THE URGENCY OF REGULATING DIGITAL SEQUENCES INFORMATION (DSI) TO PROTECT INDIGENOUS PEOPLE FROM DIGITAL BIOPIRACY

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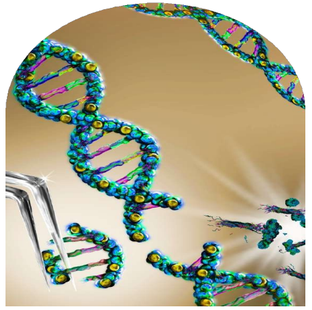

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RESEARCH BACKGROUND

In the Convention on Biological Diversity and Nagoya Protocol, the utilization of genetic resources must be based on the Principles of Prior Informed Consent, Mutually Agreed Term, Fair and Equitable Sharing.

In its implementation, there are technical difficulties in monitoring the utilization of genetic resources in term of Biopiracy.

Current technological developments have changed conventional biopiracy into digital biopiracy

The protection and preservation of genetic resources cannot be separated from the Traditional Knowledge of Indigenous People.

.CBD and Trade-Related Aspects of Intellectual Property Rights/TRIPS are international rules relating to Biopiracy.

RESEARCH OBJECTIVES

- This study aims to investigate the urgency of regulating Digital Sequences Information (DSI) to protect Indigenous People from digital biopiracy.
- This study also aims to reveal several obstacles from the perspective of International Law and domestic law.

Research Methodology

Research Typology	Research Approach	Data Collection Method
Normative, Qualitative	Statute Approach dan Conceptual Approach	Secondary Data, SLR

Theoretical Framework: Gustav Radbruch’s Theory and Public Interest Theory

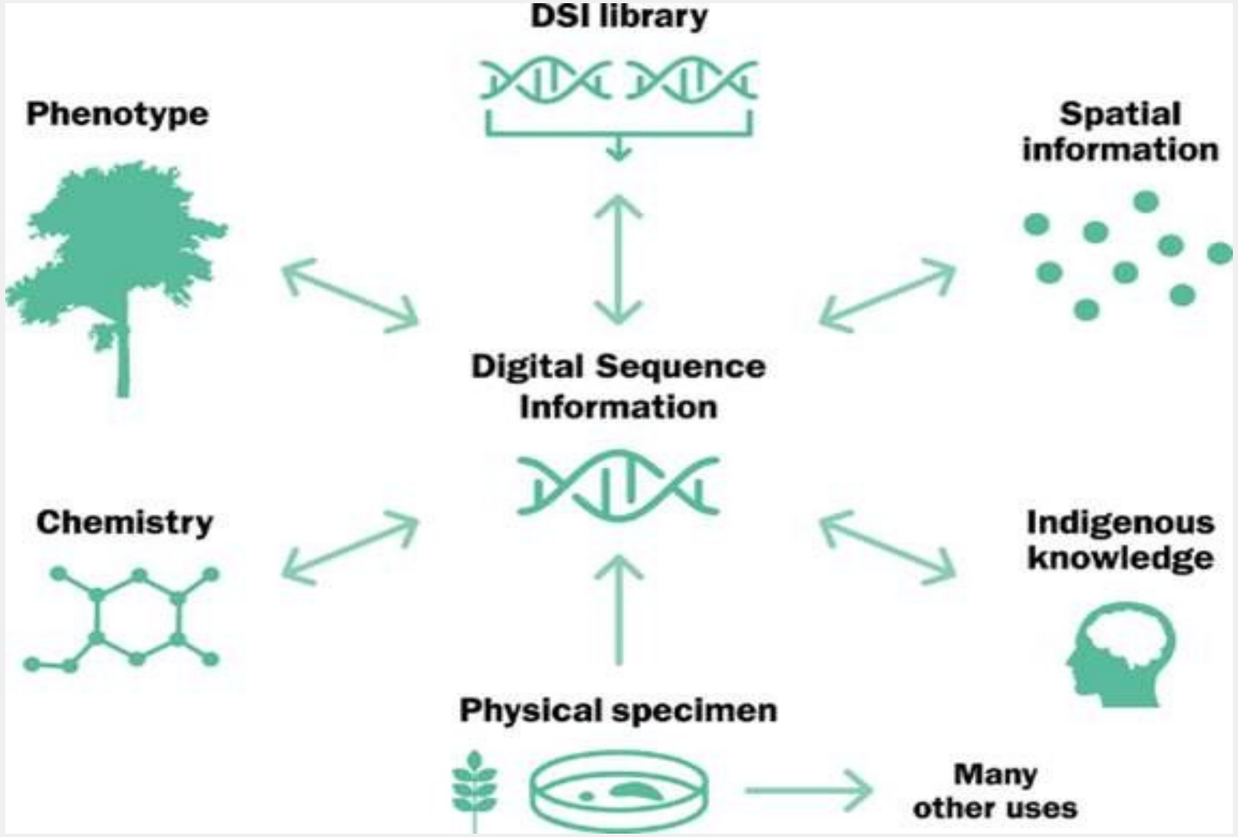
Conventional Biopiracy → Digital Biopiracy

