Marine Biodiversity and Gene Patents – Balancing the preservation of Marine Genetic Resources (MGR) and the equitable generation of benefits for society

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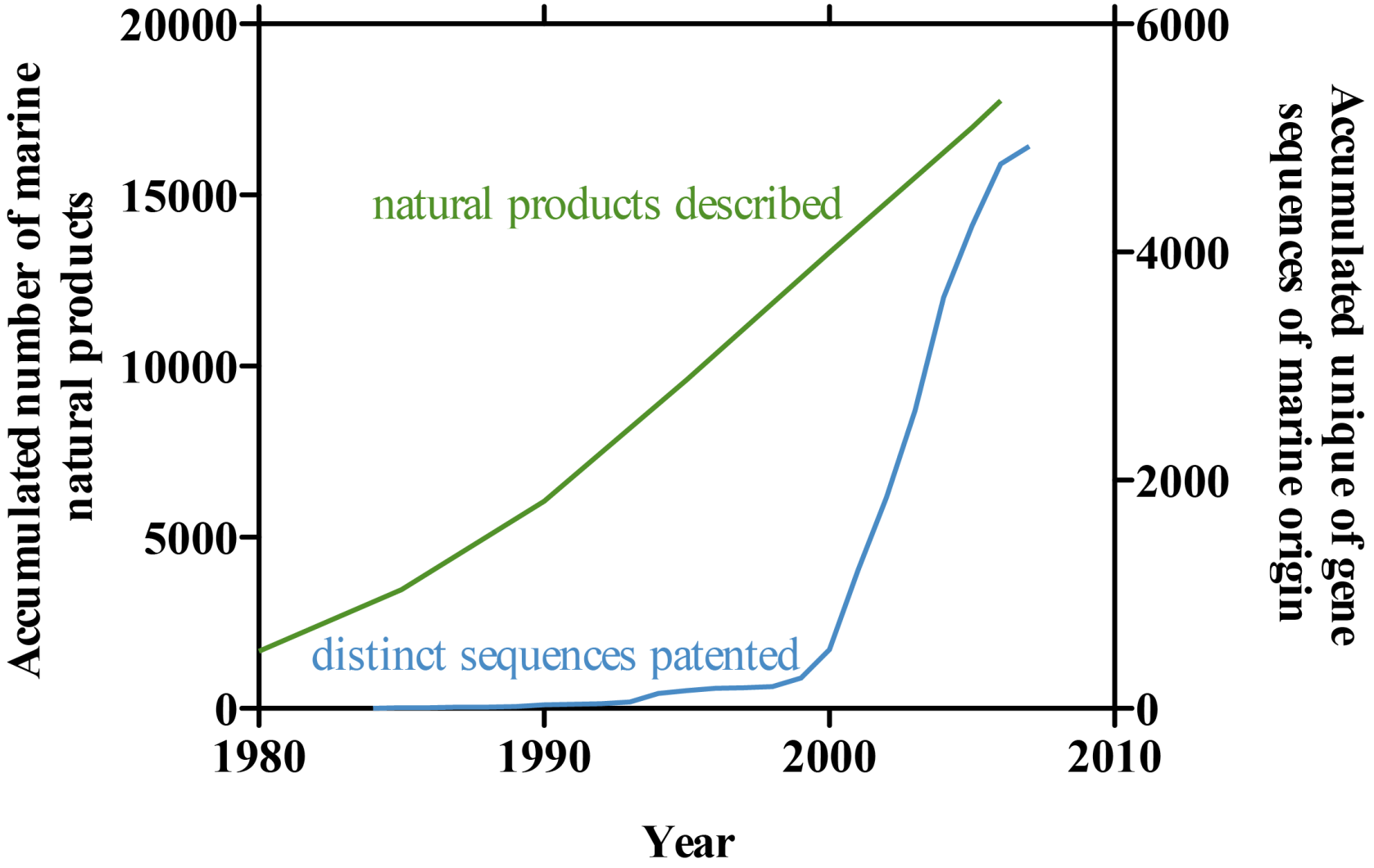
What are MGRs?

