









Benefit sharing, third party transfer and enforcement



Morten Walløe Tvedt, the Fridtjof Nansen Institute

Training on Mutually Agreed Terms: Contracts for making ABS functional

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implemented by

The two step approach:

- Supposes a trust-situation
- or a long-term interest on the user side
 - Deposit in the providers account
 - A (bank) guarantee with specific incidents that allows you to use it
- Follow-up capacity
- Caution: Australia has such a system, but till now no company has ever come back to re-negotiate. WHY?

Contract law

International law

How to regulate what is transferred?

Fiji

Private law Agreement MAT (PIC)

Accesses something unknown

Genetic resources

Norway

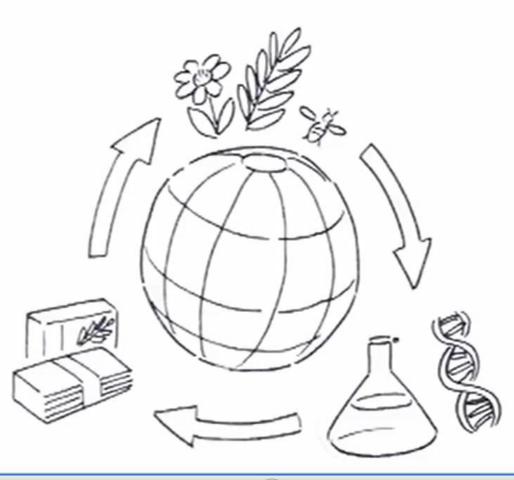
To develop something

not pre-known

- +knowledge
- +technology
- Changing form
- Relationship GRproduct



Time challenge: access-utilisation-benefits







 Relationship GRproduct



Challenges for ABS Contracts:

What is the idea of an ABS Contract?

- Regulate the research and development
 - It is a utmost dynamic object in the contract
 - The raw material is unknown and the product is to be developed
- High degree of uncertainty how to make good rules?
- How to construct mutual trust and collaboration?



Changes on the user side:

- Academics
- Master student and PhD
- Small scale company
- Public breeding companies
- Large commercial enteties
- Multinational companies
- Traders
- Collections



Likely transfers to thirdparties:

Academics

- > A commercialised company
- Master student and PhD
- > The univ./ commercial comp

Small scale company

- ➤ Bought up/ bankrupt
- Public breeding companies ➤ Privatisation/ bought up
- Large commercial enteties ➤ Merger/ bought up/ bankrupt
- Multinational companies
- > Transfer inside the corp struct

Traders

> Any selling on to others

Collections

> Any selling of/ access



Limit to a contract – binds the parties:

How can a contract adhere to these changes:

- End the rights continue the obligations (no ending/ termination clauses)
- Obligation to come back for new negotiations
- Specific regulations of scenarios
 - Collections and academic institutions
- Better to foresee different scenarios than attempt to prevent certain things from happening

From academic to commercial:

- Can be regulated what is the potential scenario?
- Secure a % of the earnings
- Better to allow this to happen



From collection to commercial users:

- Develop an Standard Material Transfer Agreement jointly for access to the material
- Clarify the discretion: Shall the country be involved in deciding on transfer or shall the collection act on behalf of the country
- Secure a % of the earnings which happens in the collection
- Regulate how this will proceed

From collection to commercial users II:

"Trusted collections" in the EU

(19) Collections are major suppliers of genetic resources and traditional knowledge associated with genetic resources used in the Union.

A system of Union trusted collections should be set in place.

It would ensure that collections included in the register of Union trusted collections **effectively apply measures** to only supply samples of genetic resources to third persons with documentation providing evidence of legal acquisition and the establishment of mutually agreed terms, where required. A system of Union trusted collections should substantially lower the risk that illegally acquired genetic resources are used in the Union.

Competent authorities of Member States would verify if a collection meets the requirements for recognition as Union trusted collection. Users that acquire a genetic resource from a collection listed in the Union register should be considered to have exercised due diligence as regards the seeking of all necessary information. This should prove particularly beneficial for academic researchers as well as small and medium sized enterprises.



From collection to commercial users II:

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"Trusted collections" in the EU:

Article 5 Union trusted collections

- 1. The Commission shall establish and maintain a Union register of trusted collections. That register shall be internet-based, easily accessible to users, and shall include the collections of genetic resources identified as meeting the criteria of Union trusted collection.
- 2. Each Member State shall, upon request by a collection under its jurisdiction, consider the inclusion of this collection in the Union register of trusted collections. After verifying that the collection meets the criteria set out in paragraph 3, the Member State shall notify the Commission without delay of that collection's name, contact details, and type. The Commission shall without delay include the information thus received into the Union register of trusted collections.

