

Ministry of Foreign Affairs

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International Law for the Resources of the Sea

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Segment 3: Marine Biological Diversity beyond Areas of National Jurisdiction

Intellectual Property Rights and Marine Genetic Resources of the Areas beyond National Jurisdiction

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1. The Problem

1. *Decides* to develop an international legally binding instrument under the United Nations Convention on the Law of the Sea¹ on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction and to that end:

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, environmental impact assessments and capacity-building and the transfer of marine technology;

A/RES/69/292, 19 June 2015

2. What use of marine genetic resources?

Example of “soil” genetic resources

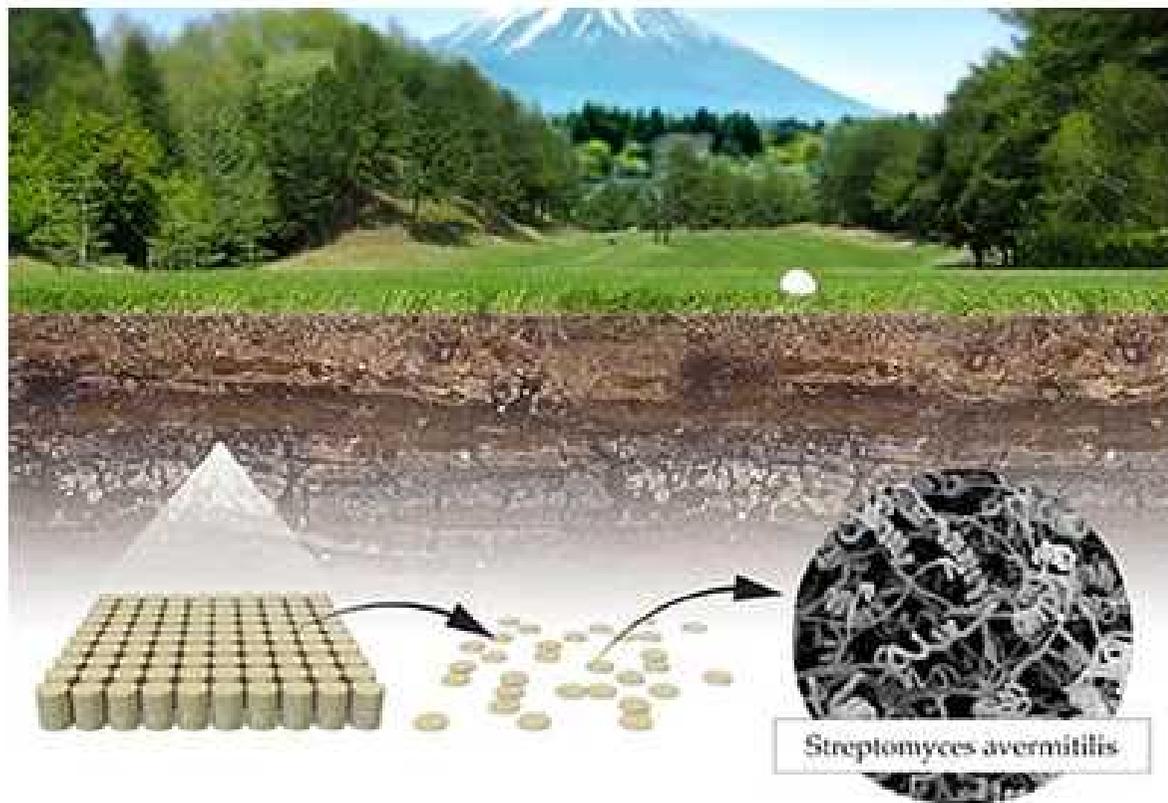


Figure 2: Satoshi Ōmura searched for novel strains of Streptomyces bacteria as a source for new bioactive compounds. He isolated microbes from soil samples in Japan, cultured them in the laboratory (inset to left) and characterized many thousands of Streptomyces cultures. From those, he selected around 50 cultures that appeared most promising, and one of these cultures later turned out to be Streptomyces avermitilis (inset to right), the source of Avermectin.