- Digital Biopiracy is a phenomenon of using genetic information through digital platform without fulfilling the principle of Mutual Agreed Term (**MAT)**, Prior Informed Consent (**PIC)** and **Fair and Equitable Sharing.**
- It is motivated by the consistent decline in the diversity of genetic resources by 6%/year since the industrial revolution.
- Causes: growing human population and the increasing use of uncontrolled resources.
- Digital Biopiracy is also motivated by the ancient idea that **genetic resources are the common heritage of mankind** and that their maintenance would be efficient if genetic information from all over the world was freely collected and stored in gene banks.

DIGITAL SEQUENCES INFORMATION (DSI)

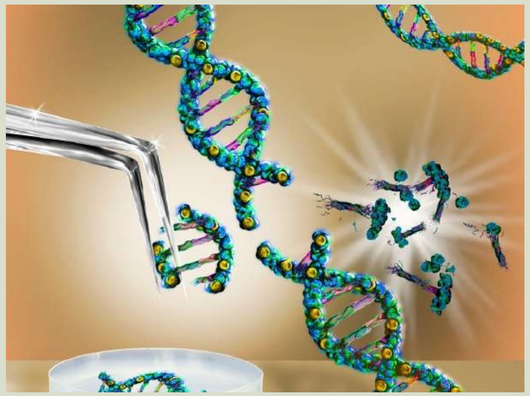
- DSI is an important tool and resources in preserving biodiversity.
- DSI was originally derived from the term ‘ Genetic Sequences Data (GSD): the sequences of nucleotides found in DNA or NRA molecules and contains genetic information that determines the biological characteristic of an organism or virus.
- With the development of synthetic biology technology, a physical genetic resources can be stored in a data base that can be accessed by everyone ⟶ digitization of genetic sequence data.
- ThiPublic Databases: platforms that provide genetic information about an organism.
    - **International Nucleotide Sequences Database Collaboration (INSDC)**
    - **GenBank**
    - **European Nucleotide Archive**
    - **DivSeek**
    - **Global Biodiversity Information Facility (GBIF)**

DIGITAL SEQUENCE INFORMATION (DSI) ELEMENTS



Literature Review

DSI



The review includes an overview of genetic engineering, an overview of DSI in genetic engineering and an overview of Public Databases.

INDIGENOUS PEOPLE

The review includes a definition of Indigenous People and a review of Traditional Knowledge.

DIGITAL BIOPIRACY

This review covers the notion of Biopiracy and Digital Biopiracy.

LEGAL THEORY

This review covers Gustav Radbruch's theory of legal objectives as well as Public Interest Theory.

