INTELLECTUAL PROPERTY RIGHTS, BIO-PROSPECTING, BIO-DIVERSITY AND TK

Professor Uma Suthersanen
Centre for Commercial Law Studies
Queen Mary, University of London
PART ONE: BIO-PROSPECTING
WHY BIOPROSPECTING IS A GLOBAL ISSUE?

- Plants are a chemical arsenal which contribute to drug and medicine production.
- Traditional knowledge is one means of obtaining trails as to which plants to harvest, use or research on.
- The hit rate of finding active pharmaceutical ingredient increases with TK input.
WHAT IS BIOPROSPECTING?

- Biodiversity prospecting / bioprospecting

- The search for valuable wild genetic resources found in wild plants, animals and micro-organisms.

- Main output - gather enough resources so as to enable the successful development of new products including food, drugs, crops, industrial products and consumer products.
WHAT IS BIOPROSPECTING?

EXAMPLE OF DRUGS/MEDICINES DISCOVERED FROM NATURAL PRODUCTS:

- Aspirin (derived from Willow Bark used as a painkiller)
- Re-serpentine (from the Indian Snake Root for hypertension)
- D-tubercurarine (from curare arrow poisons used as a muscle relaxant in surgery)
- Artemisinin (derived from traditional use of plants - Artemisia Annua or the Quinhaosu used as an anti-malarial agent)
- Vincistrine and Vinblastine (derived from traditional use of Rosy Periwinkle, now anti-cancer drugs)
Since the 15th century, European colonial expansion and development has led to the exploitation, migration and deployment of resources from Africa, South America and Asia to the rest of the world.

Examples: vast plant and animal exchange from Peru/Columbia and Europe - led to introduction of new foods and products in Europe, including potatoes and maize.

Such movements of biological resources had to be accompanied by cultural and local knowledge in relation to propagation, cultivation, or consumption.

Or else unexpected consequences - in the case of the maize, when cultivated and consumed globally amongst non-native Americans, it led to vitamin-deficiency disease pellagra - reason was specifically due to the lack of the cultural and local knowledge of the Mesoamerican alkaline processing procedure - in other words, traditional knowledge.
Bioprospecting is a win-win situation.............

- The “bioprospecting” perspective - through bio-prospecting, all three objectives of the CBD – sustainable use, conservation of biological resources, and benefit-sharing – can be met.

- In the presence of well-designed laws and contracts, bioprospecting presents a “win-win” situation
  - where benefits generated can be used for a range of purposes
  - improvement to livelihoods of indigenous and local communities,
  - biodiversity conservation programmes
  - bio-technological capacity building

Padmashree Gehl Sampath, Regulating bioprospecting: Institutions for drug research, access, and benefit-sharing, p.5.
Valuation of resources

- we now classify biological resources as economic goods
- biological resources must be ascribed a market value
- How? Propertisation of such resources
  - organic resources
  - informational resources
- all bio-prospecting activities will have to reflect the true market price by means of agreements, licenses, permits or taxes
- Hence the link to the Nagoya Protocol
Valuing bioprospecting activities

- the global market for biological resources is concentrated geographically, both in terms of production and consumption.

- More than 50% of the world’s bio-diversity resources are held in a dozen of the lesser developed states of the world.

- developing countries produce most of the genetic resources for new products
Valuing bioprospecting activities

- consumption of such resources lies outside their borders, together with any accompanying profits.

- primary gainers are industries located in the developed countries which are estimated to see anything between a US$ 20 billion to US$ 100 billion return on such goods by the year 2000.


<table>
<thead>
<tr>
<th>Year</th>
<th>Total number of FDA-approved Drugs</th>
<th>Number (%) of natural products</th>
<th>Number (%) of natural product derivatives</th>
<th>Number (%) of biologics of nonhuman origins</th>
<th>Number (%) of biologics of human origin</th>
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<tr>
<td>2012</td>
<td>37</td>
<td>3 (8.1)</td>
<td>6 (16.2)</td>
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<td>28</td>
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<td>9 (24.3)</td>
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<td>0 (0.0)</td>
<td>4 (10.8)</td>
<td>0 (0.0)</td>
<td>3 (8.1)</td>
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</tbody>
</table>
Is bioprospecting a win-win situation?

