vanagt
BUT: The Biodiscovery Pipeline is Discontinuous

Sampling
In situ

Bioresource Repository
(Ex situ)

Genetic Sequence Data
(In silico)

Chemistry

Biological screening
Functional testing

Each step may take a significant period

In addition, there may be periods of inactivity/waiting for a variety of reasons

Product
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

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

1 10 40 320 3200

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)

1. **Sampling**
   - In situ

2. **Submit OPEN**
   - Obtain Unique Identifier

3. **Bioresource Repository**
   - Ex situ

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

5. **Biological screening**

6. **Functional testing**

7. **Genetic Sequence Data**
   - In silico

8. **Chemistry**

9. **Share Data**

10. **Share Materials**

11. **Researchers accessing material provided with Unique Identifier**

12. **Unique Identifier Needed for Publication/IP**

13. **Product**
Data Must Be:
Findable
Accessible
Interoperable
Reusable

Build on
Science
Good
Practice

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

Blockchain adapters

Decentralised/Minimal traceability requirement

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