

**Marine genetic resources of areas beyond national
jurisdiction and
intellectual property rights**

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Why address intellectual property in the BBNJ context?

GA Resolution 72/249 convenes an intergovernmental Conference.

2. *Also decides* that negotiations shall address the topics identified in the package agreed in 2011, namely, the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, in particular, together and as a whole, marine genetic resources, including questions on the sharing of benefits, measures such as area-based management tools, including marine protected areas,

Report of PrepCom 7 set up the relationship between the instrument and intellectual property rights.



Role of patents in benefit-sharing

Different from the CBD concept (owner of the resources) → countries that cannot conduct research on their own (some relationship with CHM principle?)

1. Collection of MGRs for research and bioprospecting
2. Intellectual property rights – Patents

TRIPs Agreement:

- Patentable subject matter
- Rights of the patent-holder
- Patentability of microorganisms
- National patent laws
- Disclosure of origin
- The cost of Research and Development: myth or reality, or both?

Other relevant instruments

3. Provisions of UNCLOS relevant to IPRs
4. Conclusion - Is an IP *sui generis* regime for BBNJ possible?

1. Collection of MGRs for research and bioprospecting

Scientific institutions → collection and research

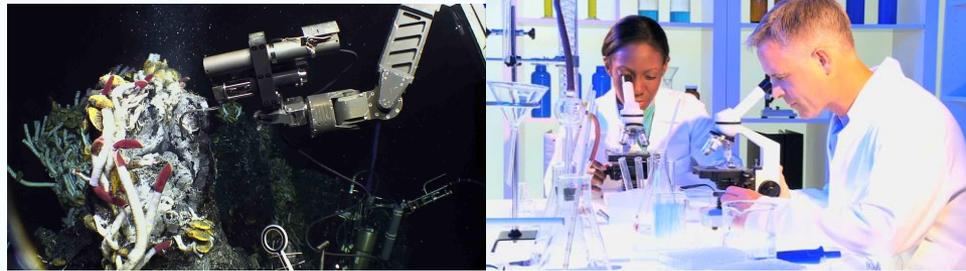
- intention: study for knowledge of an organism's role in biodiversity
- public funding

Free transfer of samples



Commercial sector → research and development

- intention: assess commercial value and develop products or processes
- private funding



2. Intellectual Property Rights - Patents

What is a patent?

→ a set of proprietary or exclusive rights granted to an inventor for a period of time.

Agreement on the Trade Related Aspects of Intellectual Property – WTO TRIPs - 1994

Rights of the patent-holder

→ **exclusive right of exploitation for a minimum of 20 years** (Art. 33 of TRIPs Agreement).

To prevent others without the consent of the patent-holder from MAKING, USING, OFFERING FOR SALE, SELLING or IMPORTING FOR SALE (Art. 28 of TRIPs Agreement).

→ **Payment of royalties to patent-owner.**

For an invention to be patentable, it must satisfy three key criteria of article 27 of the TRIPs Agreement



Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

Art. 27 Requirements → cumulative

Novelty – The invention should not be publicly known in any way, anywhere in the world.

Inventive step – The invention must be something that represents an improvement over any existing product or process that is already available (not obvious to the expert).

Industrial application – The invention must be useful and have some form of practical application. It should be capable of being made or used in some form of industry.

National patents laws



→ **divergence in interpretation of “invention”** → biggest controversy: organisms already existing in nature which existence was not known and isolation of existing organisms (**Invention vs. mere discovery**).

Patentability of microorganisms

TRIPS Agreement, para 3 of Article 27 “Members may exclude from patentability”:

“plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals ...”

Are microorganisms subject to the patentable subject matter requirements?



Article 28 of TRIPs → the patent holder has the right to prevent others from “making” the patented good.

European Union: “Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature” (European Directive on Biotechnological Inventions (98/44/EC).

US, Australia, Canada, Indonesia, Japan, Singapore: full patentability of animals and plants without particular restrictions.

Brazil, Andean community, Thailand, Argentina: exclusion of plants and animals.

MARINE GENETIC RESOURCES - PATENTS

- Large number of patents with living resources as source of microorganisms (including Extremophiles)
- Difficult to determine whether specimens were collected within or outside national jurisdiction (e.g. “a deep sea hydrothermal vent”, “high seas”)
- Industries:
 - Pharmaceutical
 - Agriculture
 - Aquaculture
 - Food
 - Cosmetics
 - Biorremediation
 - Others

SOME PRODUCTS

- * New England BioLabs Inc. (US) → **Deep VentR® DNA Polymerase** obtained from a bacterium carrying polymerase genes *Pyrococcus sp*, an extremophile and **Therminator DNA Polymerase**, from the DNA polymerase of *Thermococcus Sp*,
- * Sederma (France) → **skin protection products** providing high resistance to UV and heat exposure on the basis of enzymes isolated from the extremophile *Thermus thermophilus*,
- * Roche → *T. thermophilus* and other thermophiles to develop improvements in the amplification of nucleic acids,
- * Diversa Corporation → **Pyrolase™ 160 enzyme** (used to reduce viscosity), and **ThermalAce™ DNA Polymerase** (used in DNA sequencing),
- * HyTest Ltd. (Finland) → **Thermus aquaticus DNA polymerase Taq Red** (used as an enzyme for molecular biology),
- * Promega (United States) → thermostable **Tth Polymerase**, used as an enzyme for molecular biology,
- * GeneSys Ltd (UK) → Enzyme from thermophilic bacterium *Thermodesulfatator indicus* for potential uses in biotechnology,
- * Use of marine molecules in pharmaceutical industry → for anticancer drugs, HIV (**Ritonavir**) medicines, Alzheimer medicines.
- * **Laundry detergents** from a marine fungus (*Aspergillus*) originally collected from depth of 5000m in the Central Indian Basin
- * Over 500 worldwide patents related to **krill** (pink gold) → **FISH !**

