Equity and Motivation:

Practical Building Blocks for a Fair and Functional ABS Regime

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Introduction/Caveat

- A Large Issue of Many Sides
- Insufficient analysis for 1st 10-15 years
- Very Different Perceptions of Each Group
- Systemic Malfunction
- Miscommunication
- Misunderstandings Enhance Obstacles
- System failure ⇨ internet and press

Basis (Foundation) vs. Function

- Regimes and Systems
  - are ***founded*** on commitments, mandates & policies
  - are ***functional*** through other factors
    - motivation and incentive
    - operational integration
    - practicality
- Similar for individual actions within the regime

  (*the contract* is different from the reason *why it works)*

The ABS Quest: A Functional Regime that Promotes Objectives

A *Functional Regime* under CBD Article 15 is expected to –

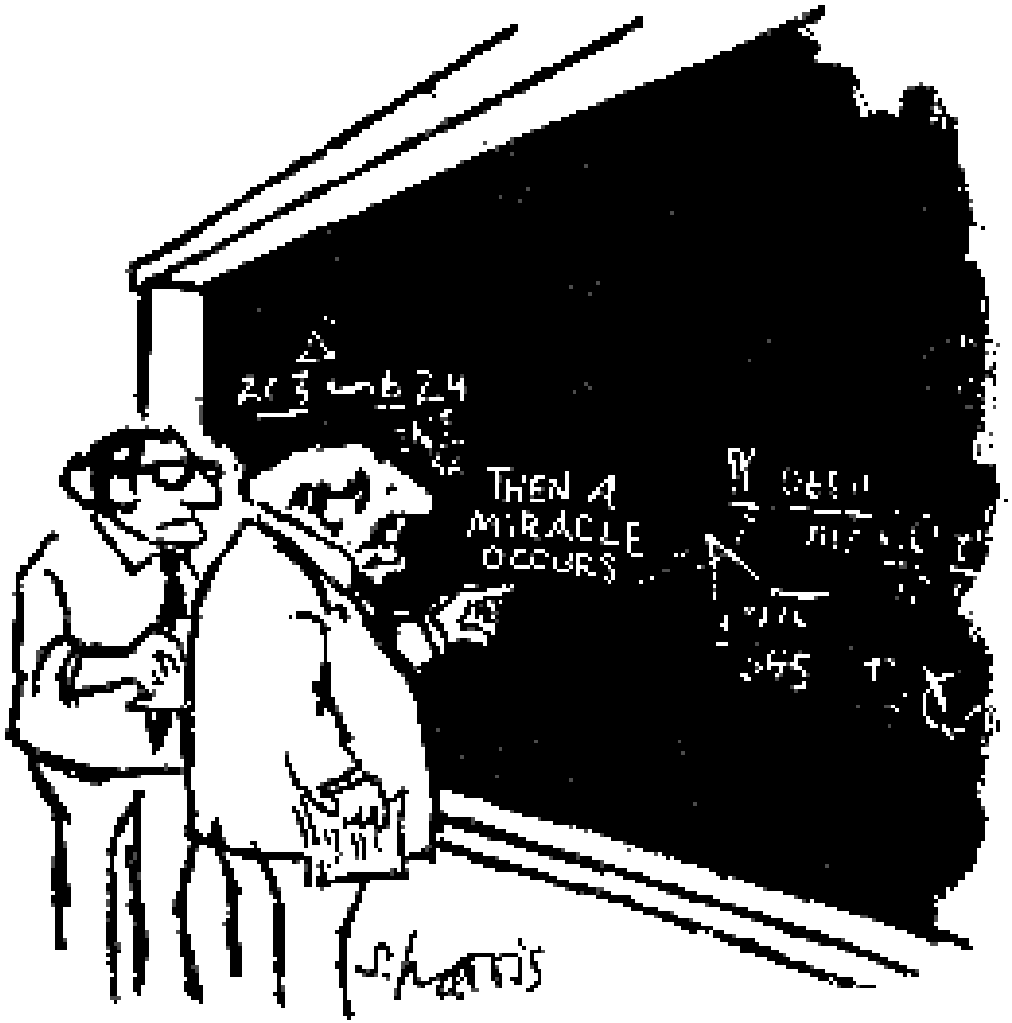
1. Integrate *benefit-sharing* with *equity*:

   Benefit sharing = payments to countries based on the utilization of genetic resources

   Equity =promotion of wellbeing, rights and interests of developing countries ("source" of the resource)

2. Promote the other "pillars" of CBD:
   - Conservation
   - Sustainable use

3. The question is "How?"



"I think you should be more explicit here in step two."

