Access and Benefit Sharing and "Digital Sequence Information": the Regulatory Challenge

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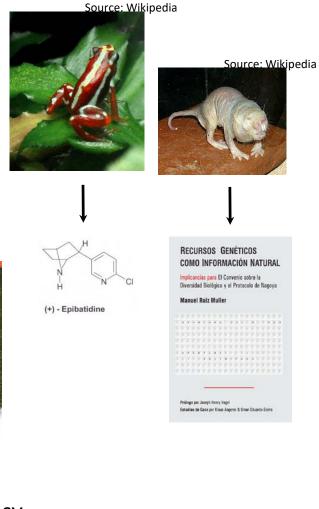
The value of genetic resources ...

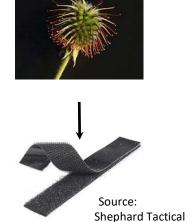
The value of genetic resources for biotechnology lies in their informational dimension and their utilization and transformation through R&D. Value is often also added through intellectual property protection.

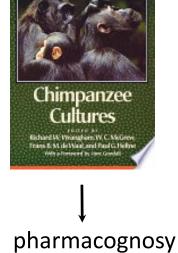
- Timothy Swanson (*The Economics of the Biodiversity Convention*, 1992)
- Joseph H. Vogel (Genes for Sale, 1994)
- Bronwyn Parry (Trading the Genome, 2004)

Ever since Francis Crick's publication of "The Central Dogma of Molecular Biology" in 1970, the immaterial nature of genetic resources has been manifest in the literature.

Source: Wikipedia







Current discussions on policy and regulatory options for "DSI"

- CBD/Nagoya Protocol
- FAO International Treaty on PGRFA
- WHO (PIP Framework)
- UNCLOS
- National processes ...

Should "DSI" be regulated?

Should "DSI" come under the material scope of ABS frameworks?

- o Industry, academia, industrialized countries: NO
- Megadiverse countries: YES
- Third bloc: YES, <u>but</u> under general "open access" rules and principles

There is a general acceptance that "DSI" is critical in biodiversity research (and development) and key for benefit sharing

1. Bilateral/transactional model

"DSI" would be regulated and governed under existing MAT, PIC, Benefit Sharing obligations and principles of the CBD, Nagoya Protocol and existing national frameworks. A transactional and bilateral approach (using contracts) involving country of origin, user and database.

2. Open access- bilateral model

Terms and conditions of the specific "DSI" database regulate benefit sharing for <u>commercial</u> <u>uses</u> of "DSI". "Open access – bilateral model" requires a country tag for "DSI" so that the User can remit benefits to the country of origin. <u>The modality involves a form of adhesion agreement and involves a user and database.</u>

3. Open access- multilateral benefit sharing

A multilateral regime regulates mainly <u>commercial</u> use of "DSI" rather than contracts and bilateral agreements. No country tag is required as monetary benefits remit to a Global or Regional Fund. Openness is bounded by the obligations of the regime. "Open access-multilateral benefit sharing" has been the least discussed system over the years and CBD COPs but seems to be the preferred alternative. <u>Elaboration is now required and is ongoing</u>.

4. Open access – subscription fees

Subscription fees are disclosed through the Terms and Conditions of the specific database and could differ for commercial or non-commercial use. Burdens could be placed on researchers and institutions from less developed countries.

5. Open access- levies

Levies could be placed on equipment purchased for the use of "DSI" (e.g. sequencers, robots, sequencing services, AI infrastructure). <u>Potential burden for developing countries</u>.

6. Open access - capacity development

No specific benefit-sharing obligations for "DSI". Benefits are assumed to be diffused through the commercial and non-commercial use of "DSI". "Open access - capacity development " suggests benefits "trick[ling] down into society." The checkered history of trickle-down economics.