Two types of resorces

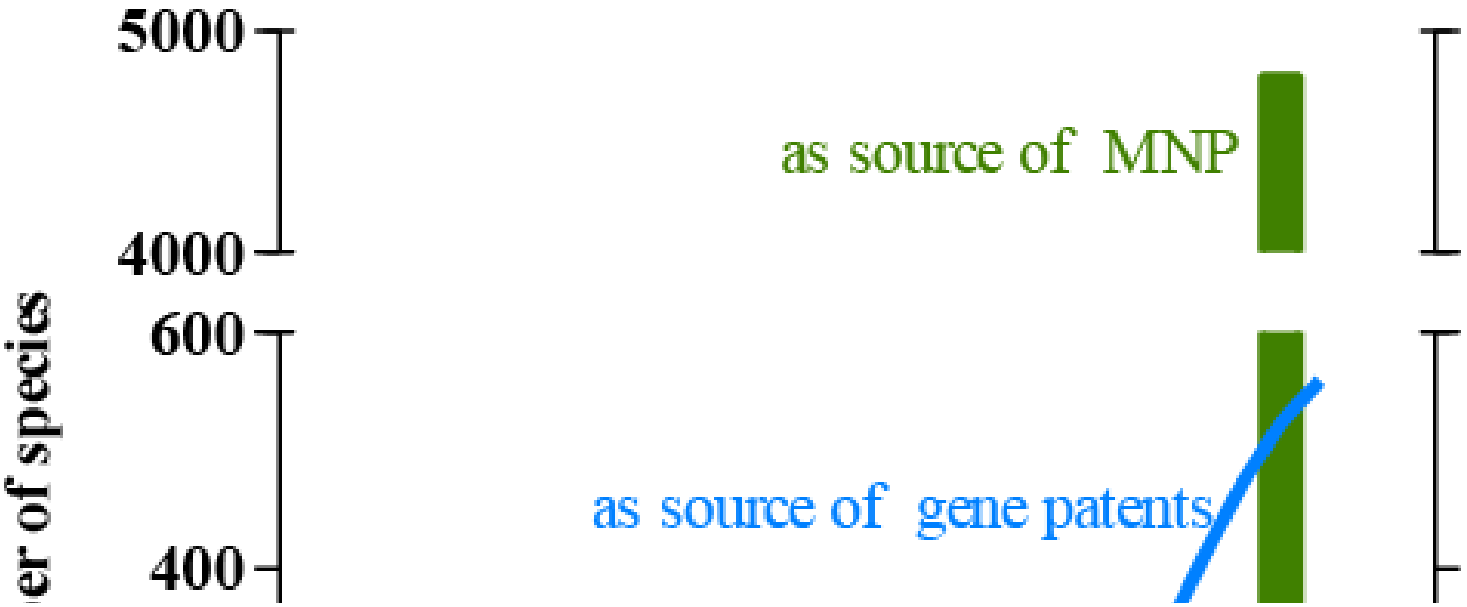
Marine Natural products
Chemical substance produced by a marine organism having pharmacological or biological activity for use in pharmaceutical drug discovery and design.

Marine genes of biotechnological interest
Genes of marine organisms, usually encoding a protein with potential commercial use in different areas (production of pharmaceuticals, cosmetics, molecular biology, bioremediation...).

Use of Marine genetic resources



Arrieta J. M., S. Arnaud-Haond, and C. M. Duarte. 2010. What lies underneath: Conserving the oceans' genetic resources. PNAS **107**:18318 –18324.



Undestimates

- Not all marine genes used industrially are patented
- Not all the patented genes are identified with their source organism in patent databases
- New genomic technologies allow to identify and use genes of interest without the need to isolate the source organism

