CASE STUDIES ON IPRS, BIODIVERSITY, CONSENT AND BENEFIT SHARING

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PART ONE: NAGOYA PROTOCOL TO THE CONVENTION ON BIOLOGICAL DIVERSITY -

IMPLEMENTATION INTO THE EUROPEAN UNION
Nagoya Protocol, 2010: Implementing 3rd objective of CBD

... the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.
Nagoya Protocol, 2010: Implementing 3rd objective of CBD

Article 7: Access to Traditional Knowledge Associated with Genetic Resources

Prior informed consent: In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention …

Prior informed consent: In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.
OBJECTIONS WITHIN EU: THE USER’S PERSPECTIVE

- 17 German plant breeder companies have challenged the EU Regulation No 511/2014 which implements the Nagoya Protocol to the CBD.

- Why?

- “The EU Regulation leads to abundant red tape, restricts access to plant genetic resources in particular for plant breeders – meaning: its utilization in breeding- and by far exceeds the principles laid down in the Nagoya Protocol itself”.

EU Regulation No 511/2014


on compliance measures for users

from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union
EU Regulation No 511/2014

- A broad range of users and suppliers in the Union,
- ......academic, university and non-commercial researchers and companies from different sectors of industry
- users of genetic resources and traditional knowledge associated with genetic resources
- for research, development and commercialisation purposes
EU Regulation No 511/2014 - What does the Regulation set down for EU users?

- rules governing compliance with access and benefit-sharing
- Users exercise **due diligence** to ensure
  - resources have been accessed in accordance with applicable laws
  - benefits are fairly and equitably shared upon mutually agreed terms.
Practically speaking, users must **seek, keep and transfer to subsequent users**:

- (a) **internationally-recognised certificate of compliance**, as well as information on the content of the mutually agreed terms relevant for subsequent users; or
- (b) where no internationally-recognised certificate of compliance is available, information and relevant documents on:
  - (i) the **date and place of access** of genetic resources or of traditional knowledge associated with genetic resources;
  - (ii) the **description** of the genetic resources or of traditional knowledge associated with genetic resources utilised;
  - (iii) the **source** from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as **subsequent users** of genetic resources or traditional knowledge associated with genetic resources;
  - (iv) the **presence or absence of rights and obligations relating to access and benefit-sharing** including rights and obligations regarding subsequent applications and commercialisation;
  - (v) **access permits**, where applicable;
  - (vi) mutually agreed terms, including **benefit-sharing arrangements**, where applicable.
Real benefit sharing will only take place as long as plant breeders actually use the resources, i.e. as long as access is not prevented by excessive bureaucratic hurdles.

Plant breeding needs a special approach since utilization of a genetic resource in plant breeding is not comparable to other forms of utilization, as e.g. in the pharmaceutical industry.

The plant breeder can only uncover the value of genetic resources during the long breeding process, and therefore the direct exploitation of genetic resources is not given.

The exact documentation on the utilization of genetic resources as required by the EU Regulation is practically not feasible.
EXAMPLE - PLANT BREEDER USERS’ PERSPECTIVE

EXAMPLE: CIMMYT wheat variety *Veery* is a product of

- 3,170 crossings
- between 51 different parental lines
- originating from 26 different countries.
- Such a plant variety has been developed over many generations and by many different plant breeders.
- “A plant breeder simply does not have the information required for documentation”
CASE 1 LESSONS: CRITIQUE BY USERS ABOUT DOCUMENTATION AND TRACING CONSENT

- The EU Regulation implementing the Nagoya Protocol undermines the basic principle of plant variety protection.

- Plant variety system was designed as an "open source" system.

- A newly bred plant variety, once placed on the market is free for use as a genetic resource for further breeding – without any further restrictions.

- This simple access will become impossible in the future due to comprehensive documentary obligations.

- May lead to a depletion of genetic diversity, and more restricted choice of plant varieties and to a slowdown of the breeding progress.

