



IP Protection of Genetic Material and Genetic Information

Legal Challenges of Digital Sequence Information for Access and Benefit Sharing

Genetic Resources - who benefits?

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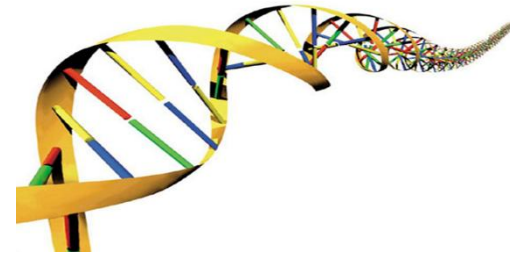
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Outline

- I. Genome Sequencing as a Historical Paradigm Shift
- II. Transformation from Material to Data
- III. IP Protection of Digital Sequence Information (DSI)?
- IV. DSI Sharing under ABS Systems
- V. Initiatives to make DSI available for users with legal certainty
- VI. Conclusions

I. Genome Sequencing as a Historical Paradigm Shift

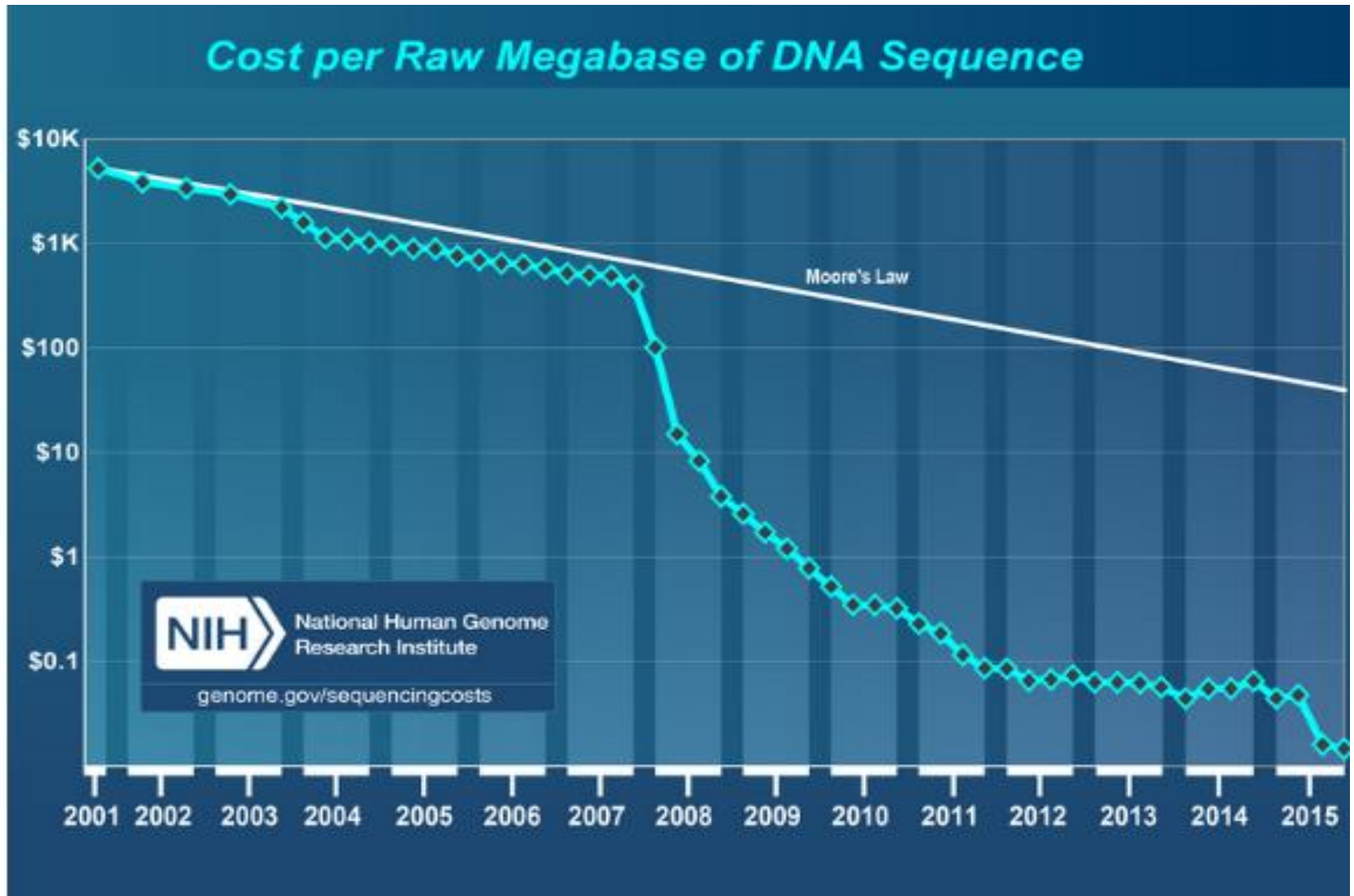
- genome sequencing leads to new possibilities and forms of information transfer
- shift **from** classical utilization of material of **genetic resources** (GR) in biological systems **towards** the extraction of the **information content** of the genetic material
- data and genetic sequence information (DSI) as key inputs and raw material for innovation processes in the life sciences
 - **definition of DSI not yet clear and currently under discussion**