Press Release, the
2015 Nobel Prize
in Physiology or
Medicine

2. What use of marine genetic resources?

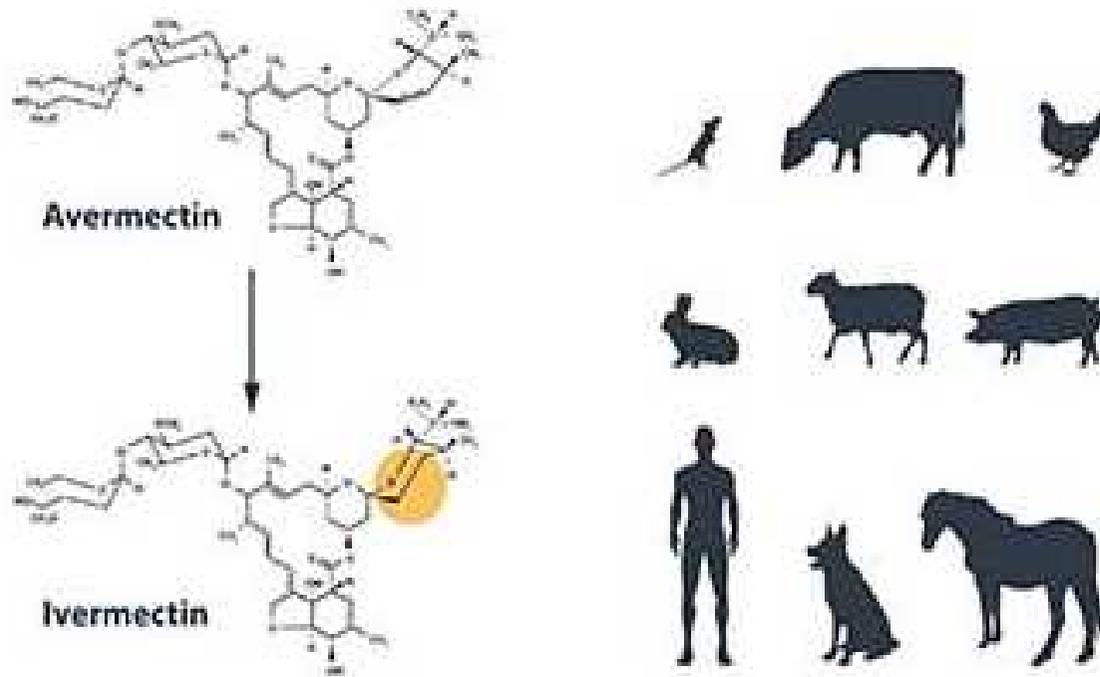


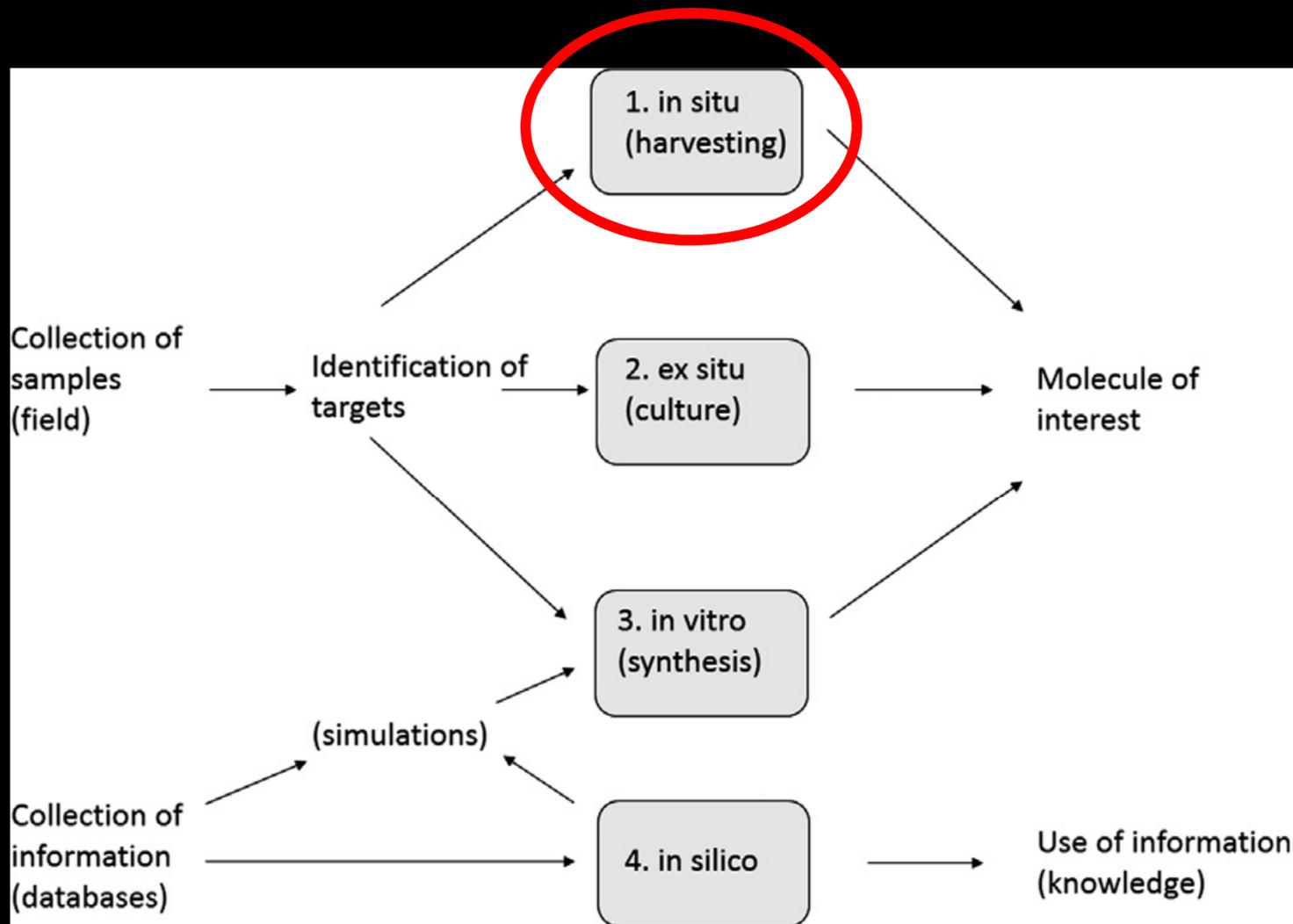
Figure 3: *William C. Campbell discovered that one of Ōmura's Streptomyces cultures was very effective in killing off parasites and the active compound, Avermectin, was purified. Avermectin was further modified to Ivermectin, which turned out to be highly effective in both animals and humans against a variety of parasites, including those that cause River Blindness and Lymphatic Filariasis.*

3. What use of marine genetic resources?

Nom	Application	Origine	Profondeur (en m)	Niveau d'étude
Discodermolide	Cancer	Éponge <i>Discodemia</i> sp.	140 Bahamas	Phase I
E 7389	Cancer	Éponge <i>Lissodendoryx</i> sp.	100 Nouvelle-Zélande	Phase I
Dictyostatin-1	Cancer	Éponge Ordre <i>Lithistida</i>	440 Jamaïque	Préclinique
Sarcodictyn et dérivés	Cancer	Corail <i>Sarcodictyon roseum</i>	Méditerranée	Préclinique
Salinosporamide A	Cancer	Actinomycète <i>Salinospora salin</i>	> 1 000 Pacifique	Préclinique
Topsentin	Cancer, Alzheimer	Éponge <i>Spongosporites ruetzleri</i>	300-600 Bahamas	Préclinique
Implants orthopédiques	Greffe osseuse	Corail	> 1 000 Pacifique	Préclinique

Jean Guézennec, *Bactéries marines et biotechnologies*, Paris, Quæ, 2014, p. 101.

