

THE ABS
CAPACITY
DEVELOPMENT
INITIATIVE



L'INITIATIVE DE
RENFORCEMENT
DES CAPACITES
POUR L'APA

Value Chain Development with GR from The Bahamas

Dr. Hartmut Meyer
Rodney Bay, Saint Lucia
25.11.2014

funded by

BMZ



Federal Ministry
for Economic Cooperation
and Development



DANISH MINISTRY
OF THE ENVIRONMENT



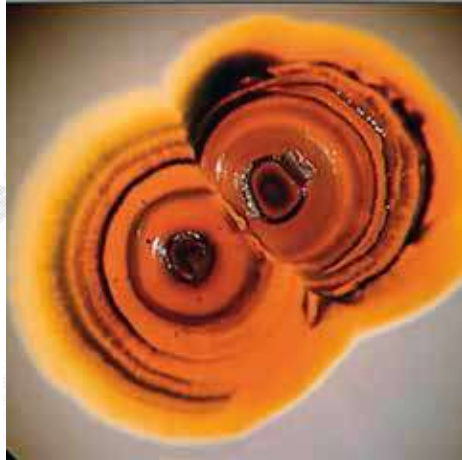
implemented by

giz

Programme Implementing
the Biodiversity Convention



Sectors: Pharmaceuticals & Cosmetics



PHARMACEUTICAL SECTOR – *Salinispora tropicalis*

Timeline of Key Milestones:

- 2005: Discovery of Salinispora tropicalis, a novel actinomycete from the deep-sea hydrothermal vent.
- 2006: Isolation of Salinispora tropicalis from the deep-sea hydrothermal vent.
- 2007: Identification of Salinispora tropicalis as a potential source of novel natural products.
- 2008: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2009: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2010: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2011: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2012: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2013: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2014: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2015: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2016: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2017: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2018: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2019: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2020: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2021: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2022: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2023: Discovery of Salinispora tropicalis as a potential source of novel natural products.
- 2024: Discovery of Salinispora tropicalis as a potential source of novel natural products.

Analysis - User and Provider Activities:

Users: The primary user of Salinispora tropicalis is the pharmaceutical industry, which is interested in the novel natural products it produces. The primary user is the pharmaceutical industry, which is interested in the novel natural products it produces. The primary user is the pharmaceutical industry, which is interested in the novel natural products it produces.

Providers: The primary provider of Salinispora tropicalis is the deep-sea hydrothermal vent. The primary provider is the deep-sea hydrothermal vent. The primary provider is the deep-sea hydrothermal vent.





Salinispora tropica from The Bahamas



The Bahamas (provider)

- *Salinispora tropica* is a marine actinomycete microfungi, until now exclusively found in marine sediments of the Bahamian coasts.
- The initial research was triggered by the potential of actinomycetes to produce potential drug candidates.
- The Scripps Institute of Oceanography (University of California, USA) as a public institution was authorised by the Bahamian government to collect and use sediment samples.



Salinispora tropica from The Bahamas



California / USA (user)

- After the description of the new genus *Salinispora* and the species *Salinispora tropica*, researchers discovered the secondary metabolite Salinosporamide A produced which showed anti-cancer activity.
- The University of California filed patents on the genetic resource and potential medicinal uses of the biomolecule.
- Nereus Pharmaceuticals filed patents on its chemical synthesis and initiated clinical studies.
- In 2014, clinical phase 2 trials are being conducted by Triphase Research and Development I Corporation.



Salinispora tropica from The Bahamas



1989: Excursion of the Scripps Institute of Oceanography (SIO) to isolate actinomycete bacteria in the context of drug discovery, under permission of the Bahamian government