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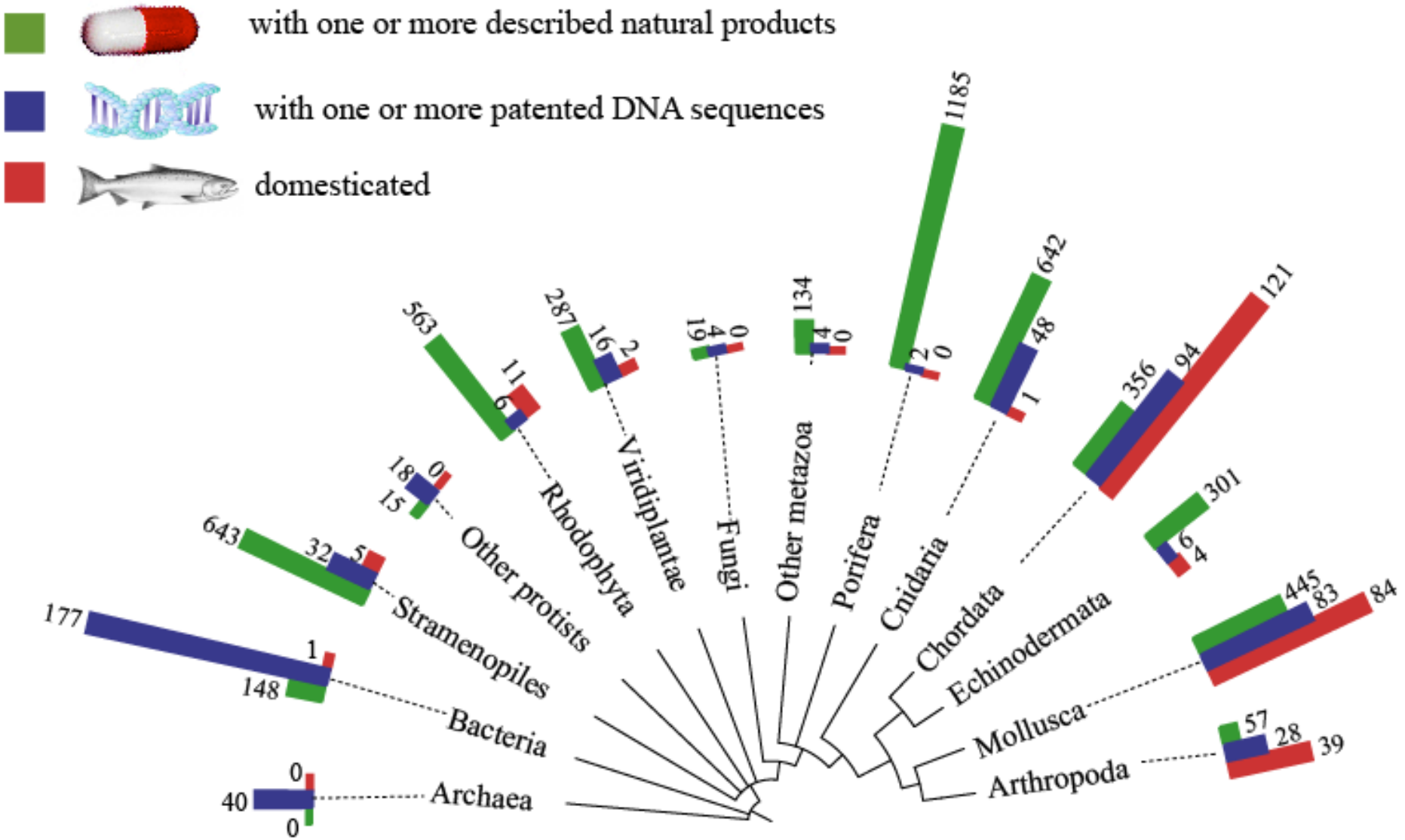
