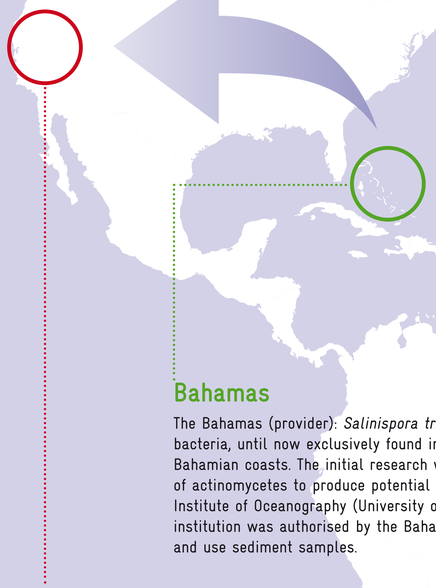
THE ABS CAPACITY DEVELOPMENT INITIATIVE

PHARMACEUTICAL SECTOR – *Salinispora tropica* (The Bahamas)



Bahamas

The Bahamas (provider): *Salinispora tropica* is a marine actinomycete bacteria, 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) as a public institution was authorised by the Bahamian government to collect and use sediment samples.

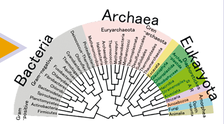
California

California/USA (user): After the description of the new genus Salinispora and the species *Salinispora tropica*, researchers discovered the secondary metabolite Salinosporamide A produced by *S. tropica* which showed anti-cancer activity via proteasome inhibition. 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.

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

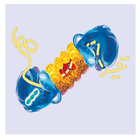
1991: Taxonomic publication of Scripps Institute Publication on the distribution of actinomycetes in near shore tropical environments



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

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

Actors: Nereus Pharmaceuticals, SIO

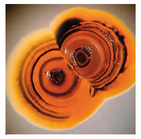


2001: Filing of US patent on a strain of the genus Salinispora isolated from marine sediments (of The Bahamas) and a method for producing biomolecules in laboratory cultures

Actors: University of California (UC)

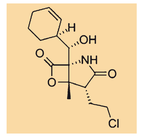
2002: Publication describing the new genus Salinispora – discovered in sediment samples from the 1989 Bahamas excursion

Actors: SIO
Funding: NSF



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

Actors: SIO
Funding: NCI



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

Actors: UC

Since 2007: Filing of US patents on the chemical synthesis of Salinosporamide A and analogs by Nereus Pharmaceuticals

Actors: Nereus Pharmaceuticals

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

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

Actors: Triphase Research and Development I Corporation

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

© Erin Gontang (Harvard Medical School)

Salinospora tropica is a marine actinomycete bacteria first discovered and described by the Scripps Institute of Oceanography (University of California). Until now *S. tropica* is exclusively found in the marine sediments of the Bahamian coasts.

Analysis – 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. These are, e.g. the initial research by a public institution, transfer of the genetic resource and research results to a research-oriented company, a series of strategic patents and 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.

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

OPPORTUNITIES PROVIDED BY THE NAGOYA PROTOCOL:
Benefit sharing could have been ensured and the R&D and commercialisation process made more transparent for the provider country through national ABS legislation and in particular comprehensive and effective PIC and MAT, taking into account sector specific milestones.

- Monitoring of the research purpose right from the beginning of the R&D process
- When the research shifted from non-commercial to commercial, the Bahamian government could have ensured its share of a possible benefit
- 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
- The Bahamas could have benefited from provisions related to Intellectual Property Rights (IPR), e.g. co-inventorship and sharing of royalties and licence fees
- Changes of ownership: MAT provisions must cover possible changes of ownership over genetic resources, derivatives, information and IPR through acquisitions or after bancrupcies. Contractual benefit sharing obligations need to be handed over to new owners.

Key institutions and provisions (checkpoints, provisions of conflict resolution) to ensure compliance are still absent on the national and international level. The entry into force of the Nagoya Protocol in October 2014 represents a crucial step towards establishing such compliance mechanisms.

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The marine organism *Salinospora tropica* creates the natural product Salinosporamide A, which is effective as anti-cancer treatment. Under the brand name Marizomib® the substance is currently being tested in clinical trials and may receive medical approval in the near future.