In order for a collection to be included in the Union register of trusted collections, a collection owner shall demonstrate its capacity to:

- apply standardised procedures for exchanging samples of genetic resources and related information with other collections, and for supplying samples of genetic resources and related information to third persons for their use;
- have samples of genetic resources and related information supplied to third persons for their use only with documentation providing evidence that the resources and the information were accessed in accordance with applicable legal requirements and, where relevant, mutually agreed terms for the fair and equitable sharing of benefits;
- keep records of all samples of genetic resources and related information supplied to third persons for their use;
- establish or use unique identifiers for samples of genetic resources supplied to third persons;

use **appropriate tracking and monitoring** tools for exchanging samples of genetic resources and related information with other collections.



Bought up/ merger:

- How to secure that the obligation follows to the next entity
- How to ensure commitment

In the event of any substantial changes in the management or shareholding of COMPANY, that alters the control structure of COMPANY and includes changes brought by a transfer of business units, merger, demerger or any other kind of corporate restructuring, COMPANY shall ensure that the obligations under this agreement perpetuate and provide written notice to the AA not less than **thirty (30)** days prior to initiating such changes.

Key element of the content of contracts:

- Parties legal persons
- Subject of the contract what is being transferred?
- Purpose
- Benefit sharing linked to specific utilisation or products (including IPR)
- Subsequent third party use
- Changes of intent
- Confidentiality
- Dispute settlement



Contract law

International law

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Accesses something unknown

Norway

To develop something not pre-known

Trigger-points for the sharing 'Utilisation of GR'

ARTICLE 2: definitions

- (c) "Utilization of genetic resources" means to **conduct research and development** on the **genetic and/or biochemical composition** of genetic material, including through the application of <u>biotechnology</u> as defined in Article 2 of the Convention.
- (d) "Biotechnology" as defined in Article 2 of the Convention means **any technological application** that uses biological systems, living organisms, or <u>derivatives thereof</u>, to make or modify products or processes for specific use.
- (e) "Derivative" means a **naturally occurring** *biochemical compound* resulting **from the genetic expression** or **metabolism** of biological or genetic resources, even if it does not contain functional units of heredity.

Task: Is this a good trigger-point in an agreement?



Benefit-sharing virtues:

- Clear and defined trigger-points
- What shall be shared?
- When?
- How to calculate?
- What happens if/ when something goes wrong?

Benefit sharing in a scoping agreement

2.4 Benefit sharing under the ABS Agreement during Actualization Phase shall be based on each party's contribution, fairness and mutual consensus.

Questions:

- Based on each contribution relative contribution.
 - Danger: low value to natural resources, high value to research
- 'mutual consensus' what happens if they do not agree?

Nestle agreement

4.1 Calculation of Benefits and payment

Nestlé will make payment to the San and Khoi of an amount of three percent (3%) of the net sales (as per Nestle accounting standards) of the Products by Nestlé, whether in South Africa or abroad. The payments will be calculated bi-annually (every six months) by Nestlé and paid to the Bioprospecting Trust fund managed by Department of Environment Affairs within two months after the end of each six month period.

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- three percent (3%)
- net sales, after all and every cost Nestle might
- as per Nestle accounting standards [themselves?]
- the Products which products the coffee machine or only this particular cappucino?
- Nestlé [which Nestlé?]
- whether in South Africa or abroad Will Nestle SA sell anything abroad?



Nestle agreement

4.3 **Non-monetary Benefits**

The Parties commit to exploring and implementing non—monetary benefits, which will be discussed during the review session specified in clause 3.2.. These will include employment opportunities, bursaries, commitment to specific community upliftment programmes, and the like.

'Benefits' shall mean all and any payments, or payments in kind, made by Nestlé to the San and Khoi, calculated as stipulated in clause 4 of this Agreement

Agreement

3.4 Benefit Sharing Agreement

This agreement is a benefit sharing agreement as envisaged by the Act, in terms of which the MIDDELMAN, the organisation that intends to pursue first the research and later the commercialization phase of bioprospecting with regard to the plant variety, undertakes to share benefits with the INDIGENOUS GROUPS as stakeholders and knowledge holder. It is specifically acknowledged that the traditional knowledge of the INDIGENOUS GROUPS has contributed towards and provided a lead for the particular discovery currently under research.

Agreement

- 4.3 Payments: MIDDELMAN will make payment to the Bioprospecting Trust fund managed by Department of Environment Affairs to be distributed by it in equal shares to the INDIGENOUS GROUPS, such payment to be-of an amount of between ten and twenty percent (10-20%) of any net benefit which the MIDDELMAN receives in respect of the products, which amount will be paid biannually (every six months). For purposes hereof, "net benefit" shall mean income received by the MIDDELMAN as a result of its commercialisation of SUBJECT MATTER less patent and commercialisation.
- Why from the net benefits that MIDDELMAN are getting?
- The definition of net benefits here makes some uncertainty regarding what is meant – some clarification would be good.

