

Bioprospecting from Marine Genetic Resources from Areas Beyond National Jurisdiction

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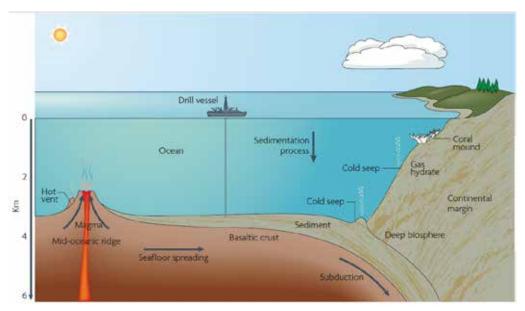
Chair of the Advisory Panel of Policy and Legal Experts – aiming to provide clear recommendations and ready-to-use solutions to address critical policy and legal barriers which impede the access and sustainable use of MGR for European biotechnological research, development and commercialisation



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"

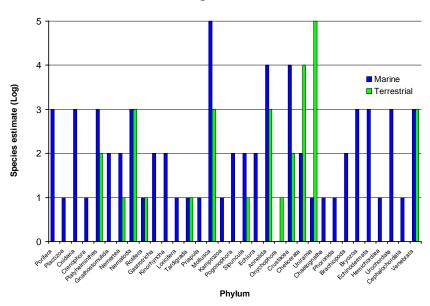


Diversity of habitat is assumed to translate to biological diversity



Marine Species Diversity

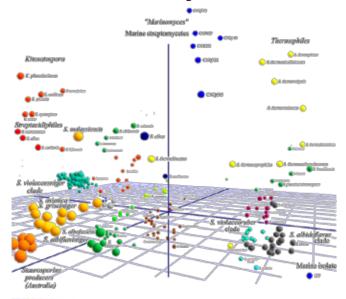
Animal Diversity





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

Microbial Diversity



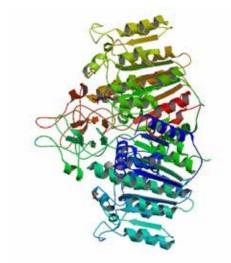


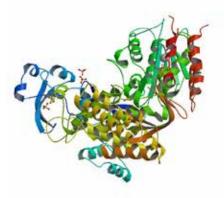
There is no clear estimate of marine microbial diversity or its economic value



Biological Diversity = Chemical Diversity







Biomolecules



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, marine genetic resources 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

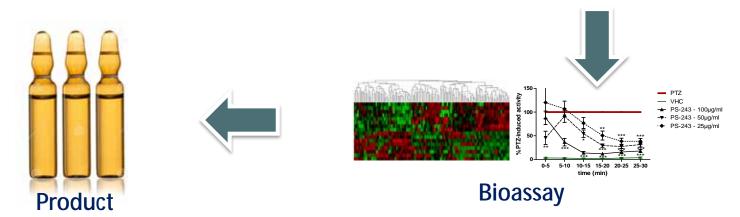
Small molecules: novel chemical structures & new mechanism of action

Materials: new properties



Bioprospecting Biodiversity Beyond National Jurisdiction





Elements of good practice already exist at all stages of the marine biodiscovery pipeline



Non-Pharma MGR Derived Products on the Market





Origin: Vent bacterium (Naples, Italy)

Production: Recombinant

Owner: New England Biolabs



Cosmetic screening infra-red rays

Origin: Vent bacterium (location unknown)

Production: Bacterial culture

Owner: Sederma (Croda)



THE NEXT-GENERATION, HIGH-PERFORMANCE ALPHA-AMYLASE FOR MASH LIQUEFACTION

Fuelzyme – Enzyme used in biodiesel production

Origin: Deep sea bacterium (location unknown)

Production: Recombinant Owner: Verenium (BASF)