Actors: Scripps Institute of Oceanography (SIO), government of The Bahamas



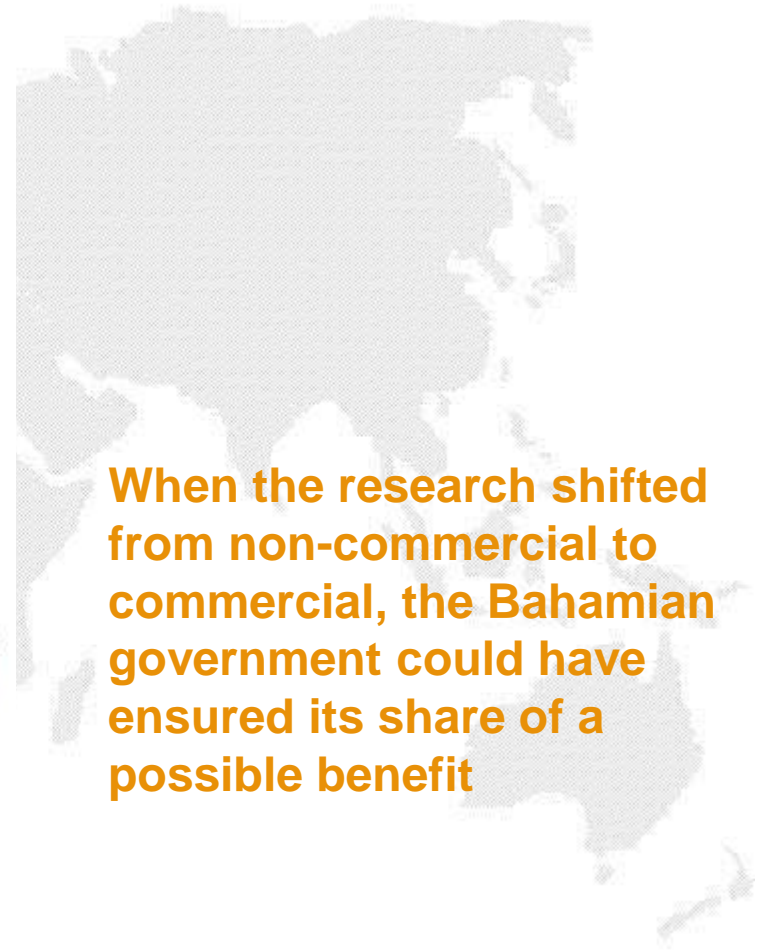
Monitoring of the research purpose right from the beginning of the R&D process



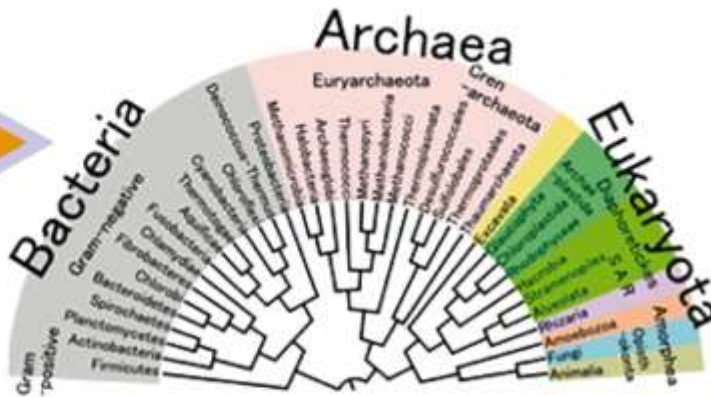
Salinispora tropica from The Bahamas



1991: Taxonomic publication of Scripps Institute Publication on the distribution of actinomycetes in near shore tropical environments



When the research shifted from non-commercial to commercial, the Bahamian government could have ensured its share of a possible benefit



Actors: SIO,
Funding: National Science Foundation (NSF),
National Cancer Institute (NCI)



Salinispora tropica from The Bahamas



1998: Foundation of Nereus Pharmaceuticals by Prof. Fenical (University of California) to develop marine drug candidates



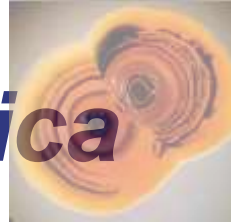
Actors: Nereus
Pharmaceuticals,
SIO



Shift from non-commercial to commercial utilisation: a second MAT and PIC, particularly in regards to monetary benefits, would include third parties, especially commercial users, in ABS agreements