Benefit-sharing calculation principles:

- Relative contribution?
- What if the GR was taken out of the scenario?
- The low value of nature as a problem
- How to calculate? Net or gross?



Building a lab:

- Identify the vision for bio-innovation
- Identify your needs
- Which institutional structure exists?
- What can each bio-prospector contribute with?
- Development aid contribution?

Griffith University and Eskites as 'best practices'

Buthan



Specific Undertakings:

- 5.1 The INDIGENOUS PEOPLE undertake and offer their cooperation and collaboration with COMPANY, if required, regarding their endorsement and marketing assistance regarding all Products as herein defined.
- Remuneration for endorsement or marketing assistance?
- Instead of b.sh?
- Who will determine what is required? Mutually accepted?
- Any legitimate reasons to say no? Procedures?

The link to IPRs - patents:

- Apply for a patent together? Common recognition as inventors
- A patent is an object for property can be transferred
- Prohibit patenting?
- Encourage patenting?
- How to ensure a part
- Relative values?



Draft some clauses for your contract:

- Subject matter that you transfer
- Benefit sharing obligations, when, how much and so on
- Thirdparties



Key element of the content of contracts:

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- Changes of intent
- Confidentiality
- Dispute settlement



Confidenciality:

- About the existence of the contract
- Terms in the contract all the terms?
- About the biological material, research, or product

Exclusivity

- For how long time shall the one user have exclusive right
 - At species level
 - At accession level
 - Increase incentive to invest vs engage with other users?



6. Other conditions (Buthan)

6.1 **USER** shall submit in English a hard and soft copy of its scoping findings in the form of reports, publications, thesis or any other documents to the AA as soon as the scoping is completed or published or expiry of the term of the Agreement whichever is earlier. The AA will have full ownership of the results of the scoping phase if **USER** decides not to enter into an 'actualization phase' of the utilization of Bhutan's genetic resources.

6. Other conditions (Buthan)

6.3 **USER** shall pay such sum of US dollar 5000 (US dollar five thousand only) to the AA as a guarantee deposit returnable on the completion of the scoping phase by **USER** in compliance with the terms of this Agreement. The interest generated from the deposit will be injected into Bhutan ABS Fund for strengthening the sustainable conservation initiatives of biological resources.

Enforcement and compliance:

- Dispute settlement
- Choice of law a two edge sword
- Alternative dispute settlement mechanisms
 - Conciliation, arbitration
- Getting assets of the company under your legislation

The Company shall pay such sum of US dollar XXX (US dollar XXX) to the AA as a guarantee deposit returnable on the completion of the scoping phase by **the Company** in compliance with the terms of this Agreement.

The interest generated from the deposit will be injected into ABS Fund for strengthening the sustainable conservation initiatives of biological resources.



GR Law – regulating Access and Benefit Sharing

International law

Convention on Biological Diversity, Nagoya Protocol and International Treaty on Plant Genetic Resources for Food and Agriculture

Regional level

Botswan.

Create pre-rial and TK

Ownership/
Grating accords

Prior informed consent

rway

Control behavior

Get a fair share of the user to:

obligations w the law

- En into agreement
- -University
- -Private law company
- -Multinational office in No



Mutually agreed terms

NP ARTICLE 15 COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

Observations:

- Oblige users under their jurisdiction; to what?
- 'Have been accessed' time problem
- 'required by the domestic access and b.sh legislation'
- The legislation of providing country essential

NP ARTICLE 15 COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING

- 2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1.
- Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1.

Observations:

- 'address' is weak no binding stuff here
- but to address is bether than not address
- go after the 'cases of alleged violation'
- No single court-case yet CBD in force sice 1993!

ARTICLE 18 COMPLIANCE WITH MUTUALLY AGREED TERMS

- 1. In the implementation of Article 6, paragraph 2 (f) (i) and Article 7, each Party shall **encourage** providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:
- (a) The jurisdiction to which they will subject any dispute resolution processes;
- (b) The applicable law; and/or
- (c) Options for alternative dispute resolution, such as mediation or arbitration.
- 2. Each Party shall **ensure that an opportunity to seek recourse** is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

Observations:

Access to the courts etc of the user country



Implementation in Norway: Nature Diversity Act (i)

§ 60 (genetic material from other countries)

1. "Import of genetic material for exploiting of genetic material to Norway, from a state which requires prior informed consent to use or export, can only happen in compliance with such consent. The one having genetic material in hand is bound by the conditions and limitations for the consent. The State/government can enforce the conditions and limitations, including by court-cases, pro-bono of the other country having established those criteria."

The one having genetic material in hand is bound by the conditions and limitations for the consent.

The <u>State/government can enforce</u> the conditions and limitations, including by court-cases, pro-bono of the other country having established those criteria.