Policy Negotiations vs. Regime Development

INTERNATIONAL NEGOTIATIONS

1. Policy negotiations
2. National "Ratification"
3. Usual results:
   - *Commitment* (agreeing to XXX)
   - *Mandate* (requiring XXX)
   - *Non-mandatory provisions*
   - *Agreed interpretations* and
   - Agree to *shared objectives*

REGIME DEVELOPMENT

1. Legislation and Practice
2. International oversight
   - Promoting agreed goal?
   - Compliance?
   - System functions equitably?
3. Eventually –formal instrument?
   - Necessary?
   - Worth the cost?
   - Examples

Policy Negotiations vs. Regime Development

ABS – NEGOTIATIONS

- Article 15 is policy

  Governments ***committing***…

  …to set national-law ***mandates***.

- A ***commitment*** is not ***a mandate***

ABS – REGIME DEVELOPMENT

- Virtually none up to now:
  - CBD/Art 15 is not a regime
    - amalgamation of national law
    - Did not happen [why not?]
  - IUPGRFA ⇨ ITPGRFA
  - Bonn Guidelines
  - Still no REGIME
- What is missing?

International Negotiations and Regimes

- 1992-2001 – Period of Missed Opportunity
- 2001-2006 – Growing feeling of Need to Act – “Ascendancy of the Outraged”
- 2007 – A fork in the Road, options:
  - Develop another unworkable system via “international environmental negotiation”
  - Serious attempt to create a functional commercial tool (salvage lost opportunity)

The Problem Up to Now

To Diplomats, Environmental Policy Specialists, Scientists and Administrators:

"ABS is simple. Two steps:

- Step 1: Require all users and access providers to participate in ABS by contract
- Step 2: Enforce by contract law"

3 Flaws in “Their View”

The Diplomat/Policy View ***DOES NOT REFLECT REALITY*** in at least 3 ways:

1. Contracts
2. Contract law and non-compliance
3. System operation and integration

1.Contracts alone cannot create ABS

PRIMARY RULE: Contracts must be ***unambiguous***

- ABS Ambiguity cannot be resolved by contract –
  - ABS is transboundary
  - ABS creates a new kind of property
  - Users exert pressure for simple, short agreements
  - Contract negotiations occur before results are known
- These problems cannot be solved by contracts.
- Unless ambiguity is resolved –
  - …Parties, courts etc., cannot enforce/implement
  - …NGOs, etc. can claim violation in all cases

2. Contract Law Cannot Enforce ABS

- Ambiguities could have been resolved in national law, if user and source countries had acted
  - Primary user countries did not require their users to share benefits with other source countries (a few discuss the sharing with the user country for use of GR from within the user country)
  - Source country alone cannot solve these problems as to users in other countries
- PLUS: Additional law is needed
  - to define parties right and ***protect weaker parties***
  - to identify and prevent ***improper business practices***
  - for ***transparency***
  - for contract system to address ***new commodities***

3. ABS Ignores Pre-existing Situation

Prior to 1992 –

- "Genetic resource" - not recognised as property
- Use of genetic resources - mostly* uncontrolled
- Practice - direct purchase of specimens "by the pound"
- GR Use – large profits from developing countries species:
  - "Deep Vent"

    first hyperthermophile DNA polymerase, (source: a *Pyrococcus* species from a hydrothermal vent in Mexican waters) **–[see slide 30]**
  - Vincristine/vinblastine

    (source: Rosy Periwinkle (reportedly) from Madagascar)
- Lots of species collection for the future, examples:
  - Kenyan Thermophyles
  - Ethiopian Endod berry (African soapberry)

How ABS Affects the System (1)

- Commercial Operations Require Legal Certainty
  - Key issue: Right to “utilise genetic resources”
    - “Right-to-utilise” is yes-or-no – no in-between
    - Requires clarity – answers to key questions:
      - What is the right?
      - When is it unchallengeable?
- Processes protecting public/sovereign resources
  - Rights of the citizens are pre-eminent
  - Processes ensure fair and open participation
  - Rules must be clear about what public may do

How ABS Affects the System (2)

- Claims and Challenges
  - Against known commercial users of natural products
  - Many different (legitimate) interpretations of key terms
  - No legal support for any effective remedy or forum
  - Indirectly encourages use of public media
  - Enables unfounded claims
  - Creates platforms for miscommunication
  - Limited incentive to resolve claims

How ABS Affects the System (3) - deleted

NOTE: This slide formerly contained an indicative table suggesting that user companies that comply with national ABS regulations and other formalities reap a competitive disadvantage, as compared with companies do not comply.