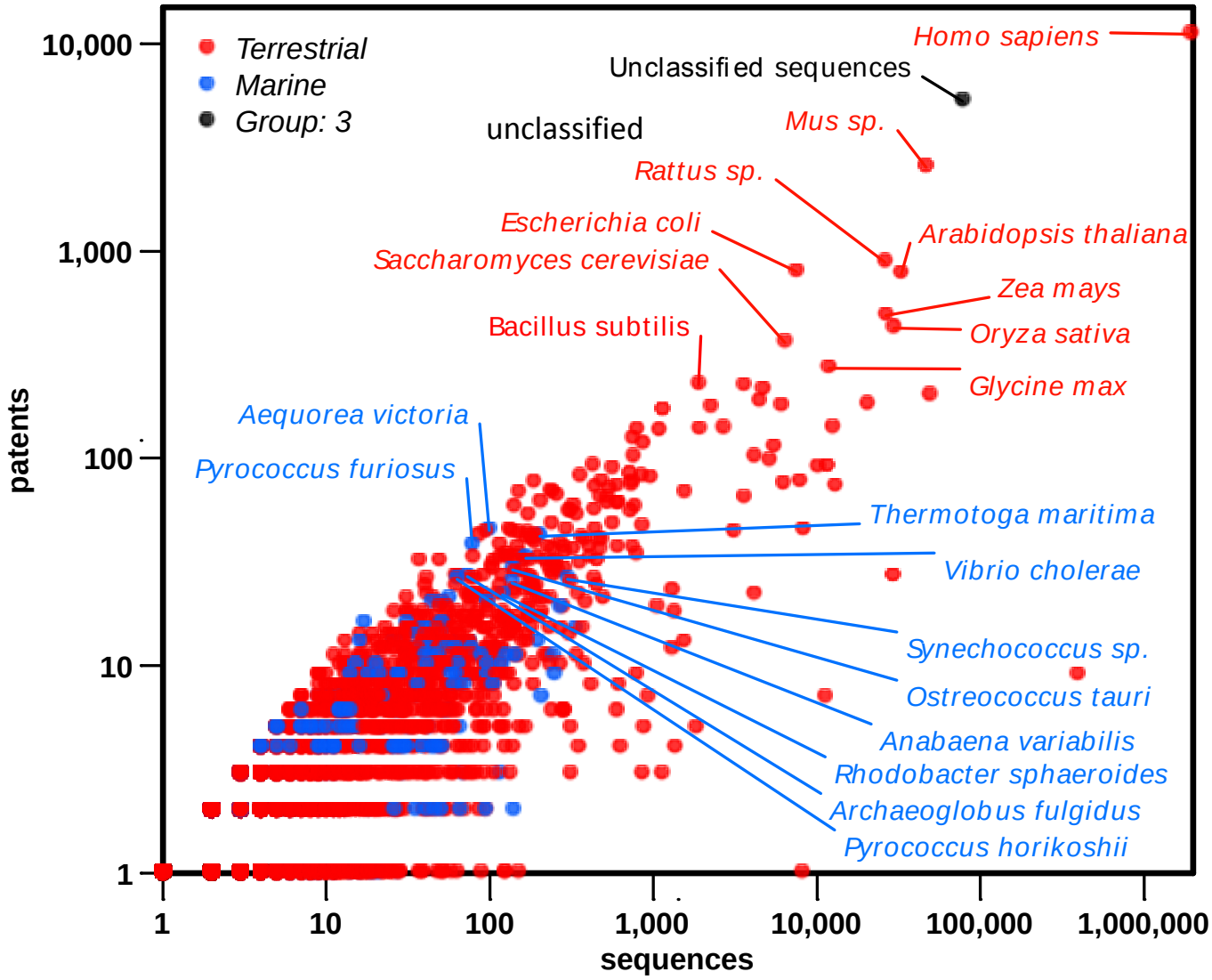
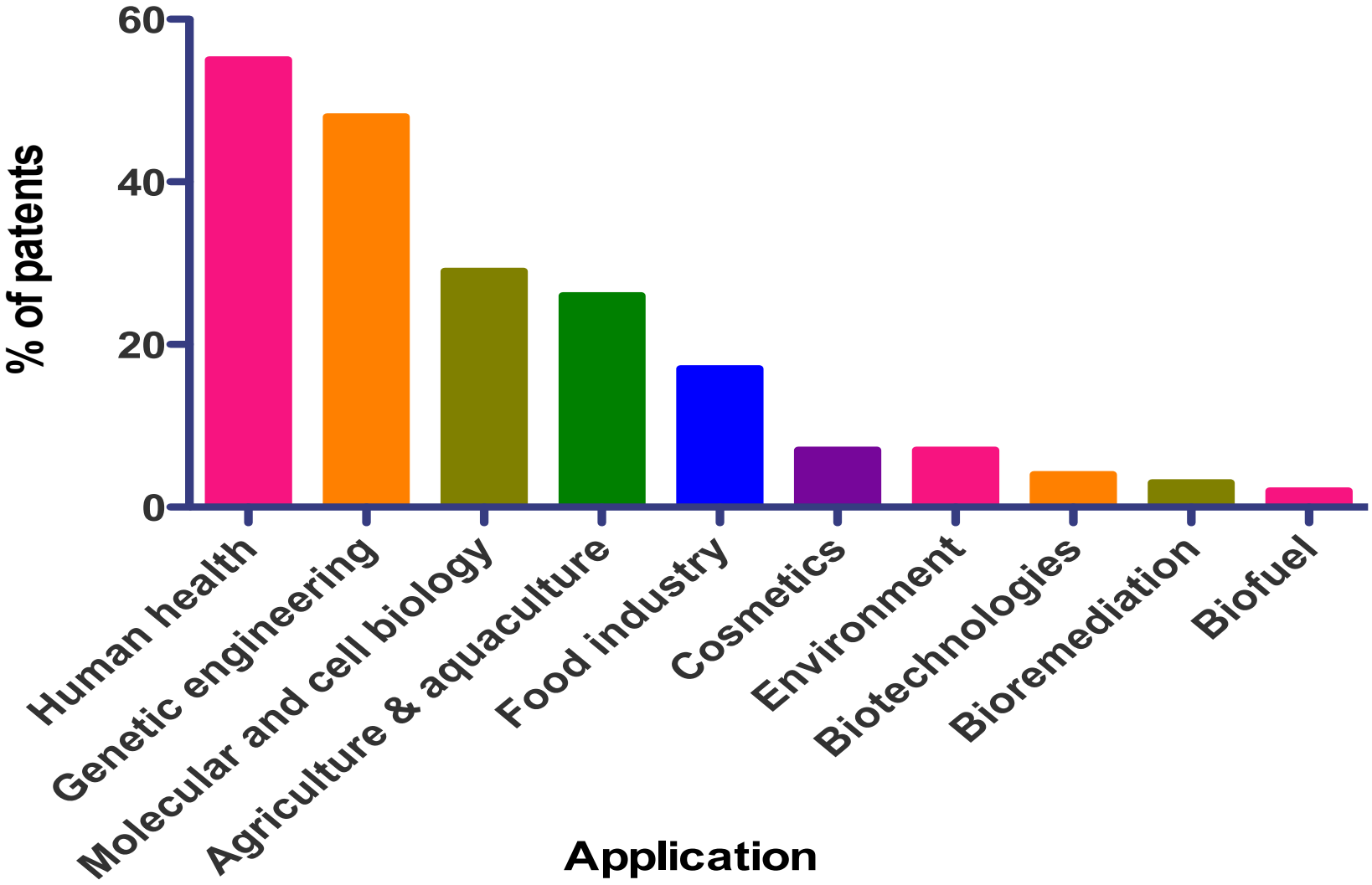
Number of described marine species