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THE ABS CAPACITY DEVELOPMENT INITIATIVE

COSMETICS SECTOR – CIMTECH (Cook Islands)

Cook Islands

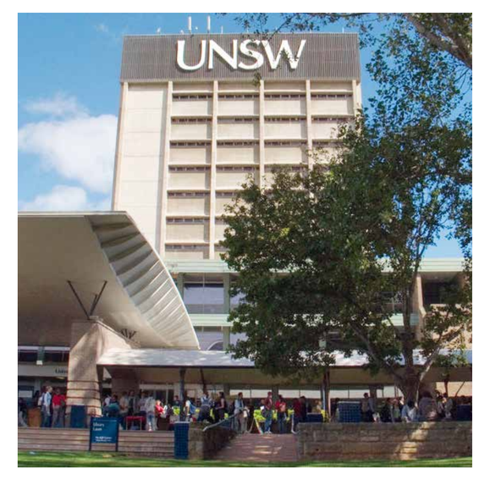
Graham Matheson from the Cook Islands performed his PhD studies at the Australian University of New South Wales (UNSW) on the effects of traditional Cook Islands medicine in the treatment of bone fractures and skin afflictions.

In 2003, he addressed the Koutu Nui – a lawfully recognised council of traditional leaders under the House of Ariki Act (1965) of the Cook Islands – with a proposal for further investigation and possible future commercialisation. The two parties signed a benefit sharing agreement and became equal partners of the newly-founded companies CIMRAD (Cook Islands) and CIMTECH (Australia), the latter being created to facilitate patent applications and fund-raising. Through this arrangement, both parties share risks, responsibilities and benefits.

Australia

In 2012, the skin-care product line Te Tika ("truth and integrity") was launched, the primary processing (plant harvest, extraction) is undertaken in the Cook Islands. Recently, CIMTECH sold the licence for two of its bio-active compounds to an Australian pharmaceutical company (Parnell Pharmaceuticals) which intends to develop veterinary medicine and possibly human drugs as well.

2000: Graham Matheson begins research on pharmacological effects of traditional Cook Islands medicine (plant extracts) on bone fractures and other medical conditions at the Australian University of New South Wales (UNSW)



Actors: Graham Matheson, UNSW

2003:
- Matheson files a proposal for investigation and potential commercialisation with the Koutu Nui who approve unanimously
- Matheson conducts a self-funded pilot study based on his own formulas

Entry point of the Nagoya Protocol (see below)

Actors: Koutu Nui, Graham Matheson

2003–09:
- Matheson signs benefit sharing agreement with the Koutu Nui
- CIMRAD is installed as a co-owned company in the Cook Islands
- CIMTECH is founded as a second company to apply for patents and raise funds, owned by an Australian trust

Entry point of the Nagoya Protocol (see below)

Actors: Koutu Nui, Graham Matheson, TM Ventures (Consulting company)

Funding: UNSW, public Australian funds, private investors

2010: Matheson finishes his PhD thesis: the plant extracts increased epithelial hypertrophy (thickness of the skin) and enhanced new bone and cartilage formation

Actors: Koutu Nui, Graham Matheson

2010–12: Construction of a processing facility and laboratory in the Cook Islands. Plant harvest and extraction of the infused oil is undertaken in the Cook Islands. Primary processing facility also includes a quality control system.

Actors: CIMTECH

2012: Launch of the skin-care product line Te Tika. The products are distributed via local hotel resorts and retail stores in the Cook Islands and Australia.

Actors: CIMTECH

2014: The Australian company Parnell Pharmaceuticals acquires a licence for two bio-active compounds for research and development of veterinary medicine for bone fractures and skin afflictions. The licence is perpetual, exclusive and includes the possible development of human drugs

Entry point of the Nagoya Protocol (see below)

Actors: CIMTECH, Parnell Pharmaceuticals

The healers (Taunga Vairakau) of the indigenous Maori in the Cook Islands possess a wide range of traditional medicinal knowledge, including applications for various plants. Specific plants are used for the treatment of bone fractures and skin afflictions: *Arnebia euchroma, Hibiscus esculentus, Vigna marina, Cocos nucifera, Terminalia catappa, and others.*

Analysis – User and Provider Activities

Despite the non-existence of legal frameworks regarding research permits, use of traditional knowledge (TK) and intellectual property rights (IPR), the CIMTECH case fulfils several key aspects of the Nagoya Protocol. Here are possible reasons why:

Just a few actors: As only two main actors were involved in the R&D process negotiations were relatively simple.

Strong Stakeholders: Indigenous and local communities play a significant role as recognised holders of traditional knowledge and thus as partners and beneficiaries of ABS agreements. The Koutu Nui is a well-organised governance institution. Agreements were negotiated at eye level.