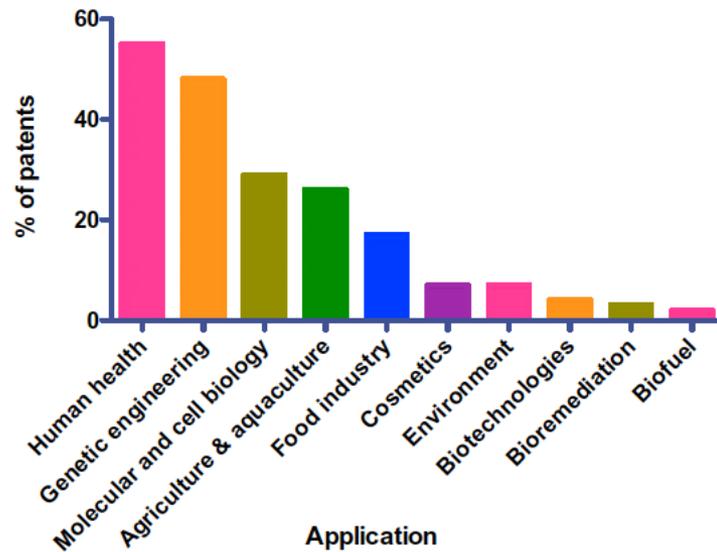


Fig. 3. Synthesis of the uses proposed in the claims or description of 460 patents deposited at the International Patent Office and associated with genes isolated in marine organisms. Because each patent claim can belong to several categories, the sum is larger than 100%.

Source: Arrieta et al “What lies underneath: conserving the Oceans’ genetic resources”

PATENT CLAIMS FOR A GENE OF MARINE ORIGIN WITH SOURCE	
Country	Marine organism patent claims
USA	199
Germany	149
Japan	128
France	34
United Kingdom	33
Denmark	24
Belgium	17
Netherland	13
Switzerland	11
Norway	9

Source:Arnaud-Haond et al “Marine Biodiversity and Gene Patents”.

Disclosure of origin

Within / beyond national jurisdiction → relevance of the disclosure of origin

IPRs regimes not drawn up for the sea

Geographical coordinates? → regular practice in science

Enforceability of patent rights dependent on compliance with a requirement of declaring origin

Juris tantum presumption → probably best way but there are some challenges:

* *A unified regime for high seas and the Area?*

* *Question of high seas and subjacent continental shelf remains.*

Role of patents in R&D: myth or reality? Or both?

Patents foster innovation

Cost of research for the development of a new drug → U\$S 1 billion in 2013 - 17/19% of revenues.

Who calculates the costs of R&D? → pharmaceutical companies participate in calculation.

A more realistic calculation → Light, D.-Warburton, R. / Gøestche, P. :

* More than 4/5 of basic research is publicly funded

* R&D 1.2% of revenues.

Other relevant instruments

Budapest Treaty on the international recognition of the deposit of microorganisms

All States Parties must recognize microorganisms deposited as a part of the patent procedure irrespective of the location of the depository authority.

Paris Convention for the protection of industrial property (WIPO)

Protection of industrial property (patents, trademarks, industrial designs, trade names, geographical indications).

Patent Cooperation Treaty (WIPO)

The International Patent System allows for international patent protection by filling only one patent application.

FAO Treaty on Plant Genetic Resources for Food and Agriculture

Provides for a multilateral system of access to plant genetic resources for food or their genetic parts or components. No intellectual property claim allowed for these resources.

3. Provisions of UNCLOS relevant to IP

Marine scientific research (MSR)

a) High seas → Parts XI and XIII of UNCLOS

Freedom of the high seas

Peaceful purposes - scientific methods compatible with UNCLOS - non interference with other uses of the sea (Art. 241).

Publication and dissemination of knowledge resulting from MSR (Art. 244).

“Marine scientific research activities shall not constitute the legal basis for any claim to any part of the marine environment or its resources”.

b) The Area → Parts XI and XIII of UNCLOS

Peaceful purposes - scientific methods compatible with UNCLOS - non interference with other uses of the sea.

No legal basis for any claim to any part of the marine environment or its resources.

“Marine scientific research in the Area shall be carried out exclusively for peaceful purposes and for the benefit of mankind as a whole” (Art. 143).

Effective dissemination of the results of research and analysis through ISA or other channels.

4. Conclusion – is an IP *sui generis* regime for BBNJ possible?

Could IPRs entail an appropriation? → it will depend on provisions on patentable subject matter.

Could patenting undermine the dissemination of knowledge arising from MSR? → it depends, patents require some degree of disclosure, so it will be subject to the specific rules.

Elements related to the IPR regime to have in mind:

- A specific patent regime for inventions based on MGRs of ABNJ does not seem to contradict TRIPs (Art. 27.1 place of invention, not place of origin of resources)
- International regime *vis à vis* national laws
- Microorganisms and MGRs from fish
- Declaration of origin → *juris tantum* presumption? – tracing (*ex situ* collections)
- Compulsory licensing → flexibility of TRIPs Agreement → a government may authorize third parties to make a product without the consent of the patent owner → important for medicines.
- Gene pools

The IPR regime did not have the sea in mind, but there seems to be no incompatibility *per se*.



Thank you!

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