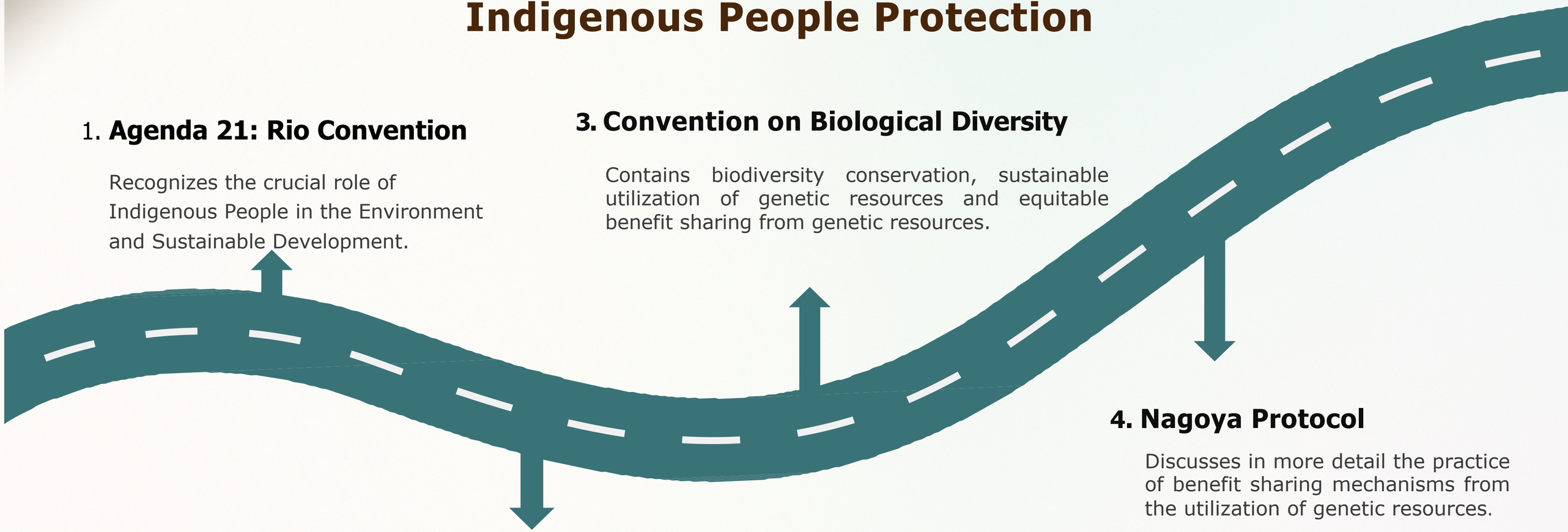
International Law Instruments in Indigenous People Protection

1. **Agenda 21: Rio Convention**

   Recognizes the crucial role of Indigenous People in the Environment and Sustainable Development.

3. **Convention on Biological Diversity**

   Contains biodiversity conservation, sustainable utilization of genetic resources and equitable benefit sharing from genetic resources.



2. **United Nations Declaration on the Rights of *Indigenous People* (UNDRIP)**

   Contains comprehensive, persuasive, and organic recognition of Indigenous People and their TK, culture, and traditions.

4. **Nagoya Protocol**

   Discusses in more detail the practice of benefit sharing mechanisms from the utilization of genetic resources.

FAIR AND EQUITABLE SHARING MECHANISM

Fair and equitable sharing arises from the utilization of genetic resources (Article 2 of the CBD).

The utilization in question is the use of genetic resources for research, development, and commercialization.

Each country shall formulate policies, legislative measures, and administrative measures (Article 5 CBD)

There is a Transboundary Cooperation mechanism for resources found in more than 1 country (Article 11 of the Nagoya Protocol)

Genetic Resources Utilization must be based on Access and Benefit-Sharing Principles (Article 15 CBD)

The Nagoya Protocol also provides provisions regarding the Multilateral Benefit Sharing Mechanism (Article 10 of the Nagoya Protocol)

POTENTIAL UTILIZATION OF DSI IN THE INDUSTRIAL FIELD

Agriculture

DSI is used to assess soil microbial quality, improve food security, and deal with food waste.

Biotechnology

Through genetic engineering and synthetic biology technologies, DSI is used to modify organisms so that they have traits superior to the original organism.