Salinispora tropica from The Bahamas

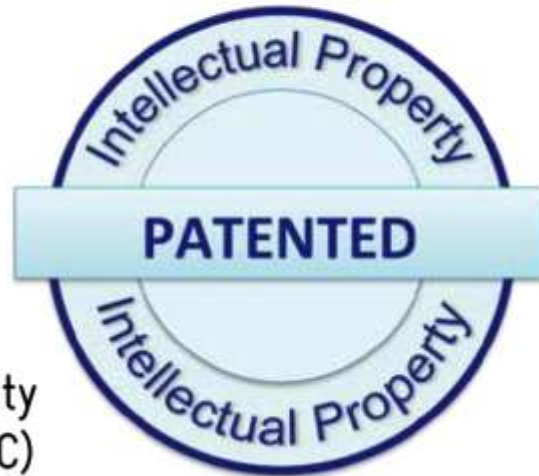


2001: Filing of US patent on a strain of the genus *Salinispora* isolated from marine sediments (of The Bahamas) and a method for producing biomolecules in laboratory cultures



The Bahamas could have benefited from provisions related to Intellectual Property Rights (IPR), e.g. co-inventorship and sharing of royalties and licence fees

Actors: University of California (UC)





Salinispora tropica from The Bahamas

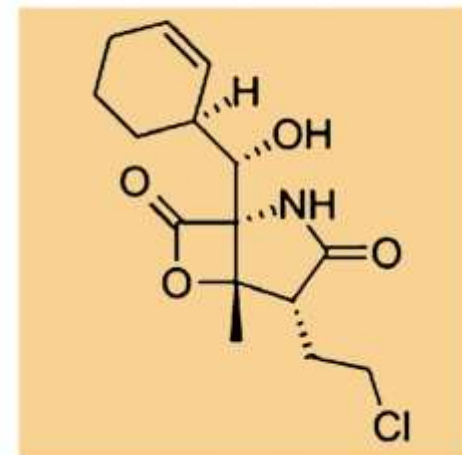


2002: Publication describing the new genus *Salinispora* – discovered in sediment samples from the 1989 Bahamas excursion



Actors: SIO
Funding: NSF

2003: Publication describing the secondary metabolite Salinosporamide A and its anti-cancer activity. The drug effectively inhibits the proteasome, an intracellular structure that is responsible for protein degradation.



Actors: SIO
Funding: NCI



Salinispora tropica from The Bahamas



Since 2004: Filing of US patent series Salinosporamides and the use thereof, claiming rights over many medicinal applications of Salinosporamides



Actors: UC



The Bahamas could have benefited from provisions related to Intellectual Property Rights (IPR), e.g. co-inventorship and sharing of royalties and licence fees

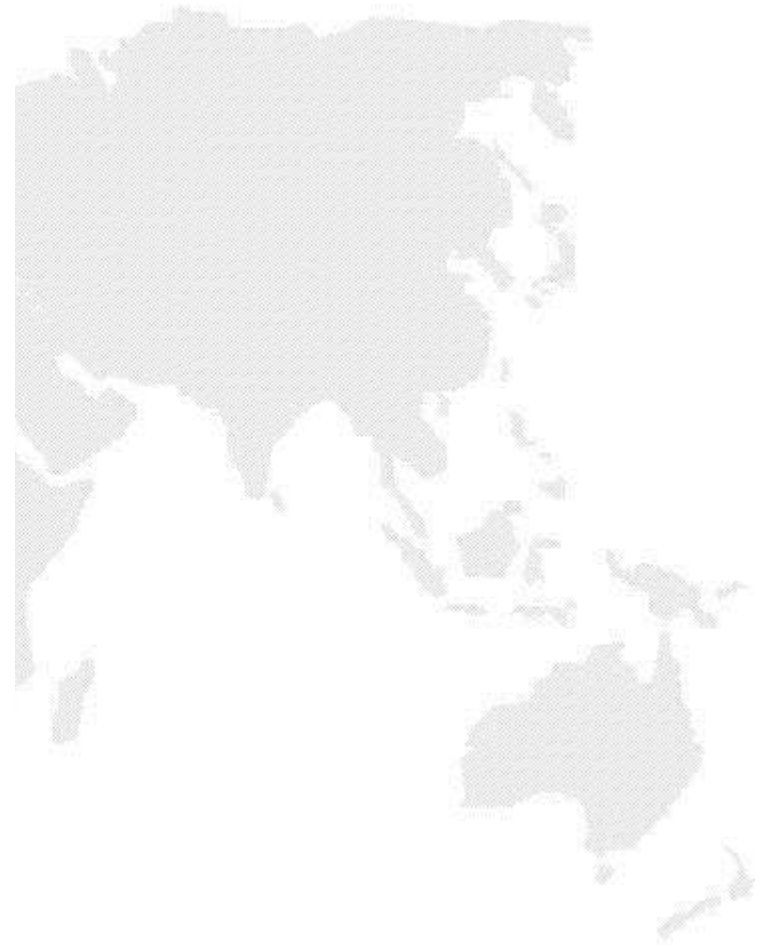




Salinispora tropica from The Bahamas



2006–08: Nereus Pharmaceuticals conducts clinical phase I trials with Salinosporamide A, known under the brand name Marizomib[®], for the treatment of multiple myeloma.