- Is this true?
PART TWO: PRACTICAL BENEFIT SHARING IN INDIA
Indian Biological Diversity Act 2002

- regulates access to the country’s biological resources and subsequent commercialization of the results of such biological research
- ‘nationalizes’ all biological resources and associated knowledge
- every transaction must have approvals at the National Biological Authority or the State Biodiversity Authority. Transactions include:
  - access to Indian biological resources
  - protecting IPRs arising from research
Indian Biological Diversity Act 2002

- foreign companies must get permissions for the following activities:
  - obtain biological resources from India
  - conduct bio-survey
  - commercialize the results of any research
  - applying for patent protection of the resulting research in India or abroad.
Indian Biological Diversity Act 2002

- The National Biodiversity Agency fixes conditions for:
  - filing patents
  - mandatory equitable benefit-sharing
  - royalty sharing of revenues earned from the commercialization of research

- To date from 2002 to 2014, no guidelines have been issued as to benefit sharing.
Kani Tribe & the “aroxyapacha” plant
Benefit Sharing Examples - Kani Tribe and “arogyapacha” plant

- Kani tribe is located in Kerala, South India
- Knowledge of a particular berry, known locally as “arogyapacha” - had knowledge of certain unique anti-fatigue/anti-stress properties of these berries
- Indian scientists working in TBGRI research centre learnt of these berries and the Kani tribe shared with them the plant which was the source of the berries
- 8 years of research on the plant - scientists managed to isolate twelve active chemical compounds with far ranging properties which included ‘anti-stress and immune-stimulating properties’ and ‘also boosts stamina, relieves fatigue, helps control tumors and activates the body’s natural defenses and cellular immune system’.
Jeevani is a product of the Arya Vaida Pharmacy which is an Indian company (Photo: WIPO Publication 769E)

All this was in 1990s - pre Nagoya Protocol and pre- Indian Biodiversity Act - no documentation, etc concerned.

Next steps?

Commercialisation,

Propertisation, and

Compensation
Sharing Examples
- Kani Tribe and “arogyapacha” plant

- TBGRI (scientists) used these extracts to create a herbalised formulation which could be marketed - Jeevani
- TBGRI filed a patent application for the same
- TBGRI entered into a licensing agreement with an Indian herbal pharmaceutical company for marketing the final product
- For physical genetic resources - Fifty families from Kani Tribe were given approximately US$ 40 each for cultivating the plant - five tons of the leaves per month bought by TBGRI for the production of Jeevani
- For informational / TK resources - incorporated a trust which would give tribe a share of the revenues earned through the sale of the formulation.
The TBGRI - Kani Tribe Benefit Sharing Agreement

- TBGRI entered into a benefit-sharing agreement with the Kani people
- A trust consisting of nine Kani tribal members was formed - through local meeting with Kani tribes
- Trust’s objectives are to promote welfare and development activities for Kani people in Kerala, to prepare a biodiversity register to document the traditional knowledge base of the Kani people, and to promote sustainable use and conservation of biological resources.
- Some Kani in different regions are opposed to the Trust, but aim is to have all adult Kani as Trust members
- Remember previous discussion on ownership, equitable title, and beneficiaries of property rights?
The TBGRI - Kani Benefit Sharing Agreement - *real benefits?*

- In 1999, Kani received first payment of **US$ 12,500** from the benefit sharing agreement.

- Funds from the Trust are earmarked to be used for a variety of projects: e.g. installing a **telephone booth**; creating an **insurance scheme** that would provide coverage for pregnant women.

- In 2006, TBGRI invited Kani tribe to form a Business Management Committee (BMC) which **sets minimum conditions** for the benefit sharing agreement, such as an **increase in license and royalty payments** - control over compensation and payment.
The TBGRI - Kani Benefit Sharing Agreement - *global model?*

- Benefit sharing agreement between TBGRI and the Kani people acclaimed as a model for similar agreements around the world
- In 2002, TBGRI received the **United Nations Equator Prize** for its work in fostering the creation of the agreement
- **United Nations Environment Program** and the **World Trade Organization** have also described the benefit sharing agreement as a **global model** for recognizing the traditional knowledge and IP of indigenous people in accordance with the guidelines of the United Nations Convention on Biological Diversity…..
- Important - International recognition helps TBGRI to have some leverage in getting a better deal for the tribe and overcoming internal political bureaucracy
The TBGRI - Kani Benefit Sharing Agreement - *critiques*?