- Two thirds of all existing species are found in the developing countries

- It is private corporations in industrial nations (EU, US and Japan) which own bio-technical tools to exploit these resources; industry expected to grow to $40/$50 billion by the end of 2000

- Profits will go to those holding patents and to the governments that make those patents possible……chemical industries, biotech companies and governments in the industrialised world **defend the intellectual property law which compensates private enterprises for the risks and expenses involved in research and development.**

- But it is risky.....with some leads going nowhere
Is bioprospecting a win-win situation?

- Resource rich countries argue the “polluter pays” principle.
- Developed countries cannot continue their present environmentally unsound patterns of living, with wasteful use of resources, unsound consumption patterns and destructive modes of production.
- Responsibilities must be allocated in light of those responsible for excessive consumption and production.
- Use of traditional knowledge must be compensated for.
ISSUES OF CONCERN: RESOURCE-RICH COUNTRIES

The unauthorised collection for commercial ends of physical organic resources - biological and genetic resources

The unauthorised collection for commercial ends of informational resources - including traditional knowledge

The misappropriation and commercialisation of genetic resources and/or traditional knowledge through the patent system or other intellectual property systems

Attribution and informed consent is missing at all stages
ISSUES OF CONCERN: USER COUNTRIES

- Unimpeded access to genetic and biological resources is important
- Unreasonable diligent requirements
- Unreasonable documentation and informed consent requirements
- Difficult to develop fair and equitable benefit sharing expectations between users and providers
- Need a reward for R&D and clinical or plant/varieties line testing
PART TWO:
BIO-DIVERSITY AND INNOVATION
CONVENTION ON BIOLOGICAL DIVERSITY, 1992

- Parties include Burkina Faso, Cote D’Ivoire and Senegal; EU, US and Japan
- Convention to protect the planet’s biological diversity which is recognised as a global asset of tremendous value to present and future generations
- Threat to species and ecosystems to be halted
CONVENTION ON BIOLOGICAL DIVERSITY, 1992

- This is a legal-economic instrument
- Primary aim = preservation of the earth’s genetic pool and diverse species by providing guidelines for the sustainable use of natural resources
- Three economic premises =
  - (1) economic and social development and poverty eradication are the first and overriding priorities of developing countries.
  - (2) nations have sovereignty over their genetic resources
  - (3) “fair and equitable sharing” principle
CONVENTION ON BIOLOGICAL DIVERSITY, 1992

“Fair and equitable sharing”:  
- "the need to share costs and benefits between developed and developing countries"
- "ways and means to support innovation by local people”.
- a basis to negotiate issues of access and benefit sharing (ABS) related to genetic resources.
ARTICLE 1 - OBJECTIVES INCLUDE

- the fair and equitable sharing of the benefits arising out of the utilization of genetic resources
- appropriate access to genetic resources
- appropriate transfer of relevant technologies
- taking into account all rights over those resources and to technologies
- by appropriate funding.
CONVENTION ON BIOLOGICAL DIVERSITY, 1992

- ARTICLE 3 - OBJECTIVES INCLUDE

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.
ARTICLE 8(j) - Important IPR provision. There are three parts to Article 8(j):

(i) respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles

(ii) promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices

(iii) encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices
Article 15 recognizes the sovereign rights of States over their natural resources, and lays down the requirements that any access should be based on mutually acceptable terms and subject to prior informed consent (PIC) of the party providing the access.