Conceptual models

"Common pools" (Gerd Winter and Evanson Chege Kamau)

https://www.amazon.com/Common-Pools-Genetic-Resources-Internationalebook/dp/B00E1EMUIQ

Variant of "Open Access - Multilateral Benefit Sharing" derives from the literature on common-pool resources by Elinor Ostrom (2009 Nobel Memorial Laureate in Economics) and work by Winter and Chege-Kamau. The application to "DSI" is an extension of historic practices of related user groups such as *ex situ* seed collections, culture collections and databases. Common pools reduce transaction costs of ABS agreements through integration, harmonization and streamlining. Because the benefits would go to a regional pool/fund rather than to one provider, "distributional justice" is enhanced but partially: other pools could form among neighboring providers and face no barrier to compete.

Conceptual models

"Mare geneticum" (Broggiato et al.)
https://brill.com/view/journals/estu/33/1/article-p3-3.xml

Applies to marine genetic resources beyond national jurisdictions. "Open access" to GRs (DSI) conditional upon making samples and data publicly available. Monetary benefits: applies upon commercial utilization of products derived from marine genetic resources through fixed royalties according to sectors.

Conceptual models

"Bounded openness over natural information" – a comprehensive multilateral ABS regime to cover the informational dimension of genetic resources (Vogel, Ruiz, Angerer, 2015)

https://www.routledge.com/Genetic-Resources-as-Natural-Information-Implicationsfor-the-Convention/Muller/p/book/9780815378952

- Facilitated access to genetic resources/(natural) information
- Y/N disclosure in IP applications when natural information used
- Commercially successful IP protected innovations channel benefits to a global funding scheme
- Monetary benefits set a priory (i.e. fixed royalty) based on industrial sector, type of utilization, etc.
- Distribution of benefits (<u>EX POST</u>) proportional to conservation of habitats (<u>countries</u> of origin ...)
- If determination is too costly or natural information is to difused across jurisdictions money is channeled towards a global public good: <u>taxonomy</u>

The economic reasoning behind "bounded openness"

- The economics for tangibles (timber, minerals, fisheries, material commodities, etc.) is <u>diametrically opposed</u> to the economics of intangibles (information) which calls for monopoly and intellectual property-like policy/legal structures to recoup costs of innovation and policing the use of results of human creativity
- If the value of genetic resources lies in their informational dimension, the *economics of informatio*n offers a robust discipline to conceptualize, understand and develop policy and legal constructs
- However, the economics of information has been largely ignored in ABS discussions: until now ...

Final thoughts

- Define and recognise "DSI"/genetic information/natural information/nucleotide sequence data as the main subject matter of ABS
- Explore not only legal, policy, anthropological/sociological dimensions of ABS <u>but most or as important</u>, the aplicable economics aka. **economics of information**
- In option consideration for ABS/"DSI", reflect on, for example a model which:
 - aligns incentives for conservation and sustainable use in a logical and reasonable way and integrates the three CBD objectives
 - allows unrestricted flows of information for research and focusses on ex post (successful commercialization) monetary benefit sharing
 - acknowledges difussion of and impossibility to put practical barriers on informational goods
 - prevents jurisdiction shopping and a race to the bottom in pricing genetic resources
 - responds appropriately to the informational nature of the subject matter
 - ensures fairness and equity in benefit sharing
 - considers <u>deductive reasoning as an option vis a vis more inductive (case study based) approaches</u>

Useful sources

Modalities/Options for DSI - Global Dialogue Report on DSI (2020)

 www.abs-initiative.info/fileadmin/media/Events/2019/6 8 November 2019 Pretoria South Africa/Report-First-Global-DSI-Dialogue-SouthAfrica-201911.pdf

Domestic measures for "DSI"

 https://www.cbd.int/doc/c/428d/017b/1b0c60b47af50c81a1a34d52/dsi-ahteg-2020-01-05-en.pdf

<u>Jurisdiction shopping over and disclosure of genetic resources (2015)</u>

 https://www.cbd.int/doc/emerging-issues/PeruvianSocietyEnvLaw-JurisdictionShopping-2015-en.pdf

Economics of information and genetic resources (2011)

 https://www.academia.edu/2025721/The Economics of Information studiously ignored i n the Nagoya Protocol on access to genetic resources and benefit sharing with Joseph H enry Vogel first author et al

END OF PRESENTATION

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