Understanding Private Sector Practices and Needs

Prerequisite to establish functional ABS systems and agreements

SESSION THEMATIC : UNDERSTANDING R&D AND BUSINESS MODELS TO NEGOTIATE BENEFIT SHARING AND INFORM ABS REGULATION

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Content

- Where are we coming from ?
- How sectors do R&D
  - Trends
  - Typologie of collaborations
  - Possible beneficiaries of BS along the R&D cycle
- How to negotiate benefit sharing
  - Identify the rights, roles and responsibilities
  - Understand the needs, expectations and constraints

“Logic” of CBD regarding Access regulations

„resource-rich„ countries shall facilitate the access to genetic resources

User

PIC / MAT

Prov.

„technology-rich“ countries shall share benefits arising from GR; facilitate the access to technologies and means important for conservation and use

Patenting of countries biodiversity seems to be moderate, but it's only part of the picture.

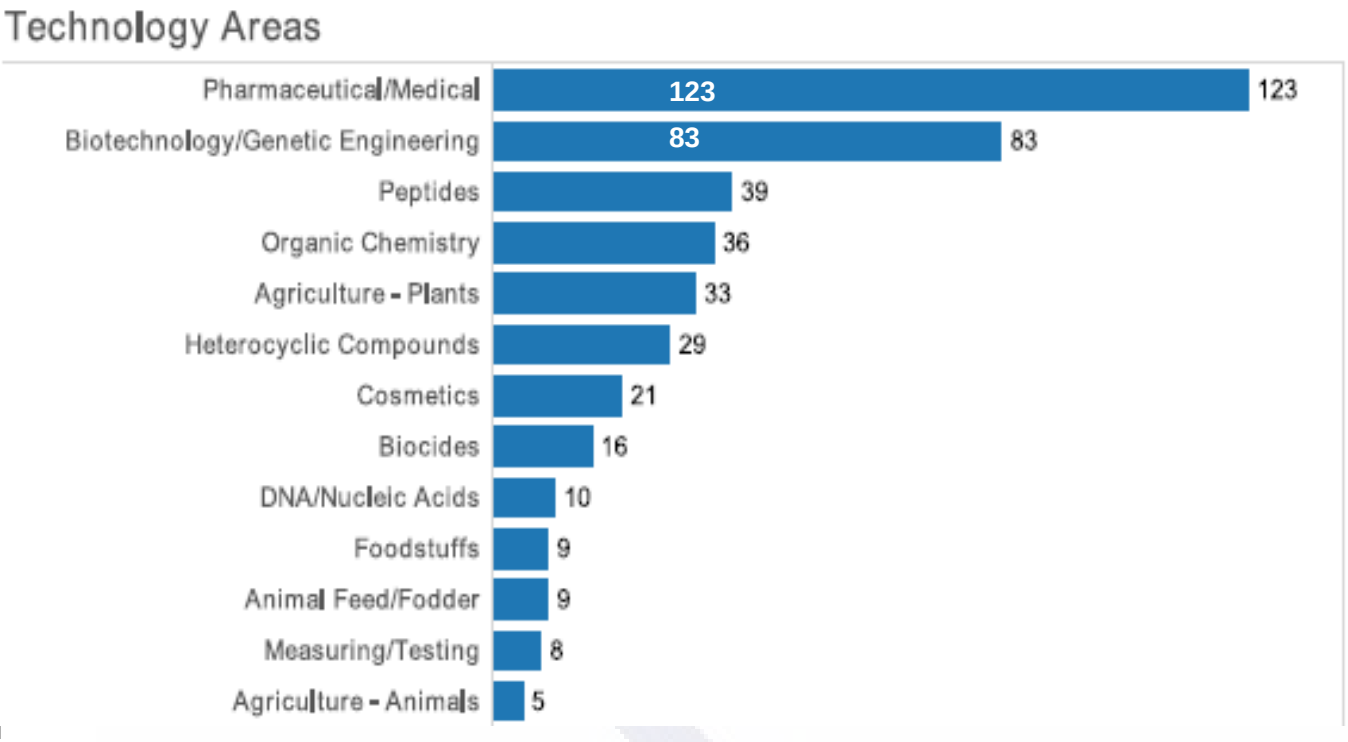
- **Study - GR business potential**
  - SEN/ CAM / KEN / RSA / MOZ / MAD (UNEP / GEF 4)
  - Assessing national enabling environments, policies / strategies / regulations / actors in place

  - **What's happening with the countries biodiversity?**
    What sectors are using GR ? What the commercial opportunities are emerging?
  - **Patent analysis (full text and GBIF crossreference)**

	Madagascar	Mozambique	South Africa	Kenya	Senegal	Cameroon
GBIF record of species	23 220	10 963	59 092	16 594	12 729	13 933
Patents specifically mentioning country name	2 451	511	11 283	3 300	2 541	?
Species known to occur in the country	6 764	1 931	6 415	3 134	5 445	1 592
Species directly sourced or potentially originating from the country	73	10	110	29	18	22

Utilisation is varied and complex

Patents classified by technology area, Madagascar.

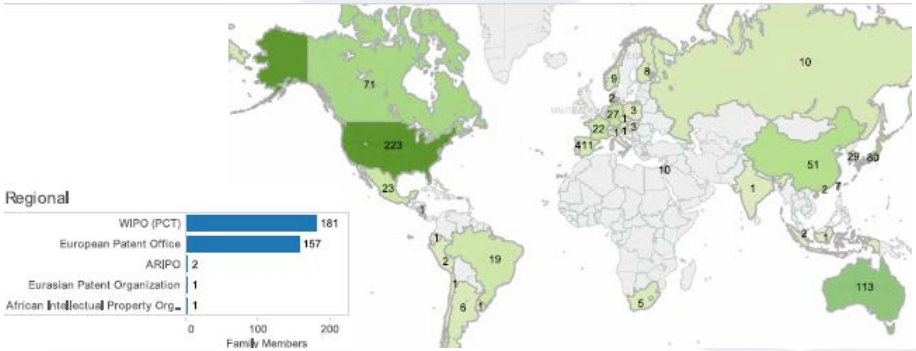


Source: study - GR business potential

One species – many careers …..