I. Genome Sequencing as a Historical Paradigm Shift

- genome sequencing leads to an **exponential growth** of data due to **technological progress** and **decrease of costs**
- new challenges for data acquisition, storage, distribution, and analysis
 - genomics / **gene sequencing** is a «**big data**» science
 - revolutionary transformation in the **use of GR** undergoing radical changes and
 - may be considered as «**4th industrial revolution**»
 - **historical paradigm shift** in the use of genetic resources

I. Genome Sequencing as a Historical Step



II. Transformation from Material to Data

- due to technological progress in molecular biology and bioinformatics decreasing costs of genome sequencing transition will this have tremendous impacts research and on new genomic technologies (eg CRISPR/Cas9)



- transition from material to data
- new approach to collect, aggregate, compile, analyse, interpret and utilize **information** in its **own right**
 - challenges for the legal system

II. Transition from Material to Data

- background:
- transition from GR to DSI leads to a **transition** of **legal frameworks** which regulate the exchange and transfer
 - **is the current legal set-up suited to cover this transition?**
- questions:
- regulation of DSI through the ABS regime?
- multiple and asymmetrical **disruptions** in **ABS and IP law** as a consequence of genomic sequencing and the big data it generates?
- **IP protection** of data resulting from genome sequencing?

III. IP Protection of Digital Sequence Information (DSI)?

Patent Protection?

- Myriad case

(Association for Molecular Pathology/
Myriad Genetics, 2013)



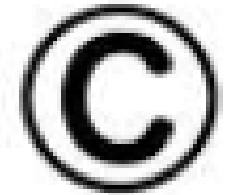
US Supreme Court ruled that **human genes cannot be patented** in the US because **DNA** is a «**product of nature**»

→ patent for DSI?

- in principle **no patent protection** in the US (and under other jurisdictions as well)

III. IP Protection of Digital Sequence Information (DSI)?

Copyright Protection?



- copyright = legal right, that grants the creator of an **original work** exclusive rights to determine and decide whether, and under what conditions, this original work may be used by others
 - data from genetic sequencing = original work?
- copyright for genetic data similar to the source code of software?
 - similarity to a **software copyright**?

III. IP Protection of Digital Sequence Information (DSI)?

Sui Generis Protection?



