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Access
and
Benefit
Sharing

ABS Capacity Development
Initiative for Africa

Functionality of the Nagoya ABS Protocol

*with a view to AnGR and a side-look to Anti-
Counterfeiting Trade Agreement (ACTA)*

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**Original paper FNI Report 9/2010 with *Olivier Rukundo, Ilm law*
December 9th 2010, International Technical Expert Workshop**

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Relevant projects:

Animal Genetic Resources:

- ***Process Patent Protection in the Field of Animal Breeding and Farm Animal Genetic Resources (In co-operation with Magnus Finckenhagen, 2008)***
- ***Patenting in the Field of Animal Breeding and Animal Genetic Resources (2008)***
- ***Vageningen FAO project about AnGR: Animal Genetic Resources – Exchange, Conservation and Sustainable Use – Policy and Regulatory Options (January 2007);***

Aquatic and Marine Genetic Resource:

- ***Ongoing projects on Aquatic Genetic Resources (Marine Biobank, Norway and India)***
- ***Access to and Property Rights of Aquaculture Genetic Resources – Norwegian Perspectives (The Journal of World Intellectual Property (2006) Vol. 9, no. 4, pp. 392–412)***

Bioprospecting and the Convention on Biological Diversity:

- ***Functionality of an ABS Protocol before the 2th Montreal Meeting***
- ***'Genetic resources' in the CBD – the wording, the past, the present and the future (2010 with Peter Johan Schei)***
- ***Beyond Access – Options for implementing CBD in User Countries (2007 with Tomme R. Young)***
- ***Elements for Legislation in User Countries to Meet the Fair and Equitable Benefit-Sharing Commitment (The Journal of World Intellectual Property (2006) Vol. 9, no. 2, pp. 189–212)***

International Patent Law and Genetic Resources:

- ***One Worldwide Patent System: what's in it for developing countries? (Third World Quarterly 2010)***
- ***A Path to One Universal Patent (Journal of Environmental Policy and Law 2008)***
- ***How will the new WIPO draft Substantive Patent Law Treaty affect Genetic Resources? (Journal of World Intellectual Property 2005 no 3 May);***



FNI's ABS Project Team



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ABS Publications:

- **Functionality of an ABS Protocol**, Morten Walløe Tvedt and Olivier Rukundo, 9/2010
- **Cameroon Case studies of ABS**, FNI Reports 8 & 10/2010
- **Analytical tools for ABS cases studies**, Kristin Rosendal. FNI Report 7/2010
- **‘Genetic Resources’ in the CBD The Wording, the Past, the Present and the Future**, Peter Johan Schei and Morten Walløe Tvedt, FNI Report 4/2010
- **International Agreements and Processes Affecting an International Regime on Access and Benefit Sharing under the Convention on Biological Diversity – Implications for its Scope and Possibilities of a Sectoral Approach**, Regine Andersen, Morten Walløe Tvedt, Ole Kristian Fauchald, Tone Winge, Kristin Rosendal and Peter Johan Schei, FNI Report 3/ 2010
- **Balancing Building Blocks of a Functional ABS System**, Tomme R. Young and Morten Walløe Tvedt, FNI Report 7/2009



Background for studying functionality:

Original study-object the draft protocol before the second resumed meeting.

- The topic is to analyse the functionality of the draft with respect for the whether it is likely to contribute to the fair and equitable benefit sharing
- Combine existing law with the draft
- Consider consequences, possible and obstacles

This paper: the Nagoya Protocol, with the aim of combining the Protocol with insight in AnGR for the purpose of identifying legal functionality



Legal functionality:

Reflection upon potential for a legal system to contribute to defined objectives

In ABS: Balance between providing rules and user obligations

- 1) creating incentives for users to enter into such contracts, and
- 2) making such contracts enforceable in the jurisdictions where the genetic resources are being used

Trigger point and end point for the obligation for benefit sharing



Topics for the analyses:

- **Relationship of the Nagoya Protocol and other legal instruments for AnGR**
- **Scope-related issues relevant for AnGR**
- **Utilisation of GR as trigger-point for obligations**
- **Pathogens – the unresolved complex**



Other international instruments general I

Art 3 *bis* 4. THIS PROTOCOL IS THE INSTRUMENT FOR THE IMPLEMENTATION OF THE ACCESS AND BENEFIT-SHARING PROVISIONS OF THE CONVENTION. [...]

Observations:

- Takes a general point of departure and setting the general norm
- Includes ABS for AnGR
- It is however an open question to what extent exchange of AnGR will be covered from a practical point of view



Other int. instruments general II

Art 3 *bis* 4. [...] WHERE A SPECIALISED INTERNATIONAL ACCESS AND BENEFIT-SHARING INSTRUMENT **APPLIES** THAT IS CONSISTENT WITH, AND DOES NOT RUN COUNTER TO THE OBJECTIVES OF THE CONVENTION AND THIS PROTOCOL, THIS PROTOCOL DOES NOT APPLY FOR THE PARTY OR PARTIES TO THE **SPECIALISED INSTRUMENT** IN RESPECT OF THE **SPECIFIC** GENETIC RESOURCE COVERED BY AND FOR THE PURPOSE OF THE SPECIALISED INSTRUMENT.