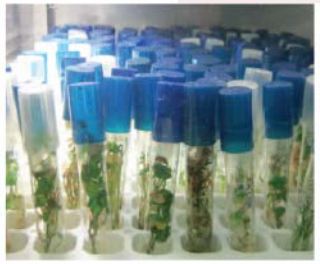
Adansonia digitata	Cosmetics	2
	Hyperglycaemia/Diabetes	2
	Skin Care	2
	Traditional Medicines	2
Adansonia fony	Cosmetics	4
	Hyperglycaemia/Diabetes	4
	Skin Care	4
	Traditional Medicines	4
Adansonia grandidieri	Animal Feed	3
	Animal Food Supplements	2
	Cosmetics	8
	Hyperglycaemia/Diabetes	5
	Skin Care	6
	Skin Disorders	1
	Sun Barriers/Sun Tan Lotion	2
	Traditional Medicines	6
	Vitamins	2

……possibly in many countries



Understand business and R&D models to guide policy makers in the establishment of effective national ABS systems

BIOSCIENCE AT A CROSSROADS: IMPLEMENTING THE NAGOYA PROTOCOL IN A TIME OF SCIENTIFIC, TECHNOLOGICAL AND INDUSTRY CHANGE*


INDUSTRY	GLOBAL MARKETS (US$)
Pharmaceutical	$955.5 billion (2011)
Cosmetics	$426 billion (2012) – natural component $26.3 billion
Food and beverage	$11.6 trillion (2009) – functional beverages $23.4 billion
Seed	$45 billion (2011)
Crop Protection	$40 billion (2010)
Industrial Biotech	$65-78 billion (including biofuels, 2010) – industrial enzymes $3.3 billion
Botanicals	$84 billion (2010)

* 2013 by Sarah A. Laird and Rachel P. Wynberg, as part of a series of SCBD fact sheets and policy briefs

ABS – the concept

Different type of genetic resources

Animal, plant, microbial

Used for different purposes

Research & development
- commercial
- non commercial

based on PIC / MAT

Different types of users operating in different sectors

- pharmaceuticals
- seed and crop protection
- personal care and cosmetics
- botanicals and horticulture
- (farm) animal breeding

A large number of actors involved, rarely one provider and one user (e.g. intermediaries)

Definition of research and development under the NP

Art 2

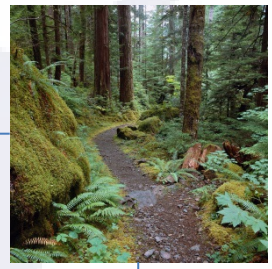
“Utilization of genetic resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.

“Biotechnology” as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

The R&D goal

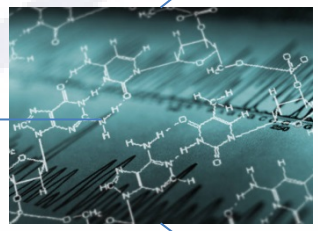
- Why?
  - **Answer a question** (technical, technological, societal) and position against the issue
  - **Valorisation** (publication, conference, intellectual property, patent) / product and services
- What they want / need?
  - Literature review
  - Partnership (limited capacity competences)
  - Samples are necessary at some point!
- What for? How it's used?
  - Confirm the initial lead & change of scale
    - Biotech : semi production
    - Agriculture: field, greenhouse
    - Comestic: in vivo test

R&D processus



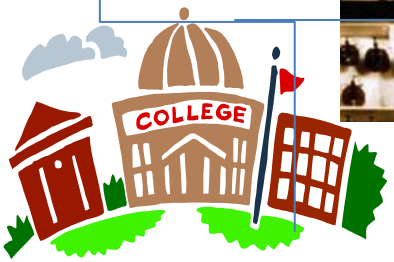
(User country)

(Provider country)