Top 10 marine and terrestrial organims in WIPO gene patents



Uses of marine patented genes



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Protection of MGRs

Is the collection of MGRs sustainable?

- MNPs
  - Mainly sesile (attached to the bottom) organisms
  - Only a small amount needed for NP discovery
  - Commercial production does not depend on further biomass collection in most cases (few mg NP in 1,000 kg of biomass)
  - Most organisms involved are not present in large enough quantities for commercial use
    - NPs are “copied” and synthesised industrially
- Genes
  - Even smaller amount of biomass needed
  - A few liters of water, sediment or a few mg of biomass needed for gene discovery
  - Production usually involves culturing (microbes) or cloning of the gene in a “domesticated” microbe

- Thus, bioprospecting is a sustainable activity

How to protect MGRs?

- **Wide range of organisms from bacteria to large animals.**
  - How to protect bacteria?

- **Most marine organisms are yet unknown**
  - At current pace of discovery >1000 years to describe marine diversity

Best strategy

General protection strategies to protect marine biodiversity

Protection of special areas

Extreme and rare environments like the Arctic, Antarctica, hydrothermal vents...

Biodiversity hotspots (seamounts, coral reefs...)

Legal framework

CBD – Protection of biodiversity within each county and their EEZ

CBD target - 10% of coastal areas protected by MPAs by 2012, but not met.

Actually only >1.17% of total oceanic surface is protected as MPA

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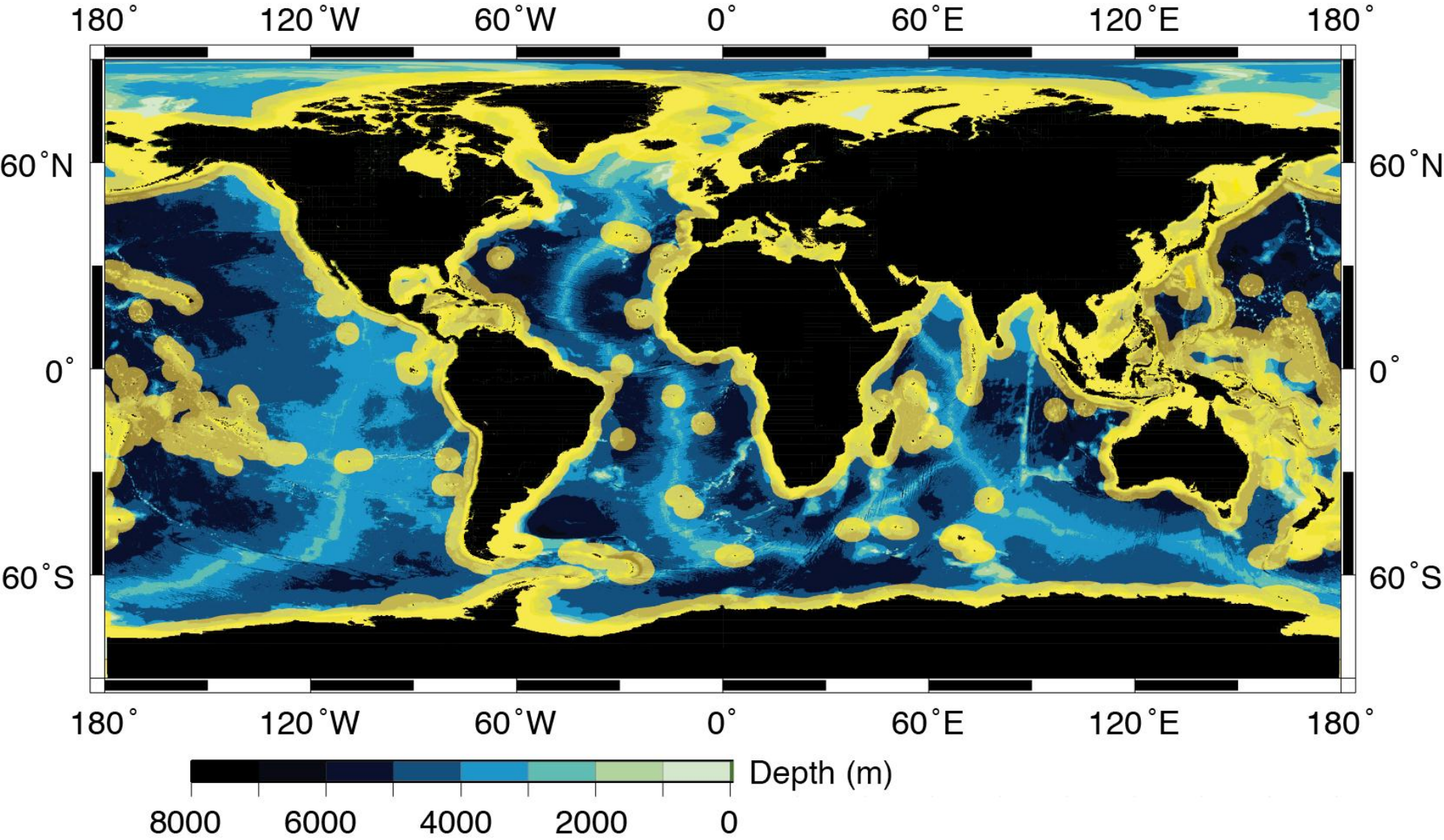