Observations:

- **General exception for specialised international abs instruments: potential for an AnGR instrument**
- **Recognises special sectoral needs**
- **Keeps the door open both for existing and new instruments**
- **Limitation: 'DOES NOT RUN COUNTER'**
- **Flexible: targets only the resources under the other agreement**
- **Creates grey-zones at the point of time of access as does the IT**



Other international instruments - past

Art 3 *bis* 1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any **existing international agreement**, except where the exercise of those rights and obligations would cause a **serious** damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.

Observations:

- **Time perspective backwards: existing rights and obligations in int. law**
- **The question is whether there are situations** ‘where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity’?
- **Somewhat contradictory:**
 - **not affect rights and obligations**
 - **not create hierarchy**



Other international instruments - present

Art 3 *bis* 3. This Protocol shall be implemented in a mutually **supportive manner** with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing **work or practices** under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

Observations:

- **Time perspective forwards:**
 - Implementation mutually supportive
 - Ongoing work and practices
- **What is meant by:** ‘Due regard should be paid to useful and relevant ongoing work or practices’?
- **‘Work and practices’**
- **‘supportive of ... CBD’**



Other international instruments – future

Art 3 *bis* 2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialised access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

Observations:

- **General exception for specialised international ABS instruments: potential for an AnGR instrument**
- **Recognises the special sectoral needs**
- **Keeps the door open for new instruments**
- **(does not mean that there is a need for such instruments)**



Scope related issues to AnGR

ARTICLE 3 SCOPE 1. This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

Observations:

- AnGR are covered
- Scope-related issues were far more complicated in the draft before Nagoya (that were acquired after the entry into force of this Protocol for a Party with Parties providing such resources)



Special considerations

Art 6 In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall: [...]

(c) **Consider the importance** of genetic resources for food and agriculture and their special role for food security.

Observations:

- **Basis in the Nagoya Protocol for implementing national special legislation for AnGR**
- **Potential to develop an AnGR-guideline for national implementation**
- **Issue for discussion: Perhaps a guideline will be more fruitful and functional than a treaty?**



Utilisation – for AnGR

Art 2 (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 biotechnology as defined in Article 2 of the Convention.

Observations:

- **Finally attention given to utilisation as a trigger point for benefit sharing**
- **The ‘access-point of time’ failure of ABS**
- **The interesting issue to explore is how this understanding of utilisation is made operative in the Protocol**
- **Functional for AnGR?**



Utilisation – in context

Art 2 (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.

Observations:

- Wide definition
- Relevant for AnGR as a broad set of products will be covered



Utilisation – in context

ARTICLE 12 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:

- Vague wording, similar obligation as in Art 15.7
- Flexibility of the user countries in their choice of implementing
- Leaves the primary regulatory burden upon provider countries



Utilisation – in context

ARTICLE 12 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.

3. 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:

- More in detail than Art 15.7, as 'non-compliance' is regulated
- Potential to create incentives for users to comply
- Needs implementation for being functional
- Obligation to cooperate in case violation of domestic ABS



A side look at the ACTA

ARTICLE 6: GENERAL OBLIGATIONS WITH RESPECT TO ENFORCEMENT

1. Each Party **shall ensure** that enforcement procedures are available under its law so as to permit **effective action** against any act of infringement of intellectual property rights covered by this Agreement, including **expeditious remedies** to prevent infringements and remedies which constitute a deterrent to further infringements. [...]

Observations:

- Harder language: 'shall ensure' vs 'shall take appropriate, effective and proportionate legislative, administrative or policy measures '



ACTA – overview:

- Injunctions: ‘prompt and effective provisional measures’ (Art. 12.1)
- Damages
- ARTICLE 14: SMALL CONSIGNMENTS AND PERSONAL LUGGAGE [...]

2. A Party may exclude from the application of this Section small quantities of goods of a non-commercial nature contained in travellers’ personal luggage.

Art. 23.1: ‘Each Party shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright or related rights piracy on a commercial scale.’

Comparism: no clear catalogue of remedies in Nag P, no discussion of criminal remedies, even no clear obligation to include an obligation to make mandatory



Special considerations (pathogens)

Art. 6 In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall: [...]

(b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries.

Observations:

- Relevance for AnGR, 'threaten to damage ... animal ... health'
- Call for national and international procedures to determine emergencies
- **Expeditious access and benefit-sharing**



Pathogenes:

Connections to the *patent system*:

- Micro-organisms mandatory subject matter for patents (TRIPS 27)
- Will also be patentable in source countries and providing countries
- No exceptions for emergencies
- Medicines and vaccines for monopoly prices
- No obligation in the patent system of B.Sh



Pathogenes:

Typical ABS-situation

- Obvious connection between access and benefits arising – easily proven
- Huge need for access – also in the future mutations and new life-forms
- Imbalanced with patent law: no corresponding exceptions
- Compulsory licenses is not a relevant tool
- (ICCs argument: detrimental for biological diversity)

Open question how this will be and should be developed further and implemented



In conclusion:

Observations:

- Good flexibility for making AnGR adapted solutions
- Large discretion for countries in the implementation: lessen the legal functionality
- Both animals (AnGR) and threats to animal health are addressed
- Need for making a Nagoya AnGR Guideline – that is a guide for *functional* national implementation of the Nagoya Protocol with the special aims and needs of the Animal sector



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