Synthétique

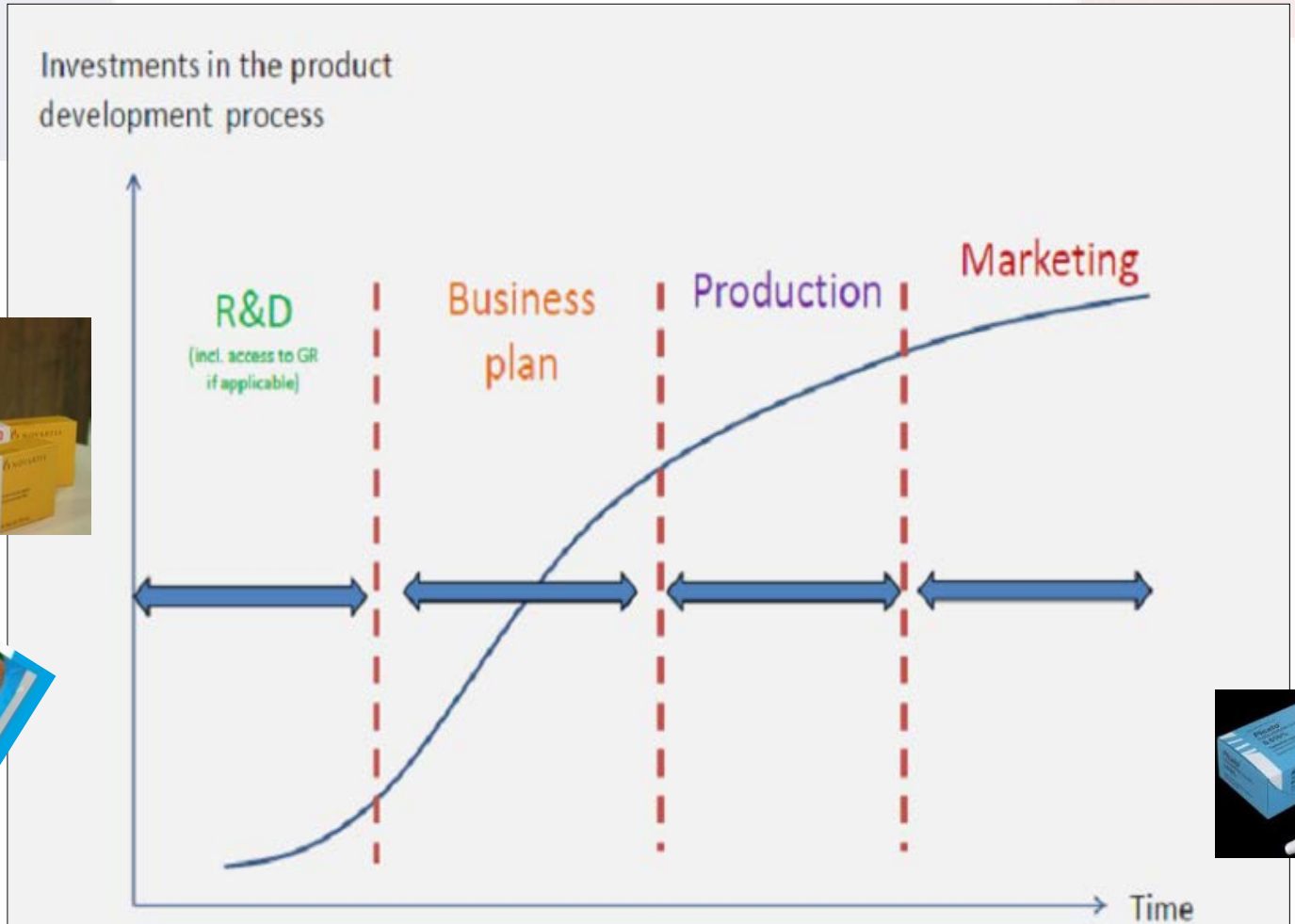
Filiére de production



2 – 8 years

A similar product developement cycle

When / what basis to negotiate PIC / MAT ?



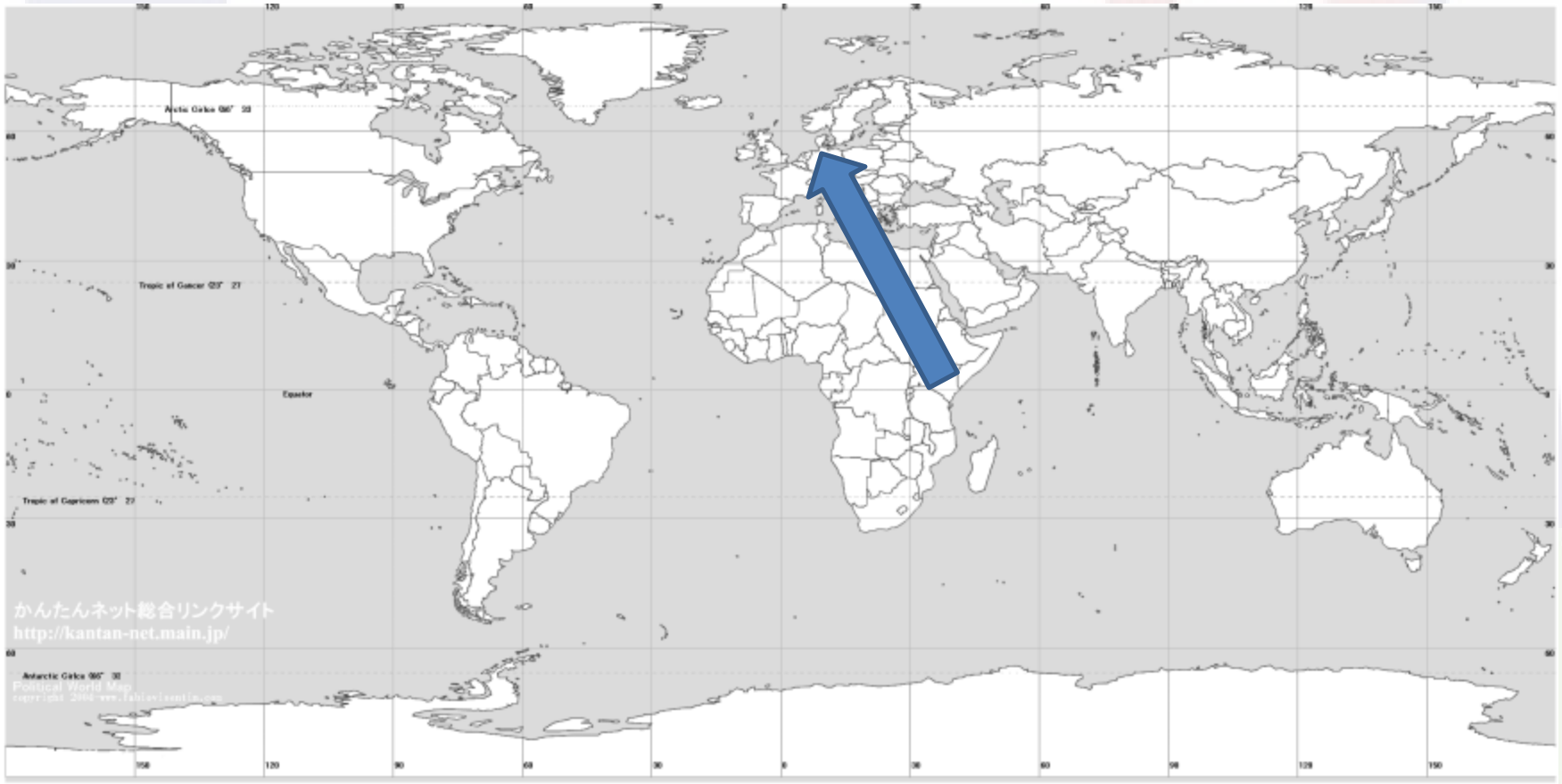
R&D practices are very different from one sector to another - Many candidates, **few successes!**

- **R&D and product development processes are complex** and differ even on a case to case basis.

