BIOBASED PRODUCTS AND POTENTIAL IMPACTS OF THE NAGOYA PROTOCOL

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What is Required to Protect Research and Innovation in Industrial Biotechnology?
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R&D in a changing legal environment

NEW LAWS AND PROCEDURES for using genetic resources (GRs) are coming into force

as countries ratify international agreement known as the Nagoya Protocol

POTENTIAL IMPACT on your decisions about

- **Where to obtain GRs**
- **Where to carry out R&D**
- **Where to commercialize**

POTENTIAL IMPACT on your <u>ability</u> to do R&D and commercialize

Why do I need to know about the Nagoya Protocol? What if:

December 2015, collect samples in Mexico, then R&D in the US. You are ready to market a product worldwide.

- May 2016 - apply for marketing approval in the EU. Do you have a certificate to prove lawful access to the samples?
- What if samples were collected in Mexico in December of 2010? Open ocean?

R&D in Denmark with fungus. Danish Nature Agency says you are utilizing fungus in violation of provider country laws, and you must stop R&D. Do you have to stop?

Collect GR#1, GR#2, and GR#3 from different countries, combine sequences from each, and get a commercially successful product. How do you share benefits with providers?

Two sources for a strain you want to use - one of them is a EU registered collection, and the other is not. Would this be important?

THE NAGOYA PROTOCOL: What, why, when?

WHAT is the Nagoya Protocol:

- International agreement - supplement to Convention on Biological Diversity
- Countries ratify and must enact domestic-level implementing measures

WHY the Nagoya Protocol:

- Convention introduced "access and benefit-sharing" w/o legal framework
- **Nagoya Protocol to provide "transparent legal framework"** for prior informed consent (PIC), mutually agreed terms (MAT), checkpoints, etc.

WHEN:

Adopted 10/29/2010; entered into force 10/12/2014

➡ now seeing new laws & procedures being enacted in ratifying countries

THE NAGOYA PROTOCOL: Mechanics

Nagoya Protocol requires:

Clear rules, predictable conditions for **access and benefit-sharing**

Competent national authority (CNA) – grant access & issue Internationally Recognized Certificate of Compliance (**IRCC**)

Enforceable measures for **compliance**

Checkpoints - collect info, issue **checkpoint communiques**

= proof of compliance

NAGOYA PROTOCOL IN FORCE: Good news and not-so-good

Good news:

- Some procedures / mechanisms more standardized
- Parties agree to recognize official forms of proof -
  IRCC, checkpoint communiques

Not-so-good news:

- Implemented on a county-by-country basis
  - each country may have different specific requirements
- May result in problems with compliance

Will your R&D be impacted by the Nagoya Protocol? Triggers

DO YOU:

- **Use GRs covered by the Nagoya Protocol?**
  - **If not excluded, then probably covered**

    Excluded: human GRs, GRs from ABNJ, GRs under other legal frameworks
  - Includes traditional knowledge (TK) associated with GRs; **derivatives**
- **Get GRs from a country that ratified the NP?**
- **Carry out R&D in a country that ratified the NP?**
- **Plan to commercialize in a country that ratified the NP?**
- **Access GRs after 10/12/2014?**

EXAMPLE: Nagoya Protocol for R&D w/ GR → valuable protein

Access to GRs

- User & provider in Nagoya Protocol countries; follow rules for PIC and MAT
- Access granted; **CNA** issues **IRCC** as proof
- **MAT** includes 1% royalty, notice of data sharing

Use of GRs

- User R&D to optimize yield & formulate product
- User complies w/ MAT, reports data-sharing event to provider **checkpoint**
- User complies with home country rules for GRs