High Level of Trust: The parties involved were in permanent dialogue. They shared ownership of CIMTECH, intellectual property rights, risks and responsibilities and, as a consequence, had equal interest in the company's success.

High Degree of Transparency: Prior to the agreement, Matheson and the Koutu Nui discussed potential opportunities and risks and were aware of the many years between investment and actual benefits.

Integrative value chain: Harvesting the plants and the primary production are conducted in Cook Islands, while the manufacturing is completed in Australia.

OPPORTUNITIES PROVIDED BY THE NAGOYA PROTOCOL:

Procedure: The Nagoya Protocol could have provided for model procedures, legal certainty and, above all, competent institutions in the negotiation process.

Graham Matheson included the Koutu Nui right from the beginning, hopefully this operating at eye level and respect for traditional knowledge will become best-practice in future ABS agreements all over the world.

Institutionalised provisions:
CIMTECH has granted the licence for medicinal application to an Australian pharmaceutical company. This could put an end to transparency and clarity as it might be more difficult to trace the medical application with the new licence holder. Both Australia and the Cook Islands have installed national ABS focal points. However, there are no institutions and provisions (checkpoints, provisions for conflict resolution) yet to ensure compliance with the agreement, neither on the national nor on the international level. The entry into force of the Nagoya Protocol in October 2014 represents a crucial step towards establishing such compliance mechanisms.

Parnell Pharmaceuticals acquire the licence for two bio-active compounds for the treatment of bone fractures and skin afflictions from CIMTECH in 2014. In a first step the company plans on developing veterinary medicine and, later, on human drugs as well.

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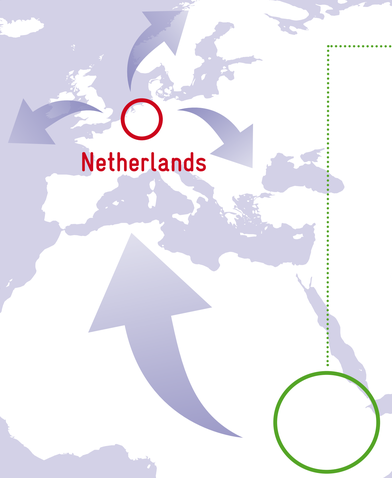
THE ABS CAPACITY DEVELOPMENT INITIATIVE

AGRICULTURAL SECTOR – *Eragrostis tef* (Ethiopia)



Ethiopia

Eragrostis tef (teff) has been a staple food for 2000 years and still is today for 50% of the Ethiopian population (traditional fermented bread injera).

Has great market potential in health food and organic food sector: Gluten-free, rich in vitamins, iron, lysine and calcium – ideal diet for people suffering from coeliac disease or anaemia and for athletes.

Can be cultivated in dry landscapes and under unstable weather conditions, grows on water-logged soils, is used in South Africa for erosion control.

1886 – United Kingdom: The Kew Botanical Garden obtains seeds from Abyssinia (Ethiopia) to initiate plantings in the colonial empire

Since 1960 – Ethiopia: The Debre Zeit Centre of Alemaya University (DZARC) performs cross-breeding experiments to improve yields and lodging resistance (stability of the stalk)

Since 1970 – Worldwide: Among others, Australia, United Kingdom, Israel and the USA, have started research projects on teff

1984 – USA: The Teff Company starts planting and commercialising teff flour and grain under the trademark Maskal Teff

2003: Memorandum of Understanding (MoU) signed between the Ethiopian Agricultural Research Institute (EARO), Larenstein University and the Dutch company Soil and Crop Improvement (S&C)

- Royalty payment, licence fees
- Co-ownership of new varieties
- Research collaboration
- Teff fund to propagate scholarships and other social projects
- Transfer of genetic material to the Netherlands for research purposes

Entry point of the Nagoya Protocol (see below)

Actors: DZARC, EARO, Larenstein University, S&C

2004: Foundation of Health Performance Food International (HPFI) – S&C treated as subordinate part of HPFI

HPFI files a patent application with the European Patent Office (EPO) – granted in 2007

Termination of MoU

- Patent covers a special drying process of the grains and the production of all subsequent products derived from the flour (e.g., flour, dough, food, beverages)
- Patent application and implementation problems lead the Ethiopian government to re-negotiate the agreementtiate the agreement

Entry point of the Nagoya Protocol (see below)