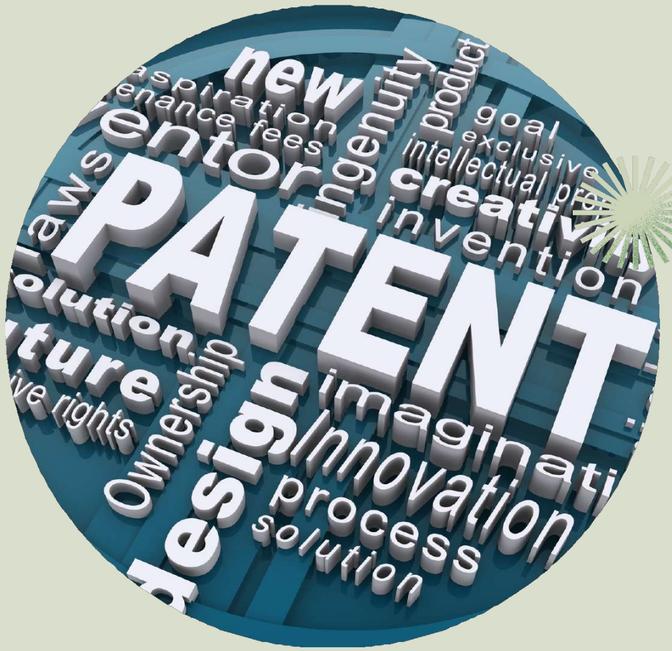
Medicine

DSI is commonly used to analyze virus types and manufacture vaccines.

Pharmacology

DSI is used to discover drugs and vaccines. Its utilization often leads to product commercialization.

Patents Derived from DSI Public Databases



No	Virus Sequence	Reference Sequence	No of Patents /Application Mentioning DSI
1.	SARS-COV 2	(NCBI Reference Sequence: NC 045512.2)	311
2.	EBOLA	GenBank AF086833	230
3	MONKEYPOX	GenBank ON563414.3	176
4.	ZIKA ZikaSPH2015	GenBank: KU321639. 1	145
5.	NIPAH	GenBank AF212302	81

Digital Biopiracy Cases

1. GM Potato Case

Lis of Patents t from DSI Public Databases

The International Potato Center (ICP) developed a Cisgenic Potato variety, which is the result of engineering the Victoria potato variety that originated in South America and has been cultivated by the Andean tribes since ancient times.

Gen	Species	Source	ID Sumber GenBank
Rpi-vnt1. 1	Solanum venture	Argentina	FJ423044.1 Sainsbury (United Kingdom)
Rpi-blb2	Solanum bulbocastanum	Meksiko	DQ122125.1 Wageningen (Netherlands)
RB (Rpi-blb1)	Solanum bulbocastanum	Meksiko	Univ. Wisconsin (United States)

2. Ebola Virus Case

Ebola virus is a virus that has been spreading in Zaire since 1976. Enter Regeneron Pharmaceuticals is the inventor of the Ebola antiviral REGN-EB-3. This drug was developed using DSI from the Ebola Virus that developed in west Africa in 2014. Unfortunately, the benefit sharing agreement does not apply in this case as the rules only require the virus to be physically accessed.

DSI in International Law

1 History of DSI in Public International Law

- DSI has been recognized in the CBD and the Nagoya Protocol, but the interpretation of DSI depends on each country
- The existence of benefit sharing that considers the rights of Indigenous People from monetary and non-monetary benefits
- The establishment of a multilateral benefit sharing mechanism: a Global Fund called Cali Fund through the decision of COP.

2. Weakness of international regulation in DSI form

TRIPs

No mandatory disclosure agreement.

TRIPs allows patenting of genetic resources through plant varieties.

This agreement does not recognize the obligation of participating countries to provide fair and equitable sharing.

WIPO treaty on IP

It does not state that DSI is part of genetic resources.

The disclosure agreement obligation is only required for patent applications based on physical genetic resources.

The treaty does not provide strict provisions regarding sanctions on parties who do not declare the source of genetic resources.