70.55% of the Earth is covered by oceans

60% of the surface area of the ocean is outside the EEZs

Corresponds to 70% of the volume of the ocean

Only a few MPAs in international waters

Access and Benefit Sharing (ABS)

Addressed by the CBD and the Nagoya Protocol (NP)

For MGRs collected within the EEZ, researchers and companies must comply to the regulations of the source country.
This ensures equitable benefit sharing in return for the use of genetic resources.

- Establish more predictable conditions for access to genetic resources.
- Ensure benefit-sharing between users and providers of genetic resources.
- Ensure that only legally acquired genetic resources are used.

For non-commercial research
CLOS
EEZs: Marine scientific research can be undertaken abroad, sovereing countries must facilitate MSR.
High seas and Area: free access for reseach, oblitation to cooperate and publish results.
CBD/Nagoya protocol
Bilateral agreements between provider country and users (permission required)
Provider states should facilitate research

Access and Benefit Sharing (ABS). Caveats and concerns

Within the EEZs

- Bilateral agreement between provider state and user
- Provider countries may be left out of the process of R+D
- Tracking the benefits to the source may be difficult
- The same resource may be present in different countries
  - When MGRs are patented benefits go back only to one country
- Royalties are often in the 1-6% of net benefits
  - Low success rate in source to commercialization path
  - A best-selling product may reach the $400 million but most sell much less →low return to provider country

Thus, the CBD goals of equitability and full utilization may become flawed.

High seas and the area

- Freedom of research
- 60% of the ocean surface and 70% of its volume unregulated
- In theory every country can access MGRs in international waters
  - But this is only theory...