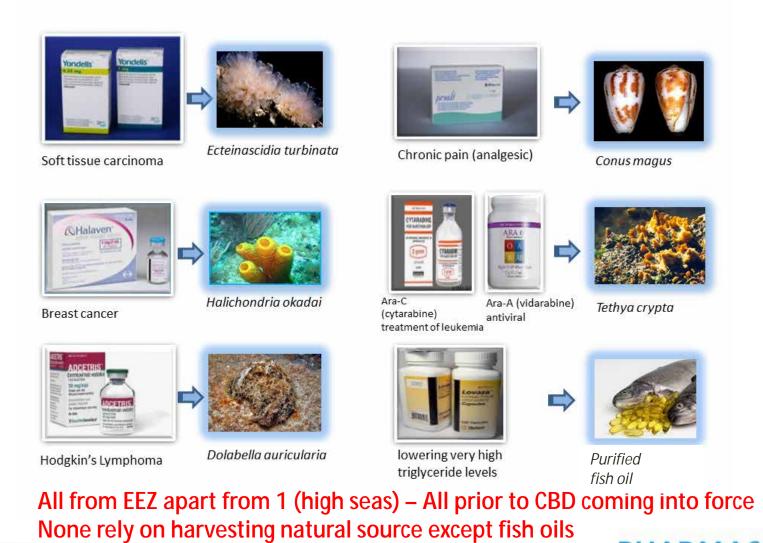
Anti biofilm agents Origin: Red seaweed

Production: Chemical Synthesis

Owner: XXXXX

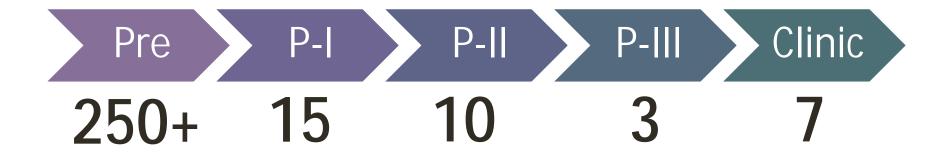


MGR Derived Pharmaceutical Products on the Market



PHARMASE

Pharmaceutical Pipeline



None from ABNJ – mainly reef derived

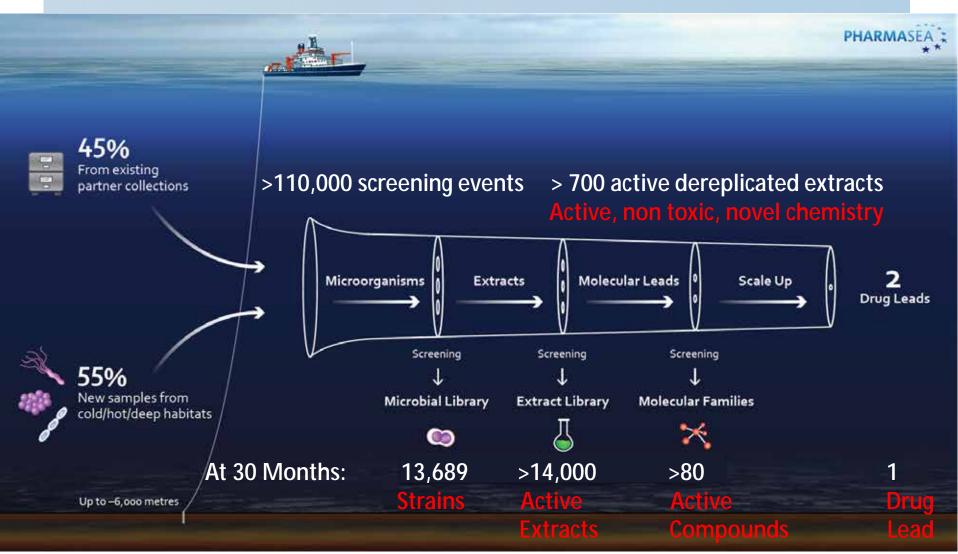
7 successful compounds came from 28,000 known marine compounds

Mainly anti-cancer with a few analgesics and antivirals

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

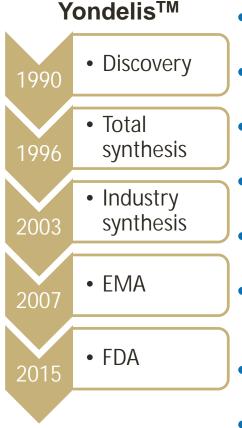


Before Getting to Preclinical Trials:





Real Benefit Scenario

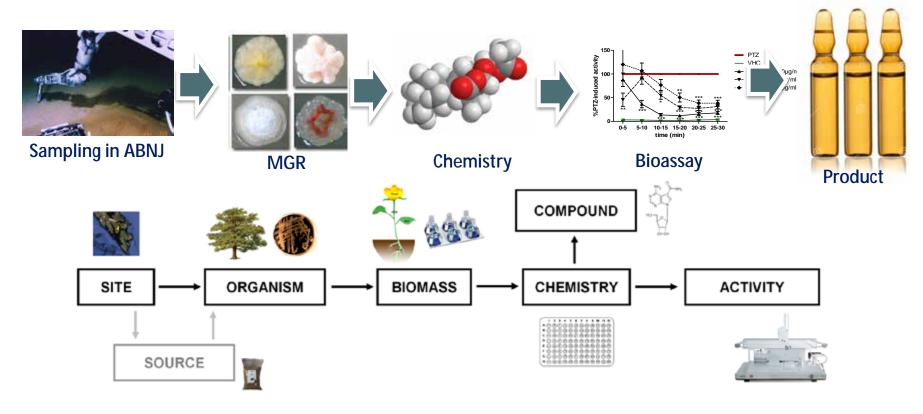


- Cost in 2014 to bring drug to market US\$2,558 M* >70% Clinical trials
- Typical industry royalties on natural products developed into drugs is 1-3%
- Halaven (Eisai), derived from a Japanese sponge makes US\$200 M per year – in principle yielding US\$ 2-6 M pa.
- Currently 7 approved marine drugs 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



Monitoring Sample and Data Flows



OpenNAPIS[™]

Functional Design

White Point Systems, Inc. 20100626

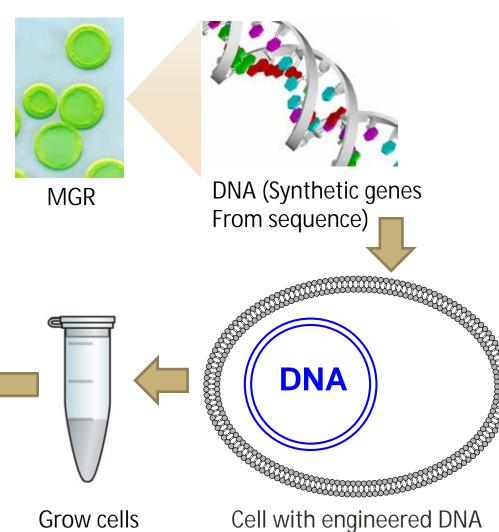
Possible to track sample from origin to exploitation (needs better databases)

Modifications to DNA or compound may make it hard to trace MGR origin



Synthetic Biology – From Genes to Products

An UNCLOS implementing agreement developed over the next few years would need to be flexible enough to deal with rapid scientific progress

























































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