COP CBD 16/2

Lack of legally binding force of CBD COP Decisions

Absence of a definitive law enforcement mechanism

Difficulty in measuring the economic value of DSI

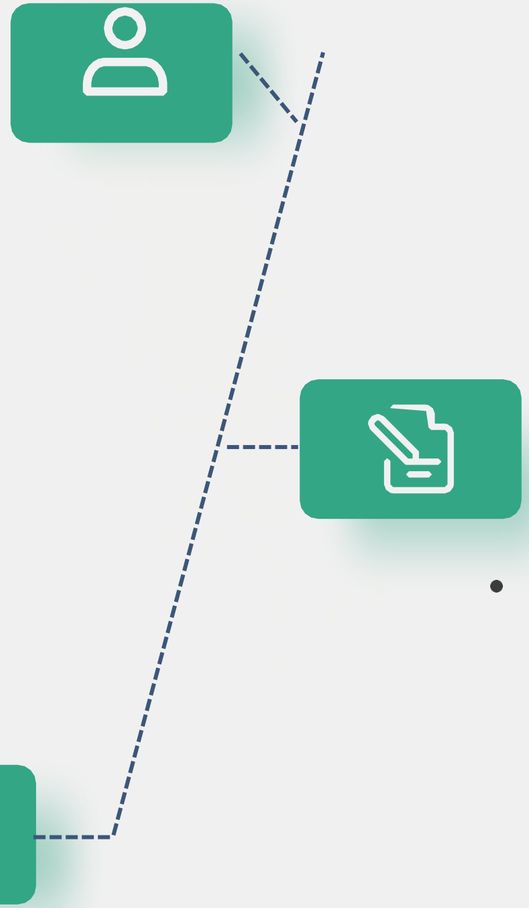
ANALYSIS OF INTERNATIONAL REGULATIONS BASED ON GUSTAV RADBRUCH'S THEORY

- Both TRIPs, WIPO Treaty, and COP Decision have failed to fulfill the human rights of Indigenous People (Justice)
- TRIPs, WIPO Treaty on IP, and COP Decision have provided benefits but do not fully reflect the interests of society
- TRIPs, WIPO treaty, and COP Decision create ambiguity in their interpretation so that they do not fulfill legal certainty.

DIFFERENCES IN INTERPRETATION OF THE STATUS OF DSI

DSI is not included in the definition of "genetic resources" but is the result of "utilization of genetic resources" and can be regulated in MAT agreements.

- There is an imbalance in utilization between developed and developing countries.
- There are many patents derived from DSI but there is no benefit sharing obligation



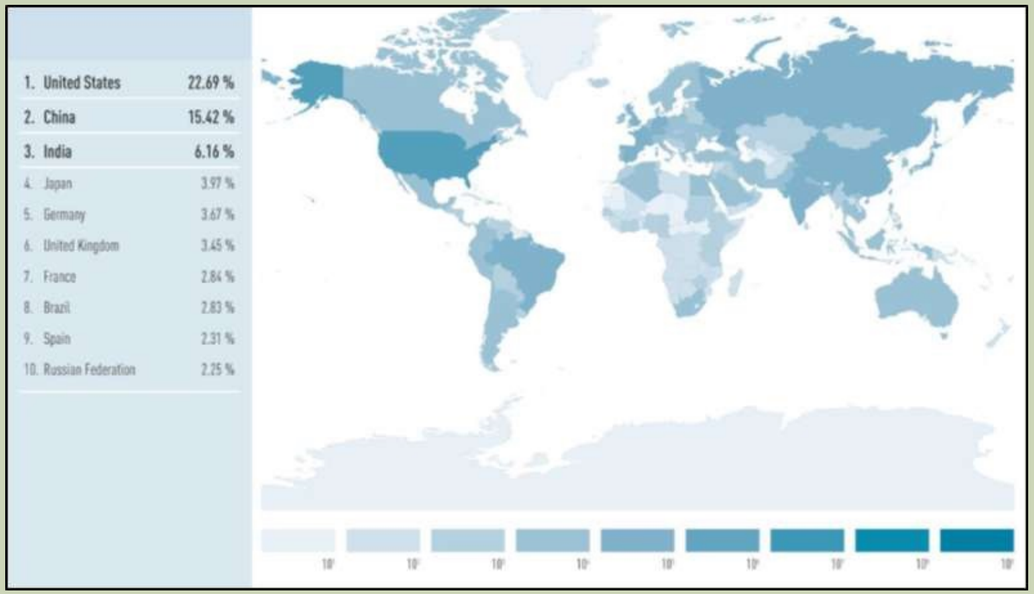
DSI are interpreted as "genetic resources" and therefore subject to the PIC and MAT Principles.