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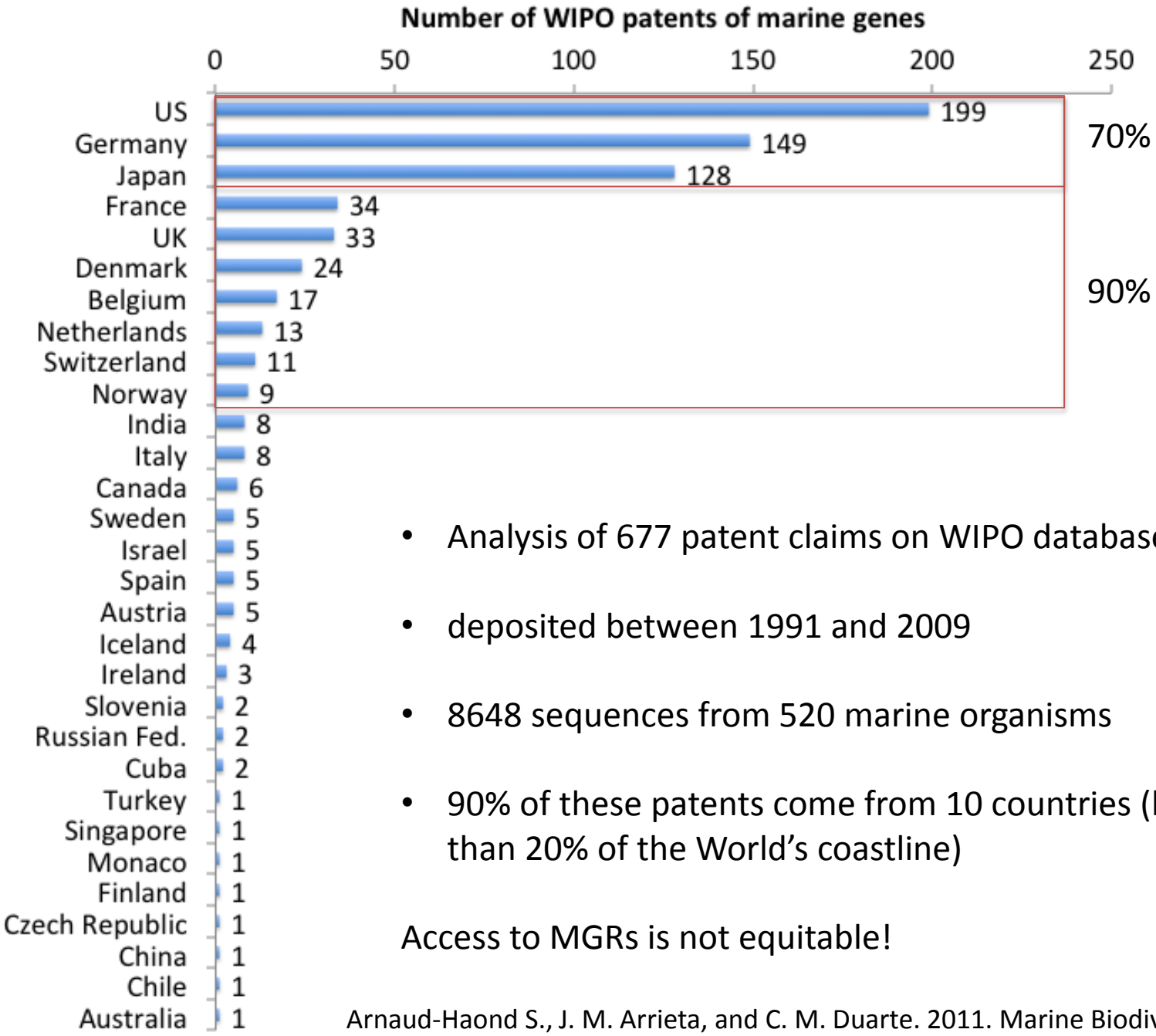
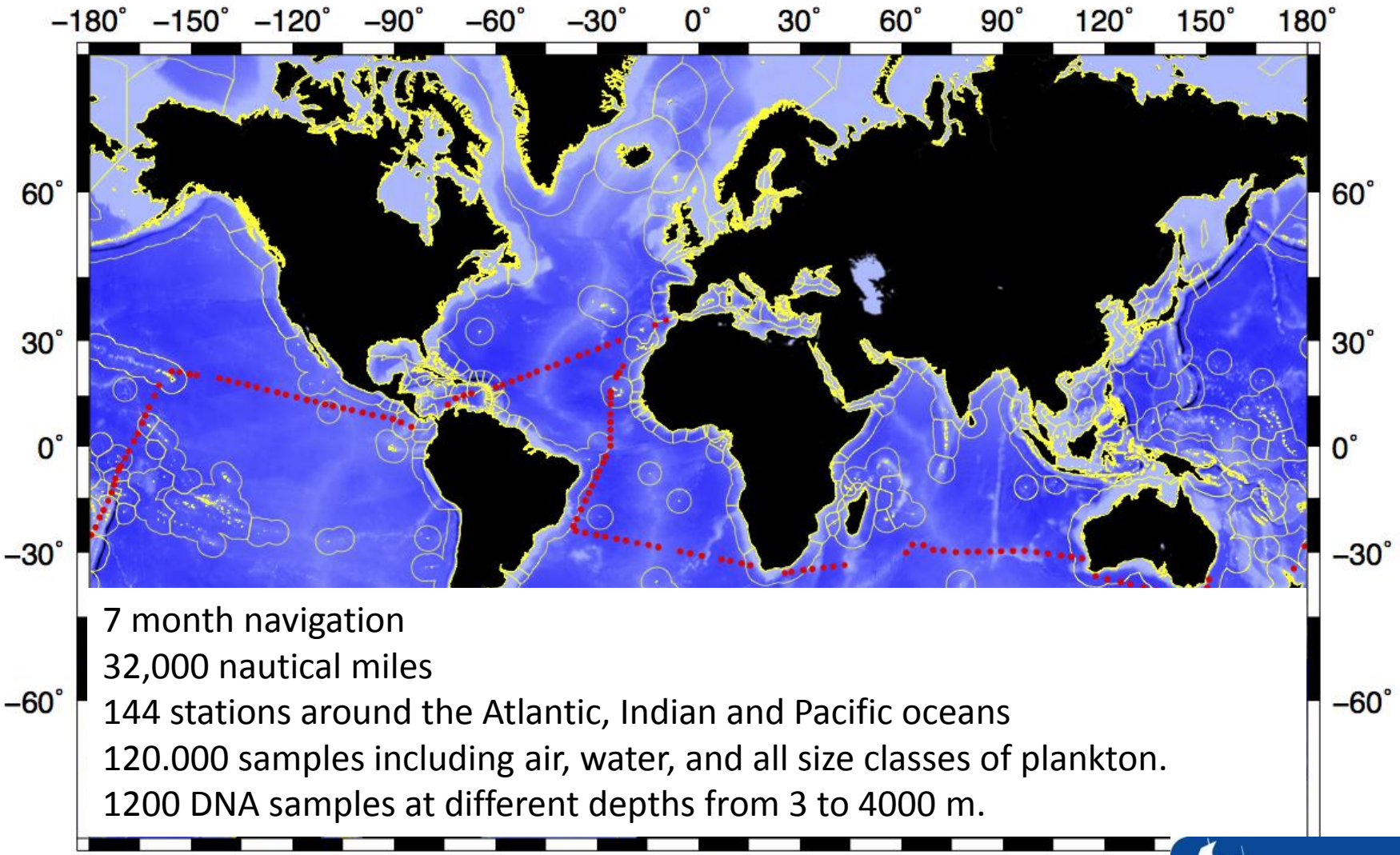


- Analysis of 677 patent claims on WIPO databases
- deposited between 1991 and 2009
- 8648 sequences from 520 marine organisms
- 90% of these patents come from 10 countries (less than 20% of the World's coastline)

Access to MGRs is not equitable!