- if there is no IP protection under patent and copyright law is there an *sui generis right protection*?

example: *protection of databases* under *EU Directive 96/9/EC*

- *database* = «collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means»
- *special protection for databases* separate from general copyright law

III. IP Protection of Digital Sequence Information (DSI)?

- The *sui generis* right ...
 - prohibits the extraction or re-utilisation of any database in which there has been a substantial investment in obtaining, verifying or presenting the data contents
 - does not require for creativity or originality
 - right lasts 15 years from the date the non-creative database was made
 - *sui generis* rights granted under this Directive does not apply to databases created by companies located outside the EU
 - EU companies have greater protection for their databases than companies in the USA

III. IP Protection of Digital Sequence Information (DSI)?

two types of protection for databases



copyright protection for «the intellectual **creation** involved in the selection and arrangement of materials»

→ protection of databases that meet the requirements for «creativity» of the work



sui generis protection for «an **investment** (in human and technical resources and effort and energy) in the obtaining, verification or presentation of the contents of the databases»

III. IP Protection of Digital Sequence Information (DSI)?

Sui Generis Protection?

- such databases may not be creative but they require a **quantitatively** or **qualitatively substantial investment** in terms of resources and/or time spent
 - non-creative databases protected by the EU Directive
- however: EU Directive does **not provide protection** for software used to create the database or for **material contained in the database**
(only the scheme of the database that is protected)
 - also no protection of genetic data in a database resulting from genome sequencing / DSI

IV. DSI Sharing under the ABS System

- the Nagoya Protocol (NP) defines GR as **material** from an organism that **contains DNA, RNA, or proteins**
- collecting a **sample of tissue** from an organism **falls under the NP**
- current **debate** about **whether DSI** derived from GR are **also included**
- since the NP covers all benefits from utilization of GR, it would also cover DSI derived from GR sample collection
- problem: terminology of DSI not yet clear and sufficiently defined

IV. DSI Sharing under the ABS System

background and consequences:

- DSI enables international transfer of genetic sequences without moving GR / organisms across borders
- the **free use of DSI**, however, without benefiting the nations where the GR comes from may create a **conflict** with the **NP** and the **ABS system**
 - fair use of DSI must be balanced with benefit sharing under the ABS system

IV. DSI Sharing under the ABS System

Example of DSI Sharing

- **International Nucleotide Sequence Database Collaboration (INSDC)** as a collaboration of sequence databases in the US, EU and Japan is providing access to nucleotide sequence since more than 30 years
- more than three trillion annotated nucleotide bases shared **free-of-charge** on the INSDC
- free-of-charge use of pre-existing, publicly available data safes research funding
 - sharing data enables a more robust scientific enterprise that ultimately benefits society globally