- PIC obligations will make free and open access to DSI.

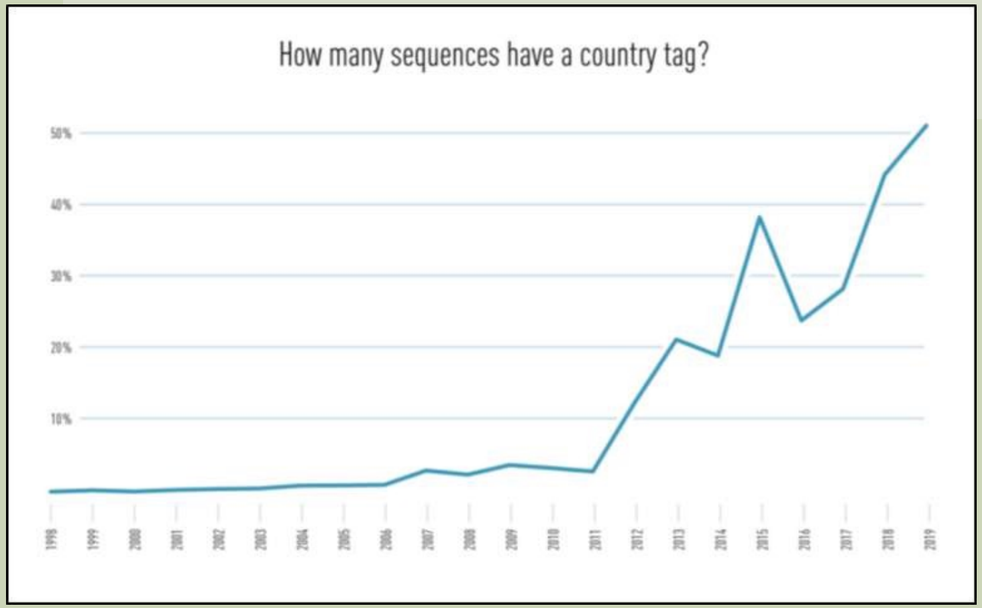
DSI is not defined as a "genetic resource" but is the result of "genetic resource utilization" so monetary benefits need to be shared from its commercial use.

Difficulty Identifying Contributors, Users and DSI Origins

Most Public Databases do not require contributors or users to create an account or sign a usage agreement. This has an impact on the application of the ABS Principle.



There are hundreds or even millions of sequences in INSDC that do not have information on the country of origin. This is due to the large amount of data and overlapping data in Public Databases.



Constraints on DSI Regulation in Domestic State Regulations

Some countries such as the Philippines, Pacific Island and Iraq do not regulate DSI for the following reasons:

- Lack of understanding of the implications of including or not including DSI in ABS
- Lack of qualified human resources to address DSI issues
- Lack of urgency and adequate technology on DSI issues
- Lack of finance to conduct research, training and discussion on DSI issues

Although several countries have regulated DSI, none of them have reported getting fair and equitable sharing from DSI utilization.

Developed countries such as Japan (which has ratified the CBD) do not want to interpret DSI as genetic resources because Japan supports the free and unrestricted use of DSI in Public Databases.

Conclusion

- . DSI which was originally only intended for learning activities is now used to create a new product with the development of synthetic biology technology. It is also not uncommon to patent an invention that uses DSI as its raw material but is not bound by ABS principles such as the Ebola Virus Case and the GM Potato Case.
- The lack of clarity regarding the status of DSI and the inability of some countries to regulate it makes the regulation of DSI still unclear.
- Based on juridical analysis by using the theory of legal objectives by Gustav Radbruch, the inability of positive law to accommodate regulations and sanctions from the phenomenon of Digital Biopiracy which causes injustice, legal uncertainty for Indigenous People, makes regulation of DSI is an urgent.
- Some countries do not recognize DSI as genetic resources so that it does not have to be subject to the ABS principle, while some other countries consider DSI as a result of the utilization of genetic resources so that it must be subject to a Fair and Equitable Benefit Sharing mechanism.

Thank you...