- Propertisation - should it always be so patent-centric?
- TBGRI has yet to secure IP protection for it outside of India as of 2010
- In US, several companies have been using the *Jeevani* name to sell herbal or energy products.
- For example, Great Earth Inc. marketed an energy drink called “Jeevani Jolt 1000” that included the same ingredients as those in the original Jeevani, though it is unclear how Great Earth acquired arogyapacha.
- Because the companies are purchasing the arogyapacha plant from suppliers other than AVP, the Kani people are not enjoying any benefits of their traditional knowledge.
PART THREE: PRACTICAL BENEFIT SHARING IN NAMIBIA
Namibia’s Eudafano Women’s Cooperative (EWC) and the Marula Tree
Marula and the Namibian women’s innovation knowledge

- Women have long prized marula for its remarkable qualities and have used it in a variety of ways for generations for thousands of years:
  - a brew made from the bark has been traditionally administered as a cleansing ritual prior to marriage
  - use marula wood to make kitchen utensils for thousands of years

- Most important part of the marula tree is the marula oil which is produced by women in rural Namibian communities using traditional techniques - sold within communities.

- Marula oil used as
  - meat preserve
  - skin moisturizer
  - ingredient for popular foods such as jam and alcoholic beverages (local marula beer)
Marula: From local use to Eudafano Women’s Cooperative

- **BUT** only large scale, commercial use was by South African Distell Group - to make Amarula Cream, alcoholic drink popular in S. Africa

- Namibian use was *ad hoc, informal, local, seasonal and mainly women supplementing their income*

- Changed in 1999 - formation of Namibian NGO which wanted to produce marula oil of a higher quality and in larger volumes so that it could be sold as an export product for the cosmetic industry

- **With help of Namibian government**, women from rural villages joined and formed Eudafano Women’s Cooperative (EWC) to market marula products for local and export markets

- 2008 membership = over 5,000 women in 22 groups producing marula oil from wild trees.

- 2010 = EWC is the second largest producer of marula products in southern Africa
Marula - From local use to commercialisation

- Here, there was no natural link from propertisation to licensing to benefits
- Easier to capture market with direct partnership agreement
- Body Shop / African Botanics
Marula - From local use to partnership agreements and international reputation

- 2000 - EWC became the exclusive provider of marula oil to The Body Shop
- Over 140 of Body Shop’s products containing Namibian marula produced by the EWC - lipsticks, foundations, blush and eye shadow
- International fair trade certification and international reputation - Example from UK Daily Mail paper in 2013
The anti-ageing secret from Africa: Marula oil, packed with all-natural vitamin C and antioxidants, has beauty world buzzing

- Been used by the Ovambo women in northern Namibia for generations
- Famed for its skin smoothing and moisturising properties
- High levels of anti-oxidants help maintain youthful looking skin

By BIANCA LONDON FOR MAILONLINE

From vampire facelifts to snake venom serum, it seems there’s a new miracle ingredient launched every week.

The latest buzzword in the beauty world is an all-natural skin smoothing secret that African women have kept secret for years - until now.

Marula oil has traditionally been used by the Ovambo women in northern Namibia for generations because of its skin smoothing and moisturising properties - and now it’s hitting the mainstream.
Marula: from local innovation to PhytoTrade Africa to benefit sharing

- EWC becomes early member of PhytoTrade Africa - non-profit trade association of the natural products industry in southern Africa with private sector, development agencies, individuals and other parties.

- Through its membership in PhytoTrade, EWC receives fair prices for the marula products it produces for international markets.

- Membership in PhytoTrade Africa ensures **fair compensation and payment** - local producers receive compensation for the use of their traditional knowledge.

- The partnership is rooted in local or traditional knowledge and innovation in rural communities - also helps to ensure that such knowledge continues to be passed on to younger generations.
Marula - Partnership and Joint Ownership

✦ Another joint partnership between the rural Namibian marula producers - EWC and PhytoTrade – and a specialized international R&D company - Aldivia S.A. which specializes in producing natural and organic ingredients for cosmetic manufacturers.

✦ With further R&D, the active chemical ingredient in the Marula Oil - Maruline - was isolated - a 100% natural marula oil with enhanced antioxidant properties.

Marula to *Maruline* patents: What benefits to rural Namibian female community?

- Created viable international market for marula and *Maruline*
- Local value is added, traditional culture is preserved, food security is enhanced; linking rural producers with international companies
- Demand in 2008 shot up to **twenty tons of oil worth over US $20 million**
- Retail prices for cosmetics with marula sell for **four times** more than products without it
- Marula producers were receiving over **US $60,000 annually** and by 2010 were receiving US $2.35 per kilogram of marula.