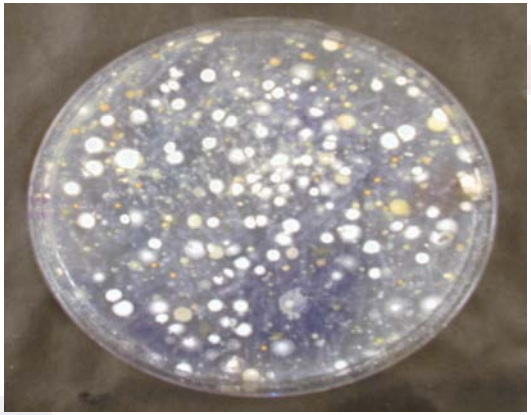
- Common elements to the 4 sectors:
  - e.g. **go/no go** decisions throughout the R&D process
  - **Confidentiality, exclusivity** & **IP** considerations
  - Development of **science / technology is changing industry practices** (e.g. genomics)
  - **One-off and continuous access to GR is complementary** rather than exclusive

Crossing over of ingredients from one sector to another

Microorganisms & Enzymes



Microorganisms & Enzymes



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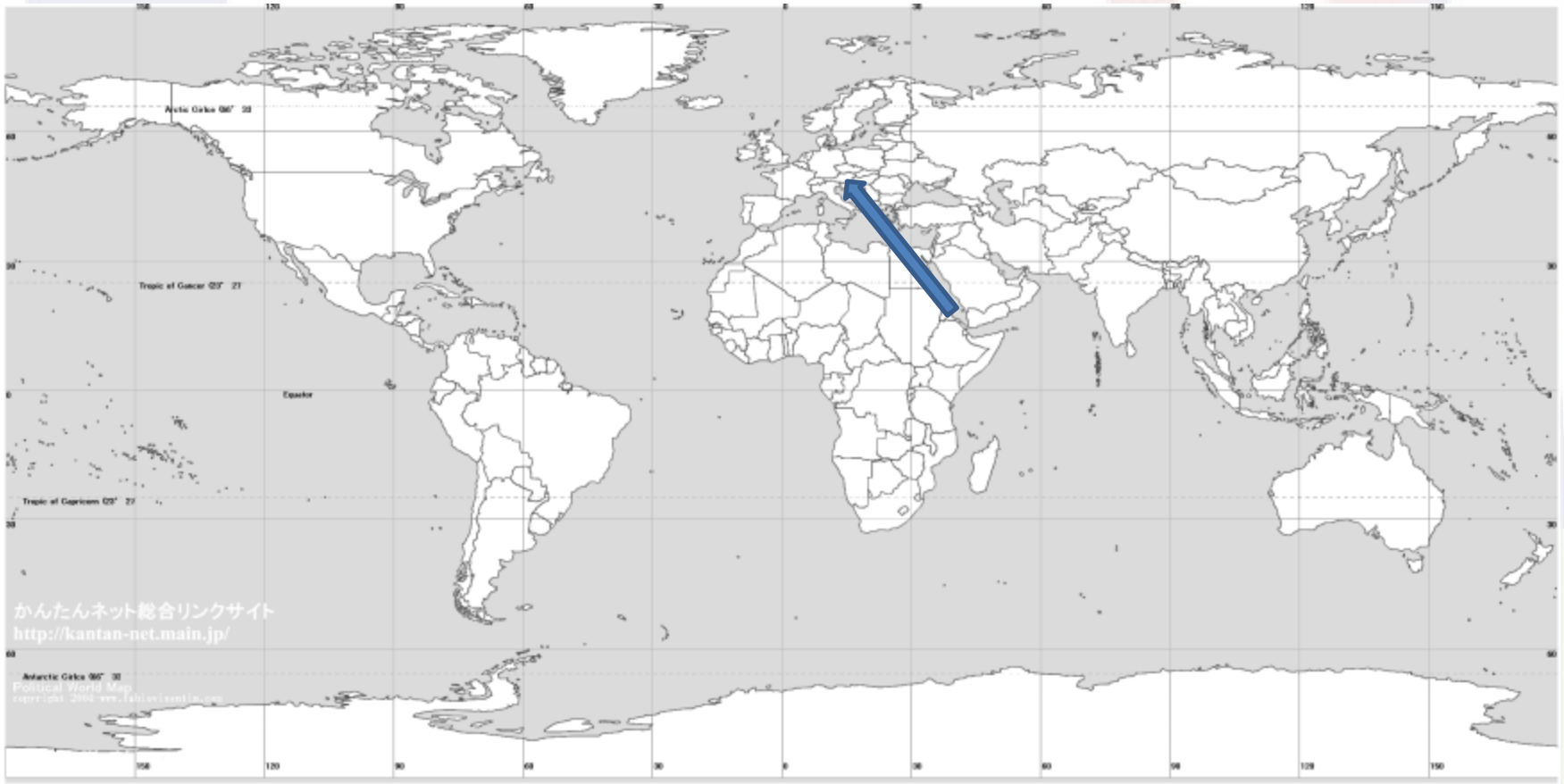
Biotechnology