Article 16 recognizes the need for access to and transfer of technologies among Contracting Parties as essential elements to attain the objectives of the CBD.
The philosophical underpinning of the CBD is to balance:

- the right of countries that are resource providers
- AND
- the right of the users
- so that the former too have a share and say in the benefits

It is legally binding but difficult to enforce.
... 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.
Nagoya Protocol, 2010: Implementing objective of CBD

Article 12: Traditional Knowledge Associated with Genetic Resources

In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities’ customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.
Nagoya Protocol, 2010: Implementing 3rd objective of CBD

Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:

(a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;

(b) Minimum requirements for mutually agreed terms to secure the **fair and equitable sharing of benefits** arising from the utilization of traditional knowledge associated with genetic resources; and

(c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.
Nagoya Protocol, 2010: Implementing 3rd objective of CBD

Article 10: Global Multilateral Benefit-sharing Mechanism

Parties shall consider the need for and modalities of a global multilateral benefit sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. ..
Queries

- Can any of these work?
- What about widespread genetic resources and TK? What if some groups wish to commercialise, and others do not not?
- What if it’s already published/in the public domain?
- What is fair in the case of traditional-modern hybrid products?
- Will industry leave its IP business model and make room for benefit-sharing?
- Or does the problem lie in the difficulty of finding commercial value in traditional knowledge?
- Should we just recognise customary law/local property regimes?
PART THREE: IPRs, CONTROL OF BIO-PROSPECTING ACTIVITIES AND TRADITIONAL KNOWLEDGE
IPRs in Bioprospecting and Biodiversity

- Why are intellectual property rights controversial?
- IPRs the basis by which revenue is harnessed through licensing and other fees
- IPRs widens the existing gap between the developing and developed countries
- IPRs make it difficult to place environmental costs and responsibilities on developed countries/private industries
Traditional knowledge – what it is, where it comes from

- Indigenous peoples and traditional communities producing TK and traditional cultural expressions

- New or old? Useful or useless? True or false?
- Scientific – in theory and explanation?
- Freely available or regulated and controlled?

- Questions to which answers differ depending on country and group
“What is ‘traditional’ about traditional knowledge is not its antiquity, but the way it is acquired and used. In other words, the social process of learning and sharing knowledge, which is unique to each indigenous culture, lies at the very heart of its ‘traditionality.’ Much of this knowledge is actually quite new, but it has a social meaning, and legal character, entirely unlike the knowledge indigenous peoples acquire from settlers and industrialized societies”

Russel Barsh
Traditional knowledge – what it is, where it comes from

“Indigenous peoples possess their own locally-specific systems of jurisprudence with respect to the classification of different types of knowledge, proper procedures for acquiring and sharing knowledge, and the nature of the rights and responsibilities which attach to possessing knowledge.”

Russel Barsh
The nature of traditional medicines

- Typically processed or unprocessed single or mixed natural products of plant, animal or mineral origin. Whole plants may be used, or plant or animal parts or their products.

- Not single chemicals obtained through industrial processes. Notion of ‘active principle’, that is, compound having therapeutic effect, was, and remains, alien to traditional healers whose treatments are inherently ‘impure’ allowing for possibility of synergisms between various ingredients.

- Usage justified on basis of theories of health, sickness, well-being and efficacy, and cultural and spiritual values, which most mainstream practitioners reject.

- But “tradition” and “modern” have never operated in separate worlds…
The nature of traditional medicines

“… herbal medicine and pharmaceutical chemistry have mutually supportive, simultaneous histories up to the present.”

Biomedicine and African traditional healing “were, in fact, actually adapted from one another.”

AD Osseo-Asare, A.D. (2014) Bitter Roots: The Search for Healing Plants in Africa
Nicosan Case Study
United States Patent

Wambebe et al.

[54] PIPER GUINEENSE, PTEROCARPS OSUM, EUGENIA CARYOPHYLLATA, AND SORGHUM BICOLOR EXTRACTS FOR TREATING SICKLE CELL DISEASE


[21] Appl. No.: 786,313
[22] Filed: Jan. 21, 1997

Foreign Application Priority Data

[51] Int. Cl.6 ............................................... A61K 35/78
[52] U.S. Cl. ......................... 424/195.1; 514/814; 514/815
[58] Field of Search ......................... 424/195.1; 514/814, 514/815

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Primary Examiner—David M. Naff
Assistant Examiner—Janet M. Kerr
Attorney, Agent, or Firm—Shook. Hardy & Bacon L.L.P.