Implementation in Norway: Nature Diversity Act (ii)

§ 60 (genetic material from other countries)

2. When genetic material from another country is used in Norway for research purposes or from a commercial purpose, the material shall be accompanied with information about from which country the genetic material is received or collected (providing country). In the case that the providing country requires prior informed consent, also information about such consent shall follow the material.

Implementation in Norway: Nature Diversity Act (iii)

If the providing country is another than the country of origin for the 3. genetic material, also the country of origin shall be named. 'Country of origin' means the country where the material was collected from its natural habitat. If the country of origin requires prior informed consent for access to genetic material, it shall be informed whether such consent is received. If there are no knowledge about such information, there shall be given information of the lack of information.



Let us take a practical attorney/ lawyer perspective and prepare a benefit-sharing case in Norway:

(First: information is not equal to benefits)

Therefore, needs a system to take use of the information

So, the Nature Diversity act, nor the patent act ensures enforcement

- 1. Enforcement outside the court system:
 - Without any legal vehicle: no obligation in No law; obligation to comply with the ABS-laws of all other countries must be implemented
 - An administrative decision of another country: not per se binding in Norway
 - A written contract is binding. No experience with GR-contracts. Hard to survey breach: costly and difficult. Here the disclosure may have a role.



Taking the case to court:

Access to court by a plaintiff from another country:

- Personal competence: foreign entities, not clear-cut access for the government of other countries (§ 2-1)
- Object of the dispute: "only judicial claims can be brought before a court". Prove a judicial need: easy where there is a contract; harder for administrative decision; and probably not possible if only violation of a law in another country

Paradox: it is easier to take the nice-guy (with a contract) to court than the worse-guy (without any legal vehicle)

Taking the case to court, more obstacles:

Access to court by a plaintiff from another country (cont.):

The plaintiff must have a <u>close connection</u> to the case. This could stop a Norwegian NGO to take a case on behalf of an African country to court in No. The Norwegian Gov could do this (§60.1.3).

BUT I: Lack of a specific organ to look into this

BUT II: Lack of resources to investigate and take these cases to court

BUT III: The political cost of the government to bring a national company before a court – not behalf on itself. Would be a highly political question.



Taking the case to court, even more obstacles:

- Attorney must have a license in Norway
- Substantive questions:
 - Enforceablility/validity: problem for the amd. decision; less problem for the contract; impossible for the non-vehicle.
 - Interpretation and applicability of a foreign country law

Common law/ civil law

Methodology of law

Prejudicial decision about another legal system

- ABS is unknown to each and every judge
- Will involve gene- or biotechnology and GR-issues
- Language problem of the law of another country

After this, then you only need to convince the judge that the citizens of Norway is infringing your right.

That is, that he finds it more likely that you have the right than the infringer.



Taking the case to court, even more obstacles:

- How much should the damage be?
- A fair and equitable part of what?
 - No support for this in the No law
 - No relevant practice; besides tort: thus the economic loss you have had. This is difficult to prove:
 - What is your loss from someone else gaining?
 - What is a fair share?

Conclusion: the Norwegian situation needs guidance (international clarification) from the Protocol on the following issues: - national rules regarding the mandatory-type of ABS; - assistance to the material understanding of when ABS is infringed/ the obligation of BS is triggered; - procedural issue for enforcing ABS outside courts or even by taking ABS to courts.

Changes:

- This Agreement commences on the Effective Date, and endures indefinitely, subject to the review process set out in clause 3.2 below, or until it is terminated by agreement or by a material breach of one of the Parties.
- Signature by the Parties shall bind them towards each other, and signature by the Minister of the Department of Environment will pronounce the agreement as valid and enforceable on third Parties in terms of the Act

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 This Agreement commences on the Effective Date, and endures indefinitely,

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Right ends but obligations are maintained in the situation of breach



Changes:

3.5 Commencement, Duration, and Extent

This agreement commences on the Effective Date, and endures indefinitely, **until either** the discovery results in the registration of a patent or other form of intellectual property rights, which will lead to review as set out below, or until the agreement is terminated by agreement or by a material breach of one of the parties. The date of signature of the Minister below shall provide the date on which the agreement is enforceable in public and in terms of the Act.

- Terminates why?
- Obligations endure and rights end?

8. Term of the Agreement and Termination (Bhutan)

- 8.1 This Agreement, unless terminated as provided herein, shall remain in effect for a period of **five (5) years** from the date of signing of this Agreement by the Parties. However the obligations of USER with respect to the utilization of Bhutan's genetic resources and/or associated information under this Agreement will remain in perpetuity.
- 8.2 The AA may terminate the rights under this Agreement and revoke the Scoping Permit by a written notice if USER defaults in the performance of any obligations under this Agreement and the default has not been remedied within sixty (60) days after the date of notice in writing of such default by AA.



Thank you for your attention

Morten Walløe Tvedt, mwt@fni.no, www.fni.no

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