The table was “indicative” only (not based on statistics) because I have not found any source of credible statistics about the costs of compliance with ABS formalities in developing countries (nor funding to develop my own).

One participant objected saying that compliance with ABS requirements in developing countries is NOT always more costly than non-compliance.

This comment came from a representative of the European pharmaceutical industry – the very group whose former statements have always been that the “governmentally created transaction costs of ABS are too high.”

This suggests that governmental compliance with ABS formalities is not an added cost for users, however I do not understand why, nor why, if ABS compliance is not more costly and time-consuming, companies oppose it.

Clearly, I need to undertake further research on this issue, and have deleted the table, and the conclusion that ABS is a competitive disadvantage and disincentive.

- TRY

Integration of ABS into Use of Genetic Resources (1)

- ABS is a *Commercially oriented* System
  - Motivations are Clear
  - Lots of experience in other contexts
  - How to encourage (not penalise) compliance?
- ABS's Objectives are based on *Equity*
  - The system cannot rely on unselfishness
  - Companies do not have a goal of promoting equity
  - Commercial laws and controls can be tools of equity

Integration of ABS into Use of Genetic Resources (2)

- What Motivates a Company* to comply with ABS regulations, formalities and sharing?
  - Desire to be compliant with law
  - Public opinion and reputation?
  - Awareness of legal consequences?
  - Possibility of future relationship?

Integration of ABS into Use of Genetic Resources (3)

- What Motivates Noncompliance?
  - "Legitimate" interpretations (compliance not required)
  - **[**Possible competitive disadvantage of compliance **– see slide 16]**
  - External Evidence = difficult (& expensive)/impossible
  - No compulsion or incentive in user-country law requiring user to engage in benefit-sharing with the source country.

Research and other Actions

- “Utilisation” or “middleman”?
- “Pure Research” and the Tricolour Frog
  - Facts **[See slide 31]**
  - Media focus: Suit against the pharmaceutical company
  - Problem: The impact of the “pure researcher” on Ecuador’s rights
  - Classic example of the IPR errors of ABS “experts”
- Realistic approach

Traditional Knowledge

- Rights of Traditional and Indigenous
  - Defined in national lLaw
  - Social legislation
  - Mix of genetic resource and other
- ABS
  - Agreed system of commercial rules
  - Requires uniformity across all stakeholders
  - Exceptions/protections: adopted in national social law not commercial system

IPRs and Certificates

IPRs

- Proposals demonstrate a misunderstanding
  - Not applicable
  - Not a template
  - System does not protect “little guys”

Certificates

- Useful tools for system completion
  - Not systems
  - Cannot be designed before system

Functional System Components

- **Legal Mandate**: Clear requirements
- **Stakeholder interest**: Known motivations underlying current actions
- **Economic Analysis**: Determination of the impact (cost) of alternatives
- **Enforcement/Imperative**:
- **Incentive/Motivation**:

Why comply (in light of cost)?

The Missed Opportunities

- Current source country ABS laws (only 18):
  - Cannot enforce ABS requirement
    - Find non-ABS users
    - Get redress
    - Confirm milestones and other compliance with ABS Agreements
    - Enforce agreement
  - Have not defined or clarified the concept

- User countries law could have defined the system
  - Determine which actions are actionable
  - Set up, delimit and justify an objective system
  - Prove commitment by enforcement/cooperation

The Problem Now

- Decreasing Options
  - Atmosphere of Distrust
  - Desire for “Ironclad Commitments”
- Diplomatic / Political Negotiations
  - National objectives and negotiators
  - No history of considering realistic possibilities
  - No legal (analysis) basis in for national positions
  - No effective systems in national law as models
  - Negotiations argue every word
- No Option for “System Development”
  - System must be

    Integrated - Rational - Consistent
  - Expert Development Process is needed

Thoughts about Solutions (1)

- Legal: ABS concept must be clarified
  - "*Genetic Resources*" / "*Utilisation of Genetic Resources*"
  - Design by *Experts* rather than *International Negotiators*
  - Clarify: ***What is Granted/Given by an ABS permit?***
- Policy: Mutual Recognition
  - ABS compliance will be an added cost
  - User needs a (non-monetary) benefit to balance cost
  - Benefit must come from both user and source countries