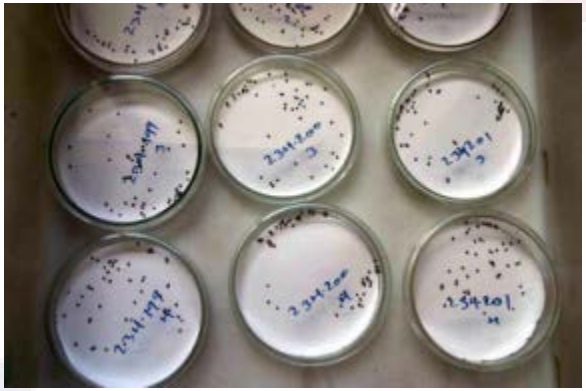
- **Market**
  - Global turnover around $ 75 billion
  - Young industry with 3 main sub sectors (green, red, white) (e.g. biochemicals, biofuels, biomaterials and some consumer products)
- **R&D**
  - Objective: prove activity and overall feasibility at large scale
  - Difficulty to understand business potential of academic R&D results & future industrial needs
- **Specifity of green biotech**
  - Focus: enzymes and metabolites from microorganisms that can endure difficult manufacturing conditions (e.g. pressure)
  - Some companies do bioprospecting (e.g. in extreme environments) but most use existing collection or domestic GR
  - Genome-mining :
    - search directly in soil or water without having to culture the organism
    - Publication of microbial genetic sequences and ability to transfer genetic material digitally
  - High degree of science and technology requires governmental support ((e.g. biofuels) partnership to complete product development

Sources: Literature review, interviews

Teff


Arctic Circle 66° 33
Tropic of Cancer 23° 27
Equator
Tropic of Capricorn 23° 27
かんたんネット総合リンクサイト
http://kantan-net.main.jp/
Antarctic Circle 66° 33
Political World Map

Teff

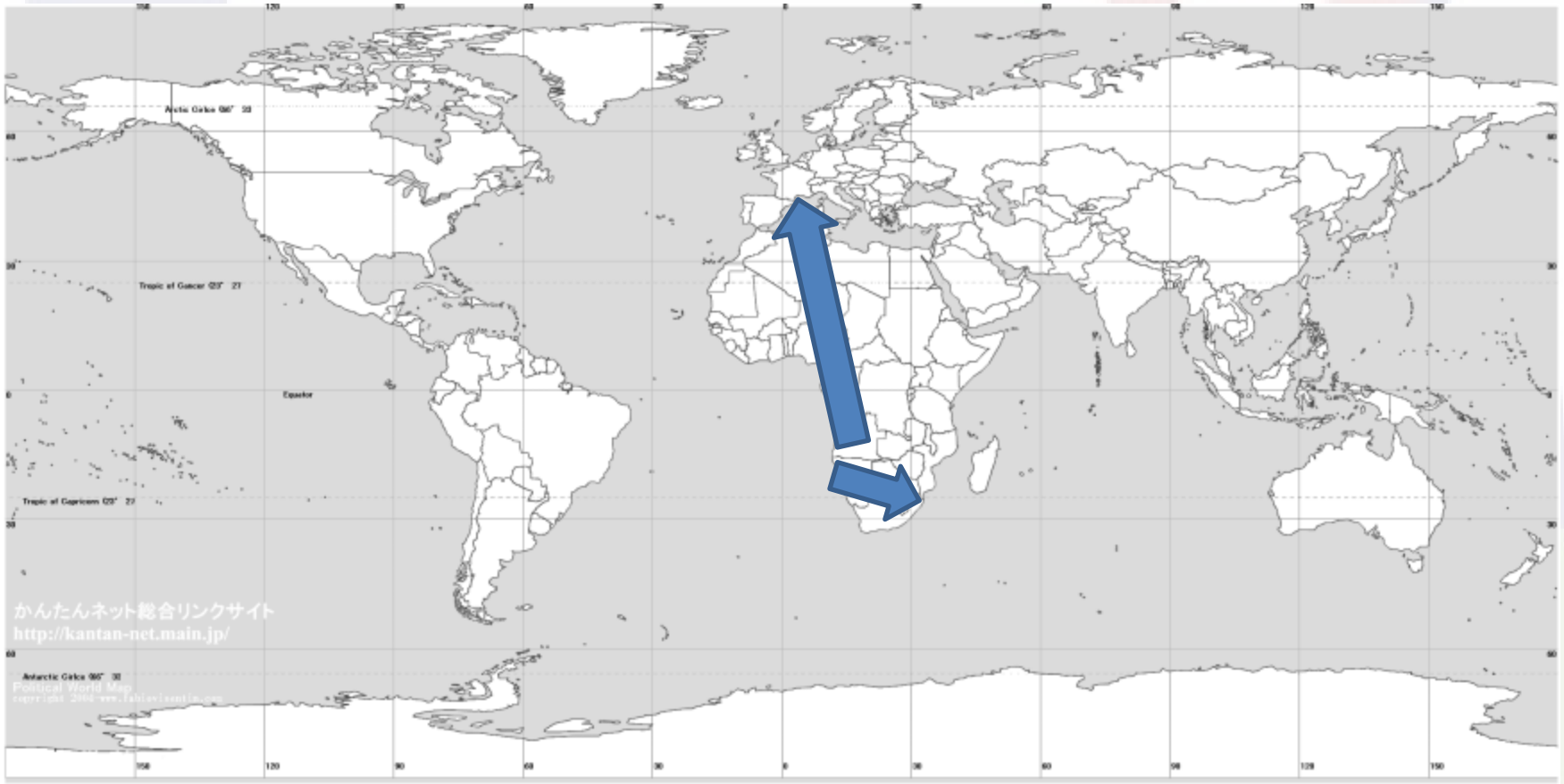


Food and beverages

- **Market**
  - Turnover of $ 11,6 trillion (2009), expected to reach $15 trillion (2015) functional beverages: $ 23,4 billion
  - Mature, dynamique and diversified sector (9 billion people to feed !)
- **R&D**
  - Objective: health benefits (e.g. weight, energy,…)
  - Low level of R&D (process improvement) but innovation is increasing : functionnal food, natural (e.g. additive free, free from…)
- **Specificity**
  - Pre R&D before corporate R&D - Use of traditional knowledge as an indication of efficacy and safety
  - Commodities dominate - use large volumes – reliability of supply is key
  - Strong competition from ingredients in large user countries (e.g. olive, grapefruit)
  - Breeding and crop protection are key, interest in wild plants for domestication
  - Increasing integration of food with other sectors and increasing consumer interest in natural products (& sustainability) suggest an increasing trend of the use of GR (relevance of ABS)