IV. DSI Sharing under the ABS System

Synthetic Biology as Next Step

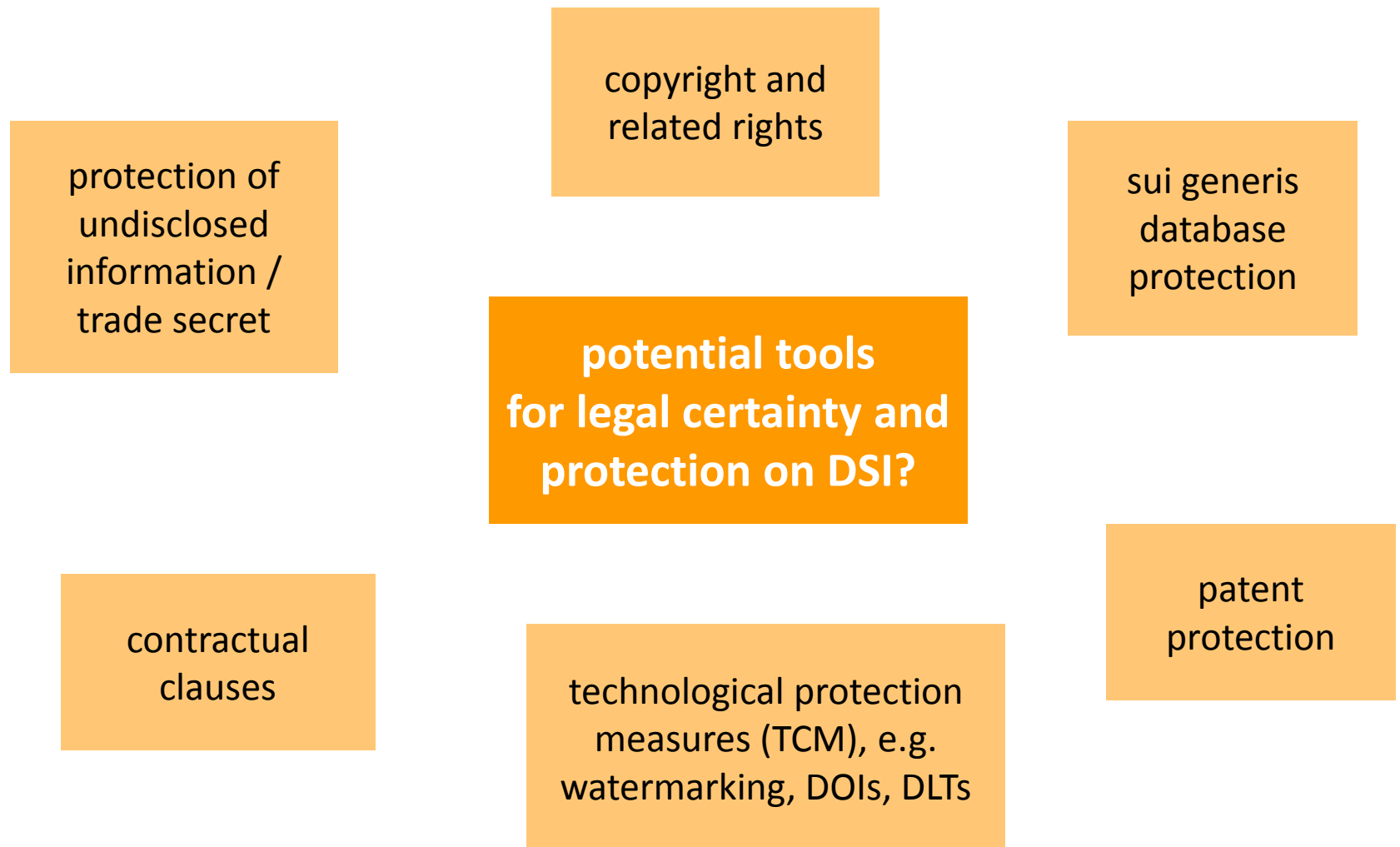
- synthetic biology may allow to **generate an organism *de novo***
 - how to regulate the use of DSI for synthetic biology?
 - challenge is to share benefits of GR from the free use of DSI
- a **ban on sharing DSI is not an appropriate solution**
 - DSI sharing offers immense benefits of DSI for global research
 - DSI sharing in digitalized research environments cannot be stopped
- in contrary:
international collaboration and sharing of DSI increases research and offers new solutions

IV. DSI Sharing under the ABS System

Solutions for DSI Sharing

- instead of restricting access to DSI platforms there are several options that are currently discussed:
 - **non-profit usage agreements for research** with contractual terms to restrict further distribution of DSI would prevent exploitation of freely available DSI and provide a basis for benefit sharing
 - **limitations for downloading DSI for non-profit usage** only could prevent the unequitable sharing of DSI
 - **distributed ledgers and encryption** have been proposed by some as a solution to share and track sequence sources in order to create profits out of DSI sharing

V. Conclusions



V. Conclusions

practical assistance with the acquisition, exercise and enforcement of rights in implementing your existing IP strategy

assistance with IP strategy development for your DSI work and research results

IP needs for adequate DSI protection

practical assistance with integrated rights management for IP and ABS over your DSI

creation of additional forms of protection (legal and technical) (e.g., sui generis rights for data, TPMs, timestamping, etc)

practical tools and systems for digital rights management for DSI

Thank you!

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