Actors: Nereus
Pharmaceuticals





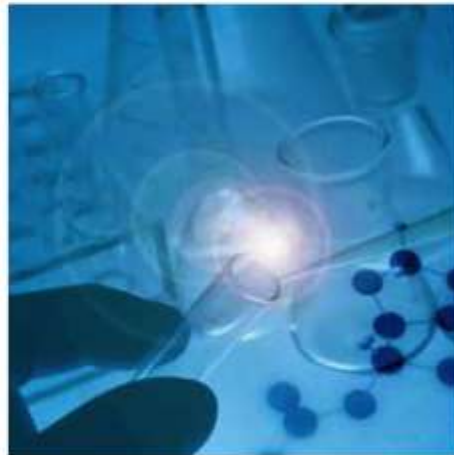
Salinispora tropica from The Bahamas



Since 2007: Filing of US patents
on the chemical synthesis of Salinospor-
amide A and analogs by Nereus Pharma-
ceuticals



Actors: Nereus
Pharmaceuticals



The Bahamas could have benefited from provisions related to Intellectual Property Rights (IPR), e.g. co-inventorship and sharing of royalties and licence fees





Salinispora tropica from The Bahamas



2012: Triphase Research and Development I Corporation takes over Nereus Pharmaceuticals



Actors: Triphase
Research and
Development
I Corporation



Changes of ownership:
MAT provisions must
cover possible changes of
ownership over genetic
resources, derivatives,
information and IPR
through acquisitions or
after bankruptcies.
Contractual
benefit sharing
obligations need to be
handed over to new
owners.

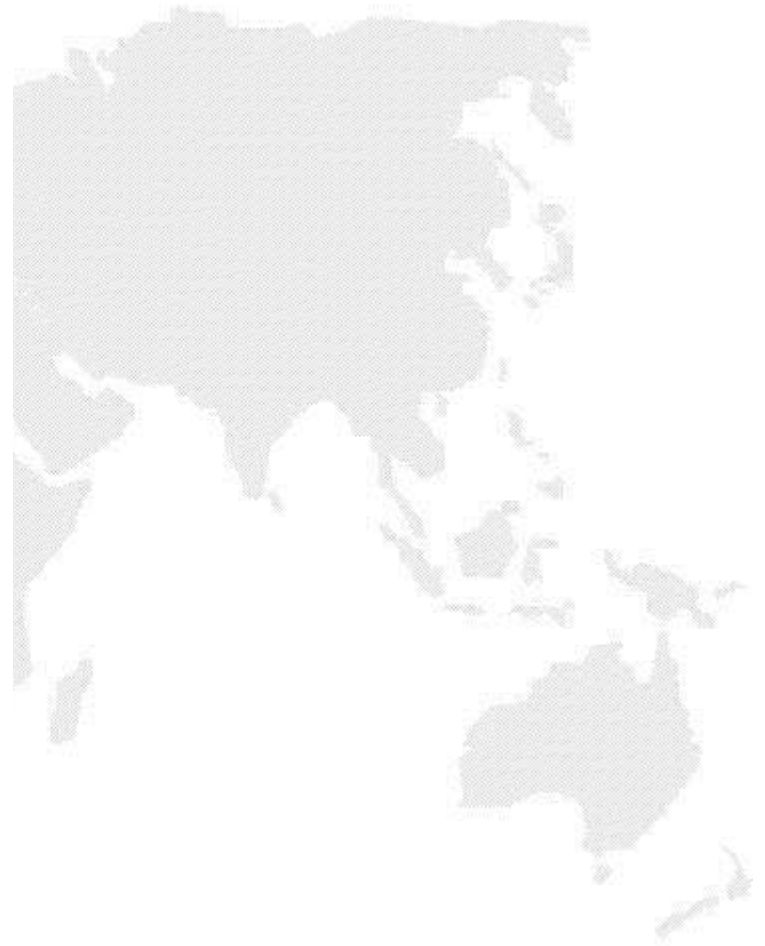


Salinispora tropica from The Bahamas



2014: Triphase Research and Development I Corporation conducts phase 2 clinical trials with Marizomib® formulations