3. What use of marine genetic resources?



Arianna Broggiato et al., "Fair and equitable sharing of benefits from the utilization of marine genetic resources in areas beyond national jurisdiction", *Marine Policy*, No. 49, 2014, p. 176, p. 184.

3. Why benefit sharing?

71. Divergent views were expressed on the relevant legal regime under the Convention regarding marine genetic resources beyond areas of national jurisdiction. Several delegations observed that, according to General Assembly resolution 2749 (XXV) and Part XI of the Convention, which they noted was part of customary international law, the seabed and ocean floor and the subsoil thereof beyond the limits of national jurisdiction (the “Area”), as well as its resources, were the common heritage of mankind. They emphasized that the common heritage of mankind, including the fair and equitable sharing of benefits, applied to the biological resources of the Area. Several delegations noted the competence of the International Seabed Authority in that regard. Some delegations also stressed that, under the Convention, the legal regime applicable to marine resources was defined by the maritime zone in which they were found, not by their nature as mineral or biological resources.

72. Other delegations stressed that Part XI only addressed mineral resources, and expressed the view that marine genetic resources beyond areas of national jurisdiction were regulated by the high seas regime in Part VII of the Convention. They observed that the mandate of the International Seabed Authority in relation to marine biological diversity was specifically set out in article 145 of the Convention relating to the protection of the marine environment with regard to activities in the Area.

Co-Chairpersons’ summary of discussions, Ad Hoc Open-ended Informal Working Group, 16 March 2010, A/65, 68.

3. Why benefit sharing?

Ten countries own 90% of the patent claims on marine microorganisms, with three of them (USA, Germany and Japan) owing 70% of the total.

S. Arnaud-Haond et al., "Marine biodiversity and gene patents", *Science* 2011: 331 (6024): 1521-2.

[T]he question of the role played by patents in the context of benefit-sharing [is] of paramount importance to countries that could not conduct marine research on their own.

Intersessional workshops, May 2013, A/AC.276/6, para. 42.

4. What are the “benefits” to be shared?

1. Monetary benefits: Patents

- A patent provides the holder with an exclusive right to an invention for a limited period of time.
- Available for any inventions, whether products or processes, in all fields of technology, provided that:
 - they are new;
 - they involve an inventive step; and
 - they are capable of industrial application [TRIPs, Art. 27(1)]
- Microorganisms isolated from naturally occurring substance may be patented.

2. Non-monetary benefits: Technology transfer / cooperation

5. Where should the question be discussed?

I.	INTRODUCTION.....	2
II.	ISSUES RELATING TO THE PATENT PROVISIONS OF ARTICLE 27.3(B)	2
A.	GENERAL ISSUES	2
B.	SCOPE OF EXCEPTIONS TO PATENTABILITY IN ARTICLE 27.3(B)	7
C.	ETHICAL EXCEPTIONS TO PATENTABILITY AND ARTICLE 27.2.....	10
D.	CONDITIONS OF PATENTABILITY IN ARTICLE 27.1 AND PLANT AND ANIMAL INVENTIONS	12
III.	ISSUES RELATING TO THE <i>SUI GENERIS</i> PROTECTION OF PLANT VARIETIES	14
A.	GENERAL ISSUES WITH RESPECT TO PLANT VARIETY PROTECTION.....	14
B.	"EFFECTIVE <i>SUI GENERIS</i> SYSTEMS" OF PROTECTION.....	16
C.	RELATIONSHIP BETWEEN THE TRIPS REQUIREMENT TO HAVE AN EFFECTIVE <i>SUI GENERIS</i> SYSTEM AND THE UPOV CONVENTION	20
D.	RELATIONSHIP BETWEEN <i>SUI GENERIS</i> PROTECTION OF PLANT VARIETIES AND TRADITIONAL KNOWLEDGE AND FARMERS' RIGHTS	23
IV.	TRANSFER OF TECHNOLOGY	24

WTO, Review of the Provisions of Article 27.3(B), Note by the Secretariat, 9 March 2006, IP/C/W/369/Rev.1.