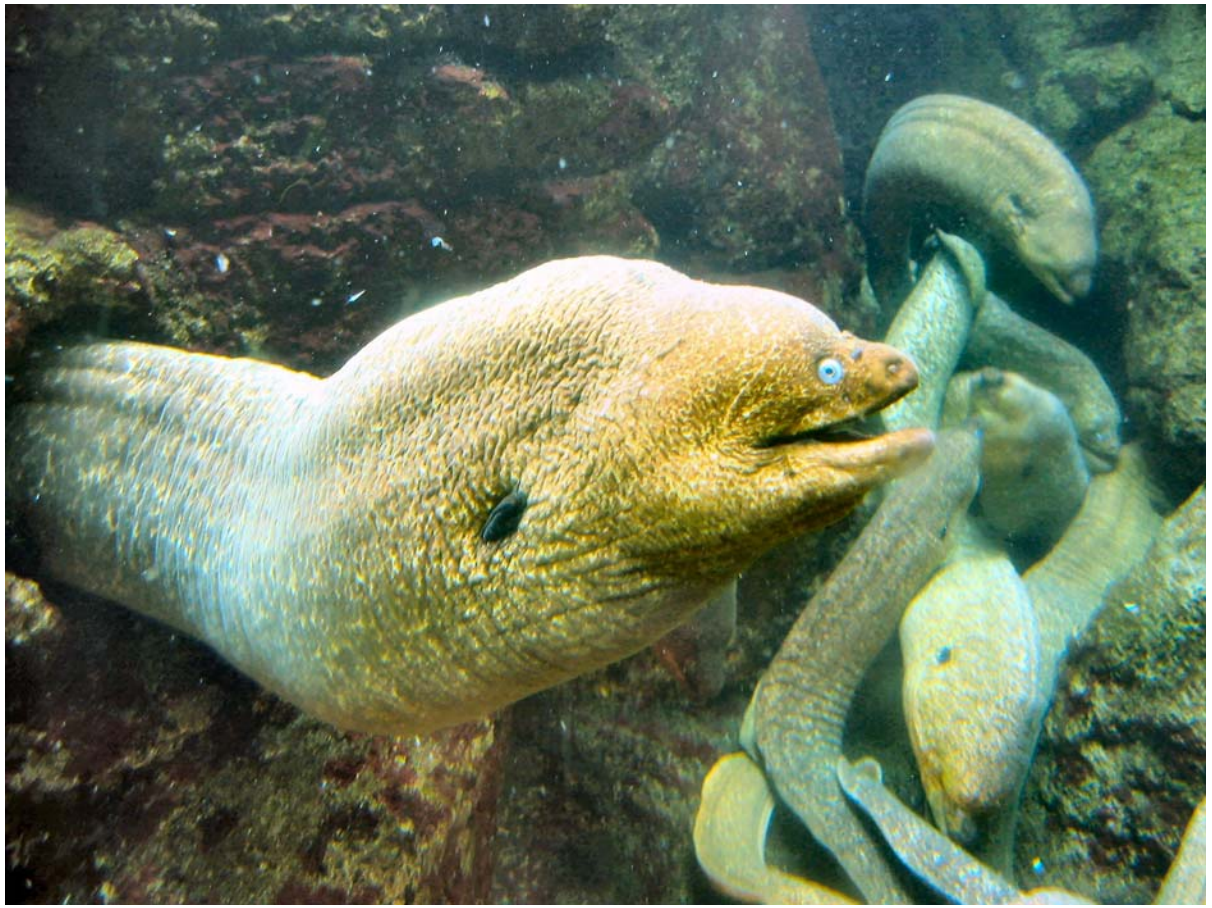
Thoughts about Solutions (2)

Even after these points are clarified, A ***SYSTEM*** IS NEEDED

- Rigourous requirements must be adopted by all countries
  - What motivates a ***COUNTRY*** to adopt ABS legislation?
  - What motivates the negotiators in deciding what is required?
- Common Agreement for Implementing User Measures

Criteria for System Development

- Overall
  - objectively verifiable
  - improving conservation and sustainable use
  - commitments on both sides
- For users:
  - **NOT PUNISH** compliant users
  - benefits for compliance …
  - …must outweigh costs
- For source countries
  - net-positive
  - Benefit must be worth the effort
  - (non-monetary incentives to users?)