Actors: Triphase
Research and
Development I
Corporation





Analysis of User and Provider Activities



User activities: The pattern observed in the *Salinispora tropica* case exhibits many typical elements of bioprospection and R&D in the pharmaceutical field:

- Initial research by a public institution
- Transfer of the genetic resource and research results to a research-oriented company
- A series of strategic patents
- The involvement of another medical company at the stage of clinical trials
- More companies will be involved if a drug could be produced and marketed



Analysis of User and Provider Activities



Provider activities: Although the *Salinispora tropica* case begun pre-CBD, the role of the provider country is symptomatic for a large number of post-CBD bioprospection cases:

- Lack of strategic approaches towards the valorisation of national genetic resources
- Lack of policy and legislative activities on ABS
- Missed opportunities with regard to benefit sharing and finally endogenous development
- Absence of monitoring and compliance mechanisms result in a lack of information on the utilisation of provider's genetic resource



Pseudopterogorgia elisabethae from The Bahamas



- 1982:** Sampling of soft corals in The Bahamas by the University of California
- 1986:** Anti-inflammatory properties of pseudopterrosines published by UC
- 1988:** U.S. patent on pseudopterrosines and synthetic derivatives
- 1990s:** OsteoArthritis Sciences Inc. tested methopterosin in phase I and II
- 1995:** Estée Lauder started to use coral extracts in cosmetics, 750.000 USD licence fees for UC per annum total amount of licence fees to UC unknown



Product Factsheet

Lipo Chemicals, Inc., USA



Gorgonian Extract® GC/PTG

The World's Most Powerful Anti-Inflammatory



A natural, highly effective anti-inflammatory ingredient ideal for:

- Skin treatment products w/the potential to irritate
- Sun/after sun products
- After-shave products
- Lotions, creams, gels
- Sensitive skin products
- Eye care products
- After care for skin exfoliation treatment

Product: Gorgonian Extract® GC

INCI name: Caprylic/Capric Triglyceride (and) Sea Whip Extract

EINECS #: 265-724-3 or 277-452-2 (and) Not Assigned

CAS #: 65381-09-1 or 73398-61-5 (and) 244058-54-6

Product: Gorgonian Extract® PTG

INCI name: Pentylene Glycol (and) Sea Whip Extract

EINECS #: 226-258-3 (and) Not Assigned

CAS #: 5343-92-0 (and) 244058-54-6

Gorgonian Extract®, is a natural anti-inflammatory ingredient that is safe, effective, and environmentally friendly. It is an extract from the marine organism *Pseudopterogorgia elisabethae* (sea whip), a renewable resource harvested from the Caribbean Sea, which consist primarily of powerful anti-inflammatory compounds called pseudopterosins.



Pseudopteroorgia elisabethae from The Bahamas



- 1990s:** University of California refused entering a benefit-sharing agreement
- 2001:** Benefit-sharing agreement concluded between Government of the Commonwealth of The Bahamas, the local company Marsh Harbour Exporters and Importers Ltd. and the U.S. company Lipo Chemicals
- 2014:** Close to 1 mill USD paid into a fund for surveys, conservation education, and resource management
- 2014:** 145 cosmetic products use coral extract from The Bahamas, 50% of these products belong to Estée Lauder
- 2014:** The Bahamas start UNEP GEF ABS project



Thank you very much!

Contact:

- Dr. Hartmut Meyer
Senior Advisor, ABS Capacity Development Initiative
Deutsche Gesellschaft für Internationale Zusammenarbeit
(GIZ) GmbH
Dag-Hammarskjöld-Weg 1-5
65760 Eschborn
Germany
t: +49 6196 793285
f: +49 6196 79803285
m: +49 171 1027839
e: hartmut.meyer@giz.de
e: abs-initiative@giz.de (secretariat)