Sources: Literature review, inteviews, EU COMTRADE, OECD, Laird & Wynberg,

Commiphora wildii



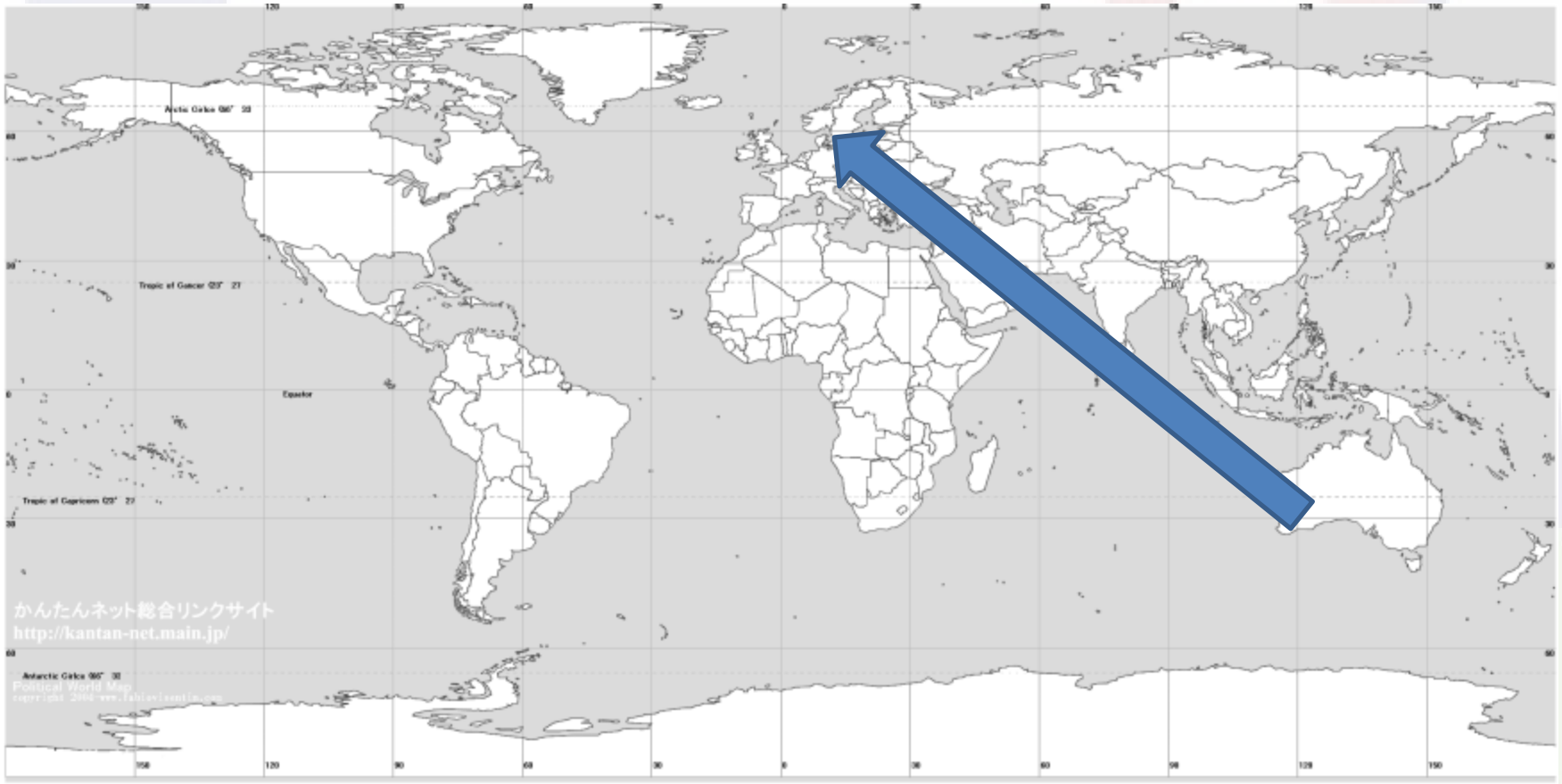
Commiphora wildii

Cosmetics & fragrance

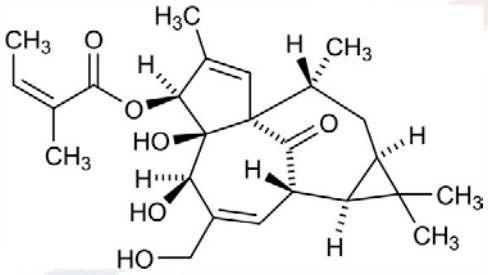
- **The market**
  - For natural cosmetics, sales of $ 26,3 billion (2011) out of a global turnover of $426 billion
  - Oils, fats, waxes, essential oils, oleoresins and plants extracts are used in 'pure natural' and in conventional cosmetics (very small quantities)
- **R&D**
  - Objective of the research:
    - Fragrance : feature characteristics of ingredients
    - Cosmetic : active principle or ingredients (additif, excipient formulation). Anti aging!
  - Major companies focus on brand strategies and intermediaries do intensive research
  - R&D investments differ: from minimal processsing of raw material to advance research
  - Speciality raw ingredients and natural compound to guide synthetisation
  - Most ingredients are cultivated to master quality, secure supply and reduce costs
- **Sector specificities**
  - Strong regulation + new Chinese regulation - narrows the focus of GR and R&D
  - Brand image is key - pressure to innovate – demand for a «*story* » but short shelve life
  - Mix use of patents - due to short shelf life of products it's an expensive tool
  - Sustainability issues are high on the agenda of B2C companies due to their marketing potential
  - Niche interest in GR from the South & in traditional knowledge (to guide R&D)