ABSTRACT
A phytochemical composition for treating sickle cell disease is provided. The composition is a cold water extraction product of a mixture containing Piper guineenses seeds, Pterocarpus osum stem, Eugenia caryophyllatum fruit, Sorghum bicolor leaves and potash. Also described are mixtures of phytomaterials used for preparing the extraction product, methods for making the extraction product, and methods for using the extraction product.

13 Claims, No Drawings
LESSONS FROM NICOSAN
CASE STUDY

Would the Nagoya Protocol have helped in this situation?

Nicosan has orphan drug investigational status in US and Europe for sickle cell anaemia

‘A mix of plants that came from native healer information and thus can be classified as a “true ethnobotanical preparation”’ [Newman & Cragg, 2007]

Nigerian traditional healer, the Rev. P.R. Ogunyale is named as a co-inventor on the more than 40 patents on Nicosan granted worldwide

Memorandum of understanding agreed between Ogunyale and the medical research institute which developed the drug

However, likely that by time Nicosan has been approved for sale in US and Europe, patents will have expired

Unclear whether the ingredients are endemic to Nigeria and available only in that country. Implications for benefit sharing?
Important lesson

A property right is acquired

Why is property relationship better than a contractual relationship?

Enforceable against the whole world as opposed to a contract which is only enforceable against the parties which sign contract

Property rights can be licensed – income can be gained

Certain property rights are recognised and enforceable globally (eg IPRs)
Lessons from Hoodia case study
Lessons from Hoodia case study

- Would the Nagoya Protocol have helped in this case?
- The San people live in Botswana, Namibia, South Africa, Angola, Zimbabwe and Zambia
- They are generally represented as the knowledge holders and therefore the owners
- Yet:
  - Hoodia grows only in some areas and is not used by all San communities in the region – previous research found that “San living in the Kalahari Desert in Namibia, South Africa, and Botswana did not appear to consume hoodia, suggesting that knowledge of hoodia was sustained among multiethnic communities in the less arid Great Karoo where it thrived.” [Osseo-Asare]
- What does this imply for fairness?
Lessons from Hoodia case study

- Late 1990s: patents filed on active compounds of Hoodia. Pfizer and Unilever, and small British start-up Phytopharm, became involved in efforts to develop Hoodia-based pharmaceuticals, natural health products, food supplements. Phytopharm paid CSIR $500,000. Unilever invested £20 m.

- Despite this, and after many years of scientific investigation and deal-making, no proven pharmaceutical value. Now highly unlikely that Hoodia will be long hoped-for first African blockbuster drug.

- There may be sufficient benefits to help improve the lives of some San people (payments made into a trust, with milestone payments promised), but doubtful will ever be substantial.
Lessons from Hoodia case study

Hoodia shows that implementing formal benefit sharing arrangements concerning trans-boundary resources and knowledge can be done.

It helped that the patents were all held by one entity, the South African government’s Council for Scientific and Industrial Research (CSIR).

Those seeking to use the active ingredients of the plant for commercial ends had no choice but to approach CSIR first. This was an advantage.
IPRs – PROPERTY OWNERSHIP, TITLES, SHARING, EQUITABLE

- Important to ask – who will own the property right?
- Physical genetic resources owned by sovereign country
- Informational resources like traditional knowledge owned by tribe/community?
- Products derived from natural resources using TK owned by?
- Under IP law in common law countries, for example, sometimes a title is split – legal title, and equitable title, in cases where one party puts resources and monies into project, but the originator of the work is an individual who is entitled to some control and benefits.
- So the question of ABS contracts and sharing MUST start from an earlier position of WHO WILL OWN THE END PRODUCT? What types of laws do you need to make sure all stakeholders have some proprietary interest or benefit?
THE END