Actors: HPFI (S&C), EPO, EARO, *IBC, Ethiopian Ministry of Agriculture*

2005: ABS agreement between the Ethiopian Institute of Biodiversity Conservation (IBC), EARO and HPFI

Implementation of the S&C and EARO foundation (SCEAR) in the Netherlands

- HPFI gets access to Ethiopian varieties for non-traditional food and beverages
- Co-ownership of newly developed varieties
- HPFI is granted no access to traditional knowledge
- HPFI cannot transfer genetic material to third parties without consent
- Non-monetary and monetary benefits are shared
- Annual research and financial reports
  - Penalty fees for breach of contract
    - Arrangements for the possibility of early termination
      SCEAR fund founded to manage royalty payments and register new teff varieties

Entry point of the Nagoya Protocol (see below)

Actors: HPFI (S&C), EPO, EARO, *IBC, Ethiopian Ministry of Agriculture*

2006: The Ethiopian government is declaring an export ban on Teff in order to improve food security in the country

Research project between HPFI and DZARC

The objective of the research programme is to develop varieties better adapted to the Dutch weather conditions.

Actors: Ethiopian gouvernment, HPFI, DZARC, Dutch plant breeders

2007: HPFI terminates the research project

Concerns of the Ethiopian Institute of Biodiversity Conservation (IBC):

- SCEAR fund solely under Dutch administration
- Outstanding payments
- HPFI failed to provide the annual reports
- In collaboration with German authorities and the not-for-profit organisation Sequa, HPFI was engaged in a project for Ethiopian farmers – initiated without consent of the Ethiopian authorities and funded with money from the SCEAR fund

Concerns of HPFI:

- Ethiopian export ban on teff is undermining the business model of HPFI
  - Slow progress in building sufficient infrastructure for the implementation of the agreement

Entry point of the Nagoya Protocol (see below)

Actors: HPFI, IBC

2008: HPFI sells EPO patent

Patent sold for **60,000 € to a partnership of HPFI directors** without informing shareholders or partners. The patent from 2007 is now owned by Prograin International bv, a Dutch company under the administration of the former HPFI director and the person stated as the inventor in the EPO patent.

Entry point of the Nagoya Protocol (see below)

Actors: HPFI

2009: Bankruptcy of HPFI

- Values transferred to companies, Ecosem/Prograin, Ancientgrain BV, Prograin International BV
- The newly founded companies are unbound by the terms of the ABS agreement

Entry point of the Nagoya Protocol (see below)

Eragrostis tef (Teff) is an annual gras and staple food for more than half of the Ethiopian population. Farmers grow Teff on approximately 20% of the country's cultivated area. In 2011/12 the total production value was 1.6 billion USD with a commercial surplus of 464 million USD.

Analysis – User and Provider Activities

INCONSISTENT IMPLEMENTATION AND COMMUNICATION BETWEEN PROVIDERS AND USERS

The relatively high number of actors involved in the teff case likely contributed to the rather complicated and opaque R&D process. Additional obstacles include:

- Unclear division of labour between Ethiopian authorities EARO and IBC
- Patents filed through the SCEAR fund, solely under Dutch administration
- Patent based on traditional knowledge (drying process of the grains) and includes rights on products – both excluded in the agreement
- Ethiopian export ban undermining the business model of HPFI
- Outstanding payments of royalties and licence fees
- No annual reports filed by HPFI

OPPORTUNITIES PROVIDED BY THE NAGOYA PROTOCOL:

Procedure:

Competent national authorities with clear competences, as defined by the Nagoya Protocol, would have provided for more transparency and legal certainty.

Information exchange with competent national authorities and ABS Clearing-House would have improved the communication between all involved parties

The ABS Clearing-House (checkpoints) and national ABS focal points could have contributed reliable and accessible information and means for monitoring (patent application, transfer of genetic material to third parties, use of traditional knowledge, status of research).

INSTITUTIONALISED PROVISIONS:
Key institutions and provisions (ABS Clearing-House, checkpoints, provisions of conflict resolution) to ensure compliance are still absent on the national and international level. The entry into force of the Nagoya Protocol in October 2014 represents a crucial step towards establishing such compliance mechanisms.

In Ethiopia, Teff is mainly used to prepare the traditional sourdough bread Injera which is served as a side dish to spicy stews. Teff is rich in vitamins, iron, lysin and calcium and, above all, is gluten-free. These attributes make Teff food a perfect diet for athletes and people with coeliac disease.

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