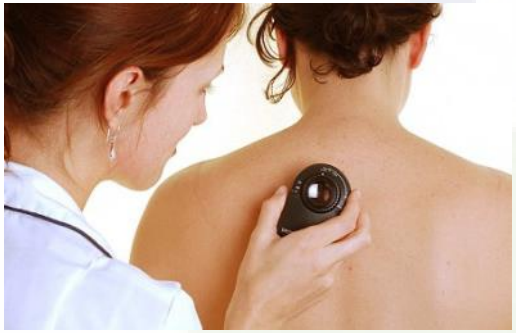
Sources: Literature review, interviews, Laird and Wynberg 2013

Euphorbia Peplus



Euphorbia Peplus





Pharmaceutical

- **The market**
  - Estimated global revenues $ 955,5 (2011) expected to reach $1,2 trillion (2016)
  - Trend: large European and American based companies to do more R&D, with manufacturing in emerging markets, where domestic companies are also on the rise.
- **R&D**
  - Objective: prove activity
  - Companies collaborate on R&D as budgets stall
  - There are many ways to develop new actives. Most large natural R&D programs have closed. -> synthetic chemistry / biotechnology.
  - Natural product programs are found in SME; governmental programs and universities.
- **Sector specificities / trends**
  - Patent cliff – impact on corporate policies and investments
  - Some collection of microorganism and marine organism but overall, limited need to access “fresh” GR from the South. Very tiny quantities of material needed.
  - Domestic biodiversity and companies collections are first choice
  - High degree of science and technology (e.g. genomics) allows
    - faster and deeper screening (especially on microorganisms)
    - possibility to grow them and overcome supply issue
  - Decreasing interest in traditional knowledge due to focus on micro-organism

Sources: Literature review, OECD, Laird & Wynberg, interviews

Huge variations :

- level of science & technology used, investments in R&D (0 - 10 %)
- need to access GR (e.g. continuous, one-off, tiny samples)
- use of TK
- SOP (larger producer / retailer vs. small specialist intermediaries)
- level of internal R&D (from 100% in house to outsource of R&D)…

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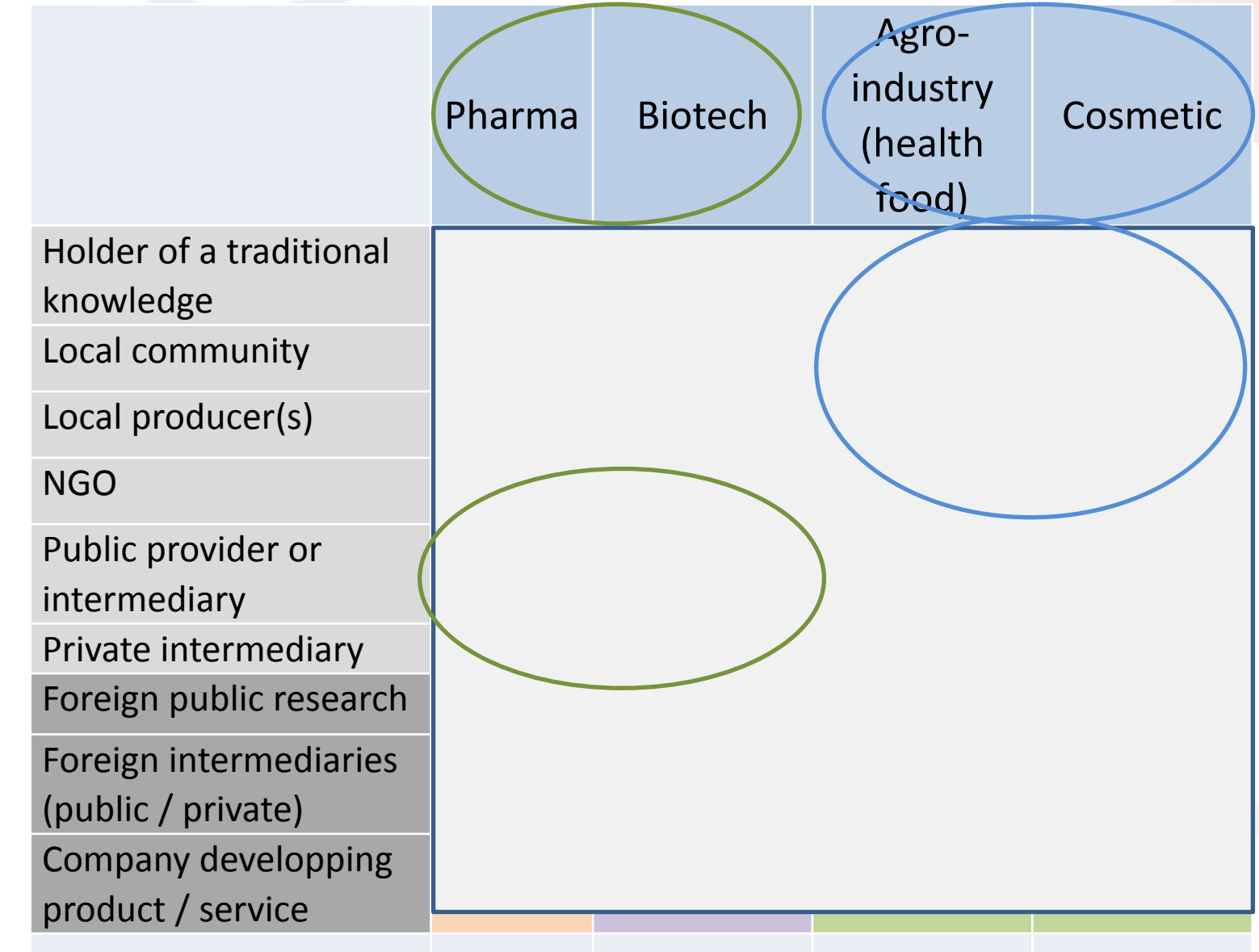
Different actors & organisation across sectors