THANK YOU!

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*Ask me about I.R.I.S

Notes for slide 13

My presentation was interrupted when I mentioned the extreme high-temperatures in which thermophiles from the hydrothermal vents (in deep ocean waters) live. I extensively research all issues I write or speak on. However, because it has been many years since my undergraduate major in chemical engineering, I sometimes express myself non-scientifically. For this I apologise. The following is from my notes:

" 'Deep vent' – the new polymerase is based on hydrothermal vent-dwelling species can live at temperatures greater than 200ºC (392ºF) owing to the high pressure of the deep ocean. Possibly other species may have even higher tolerances to heat, since sources on hydrothermal vents show temperatures greater than 250ºC (482ºF), and some confirmed readings show temperatures as high as 350ºC (662ºF). (Some newspapers give figures as high as 400ºC (752ºF). Resources to confirm these figures include the following: Humphries, S., et al, *Seafloor Hydrothermal Systems: Physical, Chemical, Biological and Geological Interractions* (American Geophysical Union, Washington, 1995.)

"Obviously, cold-tolerance is less well demonstrated by the deep ocean since the ideal gas equation will not apply to the conversion of water to ice.

"However, there are sulfide-based cold seeps which release water at lower-than-0(Celsius) temperatures. (Per Tony Koslow.)"

Other examples of pre-CBD use of genetic resources (not discussed in my presentation due to time concerns) include

- vincristine and vinblastine , two anti- cancer drugs discovered in Mexico by Eli Lilly in 1954, based on the "rosy periwinkle." (Frequently mentioned in the negotiations of Article 15).
- Taxol, discovered in 1967 in the bark of the Pacific Yew tree (*Taxus brevifolia*), is a treatment for breast and ovarian cancer.

Notes for slide 20

My presentation was again interrupted when I discussed the Tricolour Frog case. I apologise to the participants for not having the notes to hand as I gave this brief analysis. Here is a description of what the researcher and the developer did, based on first hand discussions with the individuals themselves:

- Dr. John Daly identified the poison in the frog skin as steroidal alkaloids (quite an unexpected discovery). It was observed that tricolor frogs bred outside their habitat do not produce this alkaloid. Dr. Daly and his colleagues proceeded to elucidate and analyse the chemical composition of epibaditine and, in 1992, mapped and published the structure of the epibatidine molecule. (*See* Barbara Badio & John Daly, "Epibatidine: A Potent Analgesic and Nicotinic Agonist" (45) *Molecular Pharmacology* 563-569.)

  This compound (called Epibatidine) was was patented by NIH and synthetic analogs were patented by Abbott Laboratories USA and UCB SA of Brussels among others.
- Interviews of the law firm that prosecuted US patent 6,133,253 (on behalf of Abbott Laboratories) which is the patent that includes ABT-594 confirm that Abbott Laboratories is of the view that the development of ABT-594 proceeded on the basis of information published by John Daly and the NIH. Abbott scientists had no contact with the frogs, their skins, or any epibatidine extracted from them.

This information was compiled under the ABS project by Dr. Ikechi Mgbeoji, law professor at Osgoode Hall Law School.

A complete report of our research and analysis of four of the most commonly cited claims of misappropriation of genetic resources will be published later this year in a book called *Covering ABS: Addressing the Need for Sectoral, Geographical and International Integration in the ABS Regime*.

Note on User Measures

Throughout my presentation, as in all of my discussions of the concept, I use the term “user measures” to refer to national laws in user countries which require, urge or motivate users of genetic resources that originated in other countries to engage in benefit-sharing with those countries or persons designated by them.

With my colleague Morten Walløe Tvedt (Fridtjof Nansen Institute), I have spent considerable time in evaluating all OECD countries national legislation on this point, and have found that none of them does this. A few measures are cited as first steps toward the adoption of user measures as required under Article 15:

- Voluntary disclosure of origin in patent applications – these provisions contain NO requirement, motivation or exhortation to the disclosers or other users to engage in benefit sharing.
- Provisions requiring users of the legislating country’s own resources to pay benefits *to the user country.* The best examples of these provisions are Costa Rica (a non-OECD country) and Australia.

Morten and I have between us the ability to read seven languages, and have sought help with others in a few *cases. We are aware that we may have missed some laws, and are seeking to rectify this as much as possible prior to publication of our book on this topic: Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD,* which will be published later this year.