Arnaud-Haond S., J. M. Arrieta, and C. M. Duarte. 2011. Marine Biodiversity and Gene Patents. Science 331:1521 –1522.

Malaspina 2010 Circumnavigation Expedition



7 month navigation
32,000 nautical miles
144 stations around the Atlantic, Indian and Pacific oceans
120.000 samples including air, water, and all size classes of plankton.
1200 DNA samples at different depths from 3 to 4000 m.

MALASPINA 2010

Access for non-commercial scientific research. Malaspina

Tracking the process from access to commercialization is difficult, thus many states fear biopiracy.

Under current formulation of CBD/NP

Authorization process is often complex (bilateral process)

How we did it:

- Request for sampling authorization from Malaspina to Spanish Ministry of Foreign Affairs, then from Ministry of Foreing Affairs to other Ministries and organisms of provider state.
- Usually followed by a request for clarifications
- Lengthy process up to 12 months
- End result
  - Authorization or not
  - Different requirements or restrictions
    - observers or local scientists on board
    - Request to share data

Better Access and Benefit Sharing (ABS)

Within the EEZs

- Obligation to include the provider country in the R+D process → capacity building
- Clear mandate to specify source organism and geographical provenance in patent applications.

High seas and the area

- Declare MGRs as Common Heritage of Mankind
  - This has ben done by CLOS for mineral resources of the seabed.
  - Regulate acces by:
    - International Seabed Authority (same as with mineral resources)
    - A new organism combining the expertise of CBD (conservation) and ISA (ABS)
- Establish common pools of genetic resources
  - Simplified, one-point access to commercial use of MGRs
  - Simplified access for research
  - The pools can also be used to address problems of resources shared among EEZs →simplified access for both commercial and non-commercial use.

GLOBAL GENETIC RESOURCES

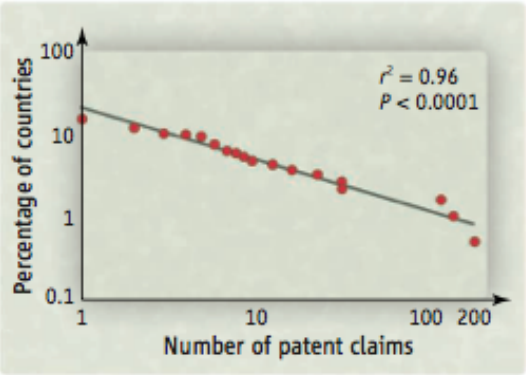
Marine Biodiversity and Gene Patents

Ten countries account for 90% of patent claims associated with marine genes, including some from international waters.

Sophie Arnaud-Haond,[1]* Jesús M. Arrieta,[2] Carlos M. Duarte[2,3]

The October 2010 Nagoya conference of the United Nations (UN) Convention on Biological Diversity (CBD) saw establishment of the protocol for improved access to genetic resources and fair and equitable sharing of benefits arising from their utilization (*1*). This allows effective implementation of provisions in Article 15 of CBD regulating access to genetic resources through mutual agreements between countries of origin of resources and those acquiring them. Yet the principle of sovereign rights of states underlying the CBD does not apply to Marine Genetic Resources (MGRs) in Areas Beyond National Jurisdiction (ABNJs), international sonable ranking of countries' accessing of resources.

We screened records in the patent division of GenBank (*7*) to extract international claims valid in all countries subscribing to the World Trade Organization (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and deposited in the World International Property Organization (WIPO). Among 677 international claims of marine gene patents deposited between 1991 and 2009, 8648 sequences from 520 species were found. Gene patent claims from marine organisms make up only 2% of the WIPO gene patents (table S1),



Patent claims associated with genes of marine origin. Cumulative distribution of patent claims showing the proportion of countries (*y* axis) at the origin of *x* or more patent claims. See SOM.

Science 331:1521 –1522.(2011)

Routledge
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Common Pools of Genetic Resources

Equity and Innovation in International Biodiversity Law

Edited by **Evanson Chege Kamau**, **Gerd Winter**

To Be Published 15th May 2013 by Routledge – 448 pages

Series: Routledge Research in International Environmental Law

Better Access and Benefit Sharing (ABS)

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    - A new organism combining the expertise of CBD (conservation) and ISA (ABS)
- Establish common pools of genetic resources
  - Simplified, one-point access to commercial use of MGRs(multilateral)
  - Simplified access for research (one common policy)
  - The pools can also be used to address problems of resources among EEZs