Possible beneficiaries of BS along the R&D cycle

Holder of a traditional knowledge Local community	• Joint ownership of relevant intellectual property rights • Food and livelihood security benefits • Social recognition
Local producers of raw material	• Contributions to the local economy
NGO	• Strengthen capacity to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources
National intermediary (public and private)	• Participation in product development • Contribution in scientific research and development programmes • Transfer of the genetic resources of knowledge and technology • Access to scientific information and research directed towards priority needs
Public administration	• Institutional capacity-building for the administration and enforcement of access regulations • Institutional and professional relationships that can arise from an ABS and subsequent collaborative activities

« Generic » Model of GR bases R&D / product development

Pre-Acces
- research proposals
-funding

- market analysis,
- pre product analyis

Research & Development

Business Plan
- production
- sales
- compliance
- marketing

Production
(commercialization)

Investments

Publications
Patents
Enterprise secret

MAT X

PIC X

MAT X1

PIC X1

MAT X2

0,5 – 10 years
upfront benefits

1 – 15 years
TT / CB / IP / publications

1 – 3 years
TT / cap dev - *nonetray*

3 – 25 years
TT / cap dev – ***monetary***

Time

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NORWEGIAN MINISTRY OF FOREIGN AFFAIRS
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Thank you

…..more on ABS and the
ABS Capacity Development Initiative

www.abs-initiative.info

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Group discussion, based on case study

- What are the **interesting benefits to harness** from an ABS contract with such a user?
- **How far** to go in negotiating those benefits?

- Some basic steps
  - Identify actors **roles, responsibilities, rights**
  - Understand actors **expectations, interests, constraints**

Some thoughts for BS negotiation

Framework:

- Legal certainty decisive for any investements, in particular the issue of scope:
  - **what's in ? / what's out?** ABS vs. Biotrade

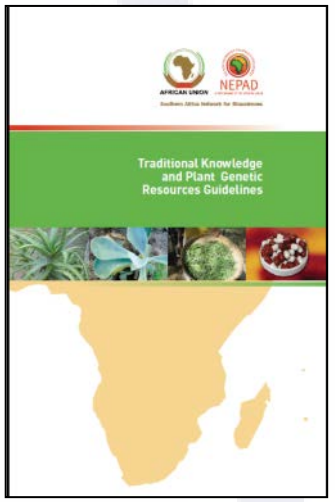
- ABS regulatory frameworks need to reflect R&D realities
  - authorisation process , **adapt timing and content of PIC & MAT**

- Recognition of different context & abilities and capacities to BS:
  - **value of non-monetary benefits**; expectation management

- Transparent and simple procedures
  - incl. clearly **defined responsibilities** and timelines

- Outreach and information on ABS
  - trust-building essential

- A **close connection between the a provider stakeholder and the public administration is a key success factor**



How this can inform ABS regulation at national level?

- Identify the national (champions) actors understand what makes them credible
- Build the picture : overall country R&D strengths and weaknesses to best target benefits
- Recognize user practices, expectations, constraints and existing benefit sharing arrangements
- Consider a range of sectors and specific GR that provide an opportunity for the development of potential markets that may produce more immediate and sustainable returns than ‘high value but low probability areas’ such as approved pharmaceuticals.

A few last thoughts to conclude

- It is the **building of partnerships and trust among stakeholders** that makes successful ABS agreements; not legislation and the threat of penalties

- **Value of national R&D –** it‘s a great asset!

- **Manage expectations** and look into feasible (non-monetary) benefit-sharing. A practical understanding and direct link with national actor is tremendous help.

- Accommodate **different needs** with **different models**. Be **pragmatic and realistic**, avoid red tape and facilitate business by:
  - Simple access procedures
  - Model clauses / business term sheets

MONETARY AND NON- MONETARY BENEFITS

1. **<u>Monetary benefits may include, but not be limited to:</u>**

- **Access fees/fee per sample collected or otherwise acquired;**
- **Up-front payments;**
- **Milestone payments;**
- **Payment of royalties;**
- **Licence fees in case of commercialization;**
- **Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;**
- **Salaries and preferential terms where mutually agreed;**
- **Research funding;**
- **Joint ventures;**
- **Joint ownership of relevant intellectual property rights.**

Non-monetary benefits may include, but not be limited to: (1/2)

- **Sharing of research and development results;**
- **Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the provider country;**
- **Participation in product development;**
- **Collaboration, cooperation and contribution in education and training;**
- **Admittance to ex situ facilities of genetic resources and to databases;**
- **Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity**
- **Strengthening capacities for technology transfer to user developing country Parties and to Parties that are countries with economies in transition and technology development in the country of origin that provides genetic resources. Also to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources;**

Non-monetary benefits may include, but not be limited to: (2/2)

- **Institutional capacity-building;**
- **Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;**
- **Training related to genetic resources with the full participation of providing Parties, and where possible, in such Parties;**
- **Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;**
- **Contributions to the local economy;**
- **Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in provider countries;**
- **Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;**
- **Food and livelihood security benefits;**
- **Social recognition;**
- **Joint ownership of relevant intellectual property rights.**