5. Where should the question be discussed?

WIPO/GRTKF/IC/28/4
ORIGINAL: ENGLISH
DATE: JUNE 2, 2014

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

Twenty-Eighth Session
Geneva, July 7 to 9, 2014

CONSOLIDATED DOCUMENT RELATING TO INTELLECTUAL PROPERTY AND GENETIC RESOURCES

Article 3: Disclosure requirement

Article 8: Due diligence

No reference to BBNJ

5. Where should the question be discussed?

Article

10

GLOBAL MULTILATERAL BENEFIT-SHARING MECHANISM

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (entered into force in 2014)

5. Where should the question be discussed?

28. Several participants were of the view that access to genetic resources in areas beyond national jurisdiction, such as the high seas, the deep seabed or Antarctica, would constitute a situation where it is not possible to grant or obtain PIC. However, a number of other participants noted that Article 10 must be within the scope of the CBD and the Nagoya Protocol, which excludes its application to areas beyond national jurisdiction. They substantiated their views with reference to Article 15 of the CBD and Articles 3 and 4 of the Protocol.

Synthesis of the Online Discussions on Article 10 of the Nagoya Protocol on Access and Benefit-sharing, 8 January 2014, UNEP/CBD/ICNP/3/INF/4.

Article 4. Jurisdictional Scope

Subject to the rights of other States, and except as otherwise expressly provided in this Convention, the provisions of this Convention apply, in relation to each Contracting Party:

(a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and

(b) In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

5. Where should the question be discussed?

(388) The Meeting thanked the Netherlands for this update. In responding to the possible negotiation of a relevant instrument to the Antarctic Treaty area, several Parties highlighted that the collection and use of biological material from the Antarctic should be discussed within the Antarctic Treaty System. It was noted that Parties should be mindful of the regulatory system of the Antarctic Treaty System and be careful of engaging in discussions on the possible application of other, possibly conflicting, regimes. The Meeting reaffirmed that the Antarctic Treaty System was the appropriate framework for managing the collection of biological materials in the Antarctic Treaty area and for considering its use. Many Parties underlined the importance of keeping biological prospecting on the agenda of the ATCM.

Final Report of the Thirty-eight Antarctic Treaty Consultative Meeting, June 2015.

6. How should the benefits be shared?

1. “kick-off” problem: disclosure of origin
2. Possible mechanisms
 - (a) Open innovation approach
 - (b) IP protection + trust fund
3. Monitoring mechanism & dispute settlement procedure

6. How should the benefits be shared?

1. “Kick-off” problem: disclosure of origin

Applicants should be obliged to disclose that they obtained the MGRs in question in ABNJ.

The consequences for lack of disclosure:

- invalidity of the patent?
- unenforceability of the patent in infringement cases?

6. How should the benefits be shared?

2. Possible mechanisms

(a) Open innovation approach

- A radical approach: denial of patentability
- A moderate approach: a patent version of “copyleft”?

○ Everyone can use the data or information

- × No use for developing States having no cutting-edge pharmaceutical or chemical industry
- × Little incentive for innovation?
- × Encourages false declarations?

6. How should the benefits be shared?

2. Possible mechanisms

(b) IP protection + trust fund

Developers of a commercial product using MGRs from ABNJ are required to pay royalties to the Fund.

The Fund would be used to protect BBNJ.

Who should manage the Fund? ISA?

See e.g. Eve Heafey, "Access and Benefit Sharing of Marine Genetic Resources from Areas beyond National Jurisdiction", Chicago Journal of International Law, vol. 14, 2014, p. 493.

6. How should the benefits be shared?

3. Monitoring mechanisms and dispute settlement procedures

How to monitor whether the obligation to disclose the origin is implemented?

What kind of dispute settlement procedures in cases where sanctions (invalidity or unenforceability of the patent) are imposed?