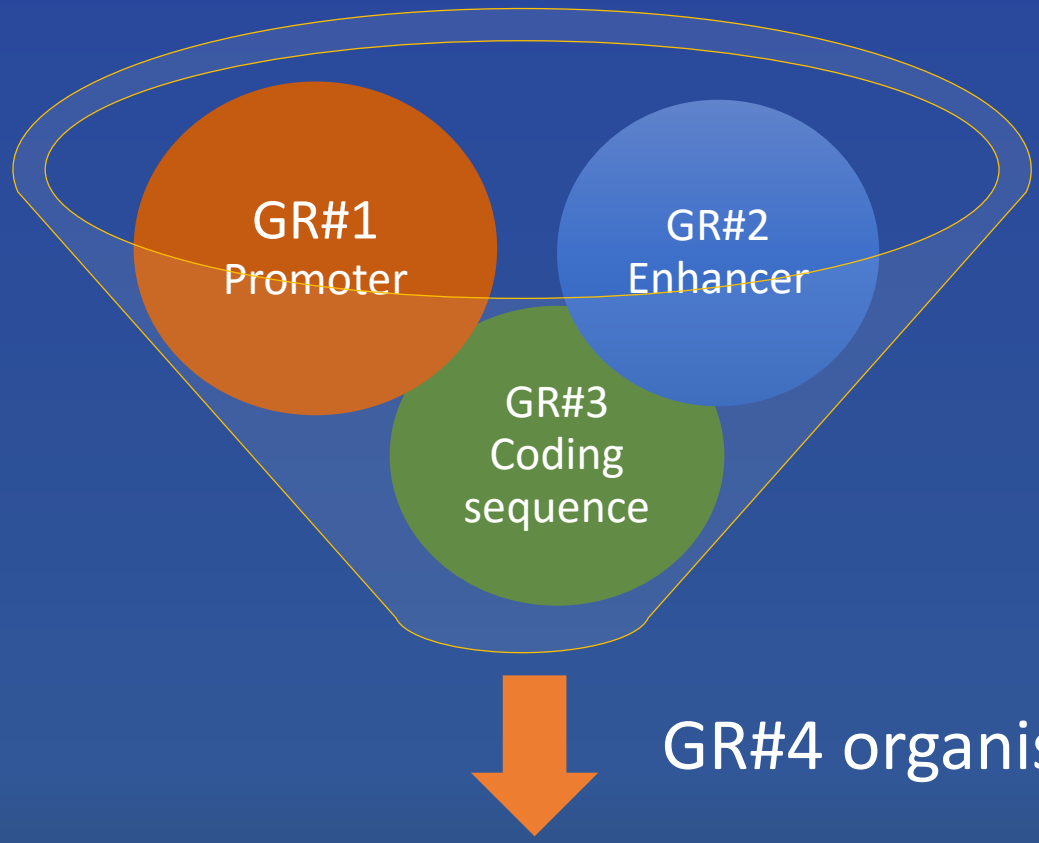
Benefits/Compliance

- User starts to commercialize product
- User shows IRCC to **checkpoints** in other NP parties to prove lawful access
- Calculate benefits that will be shared under MAT

Benefit-sharing - user pays 1% royalty on sales

EXAMPLE: What about complex R&D w/ multiple GRs?

- GR#1, GR#2, GR#3 from different Nagoya Protocol countries
- Different MAT & IRCC for each
- Combine sequences
- Express in GR#4 from non-Nagoya country
- Commercially successful product
- How to calculate benefit-sharing?



ISSUES: How are access, R&D, benefits linked?

Access → **R&D** → **Benefits**

- R&D may generate benefits by techniques **independent** of accessed GRs
- **Non-GR inputs** such as information or technology platforms may be essential
- R&D may result in **IPR-protectable** subject matter distinct from accessed GRs
- **Proportional value?**
  - From the accessed GR vs unrelated non-GR inputs
  - When multiple GRs are utilized
  - When GRs used as test, control, information, not for expression or regulation
  - From downstream inputs

ISSUES: Developing law, uncertainty

What GRs?

Tangible GRs physically accessed *in situ* in the wild or under cultivation, or *ex situ* from a genebank . . . **BUT what about "digital DNA"?**

- **Nagoya Protocol does not address digital GRs**
- National level legislation may address

Access / utilization:

- Timing of access vs. utilization?
- Is downloading sequence information considered access? utilization?

Legal framework not uniform:

- How do laws & procedures differ country-to-country?
- Countries to avoid? To favor?

RECOMMENDATIONS: Strategic planning

Develop a GR administration system

- GR audit
- GR database
- Due diligence should become routine

Identify resources

- Training, registered collections, best practices
- Advice – attorneys, consultants
- National Focal Points, ABS Clearing-House, local partners

Plan for current, future, potential ABS obligations:

- Where to access GRs, do R&D, commercialize

Thank you for your attention

Perdue IP Law, APC

Intellectual property law for the life sciences