Understanding the Business Implications of Global Access and Benefit Sharing Policies
Webinar Objective:

Through interactive discussions we will explore the intricate relationship between national and global concerns for **Access and Benefit Sharing (ABS)**, while uncovering the potential implications for industry.
Host and Moderator:
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John Billington  
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Senior Director, Policy and Partnerships  
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BIO
Access to Biological Resources and Sharing Benefits from their Utilization

An ever-expanding challenge for life sciences companies

Bart Van Vooren, PhD
Attorney, Partner, Covington & Burling LLP
Structure of Presentation

1. The Origins of ABS: Biodiversity Convention and the Nagoya Protocol
2. An extraordinary Compliance Challenge
3. A hypothetical example using SARS-CoV-2
   - Obligations in Provider Countries: Switzerland, South Africa, Brazil, India
   - Obligations in User Countries: EU, UK, Switzerland
4. The Future of ABS
5. Contact Information
The Convention on Biological Diversity and its Nagoya Protocol

The Origin of Access and Benefit-Sharing
The Convention has 196 Parties, Nagoya Protocol has 140 Parties, who legally agreed hat:

- Countries own their biodiversity, and biodiversity requires monetary and non-monetary resources
- Therefore, “users” of a country’s biodiversity should share the “benefits”
- So that countries are (1) incentivized and (2) have the resources to protect their biodiversity.
## Access and Benefit-Sharing: Legal obligations for countries and companies

**Legal Implementation**

of the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Benefit-Sharing from their Utilization

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<th>Access</th>
<th>Benefit-Sharing</th>
<th>Compliance</th>
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<td><strong>What may or must a Country do?</strong></td>
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<td>A country <strong>may</strong> require a permit in order to acquire a pathogen sample from their territory.</td>
<td>A party <strong>may</strong> require that the user agree to “share benefits” from R&amp;D on the biological material</td>
<td>All countries <strong>must</strong> check compliance with ABS laws of <strong>another party</strong> and address non-compliance.</td>
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<th>What must a Company do?</th>
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<td><strong>In the Provider Country:</strong></td>
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<td><strong>Request a permit</strong> from the national authority</td>
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An extraordinary compliance challenge
An extraordinary compliance challenge...

Source: absch.cbd.int

140
Are Party to the Nagoya Protocol

~100
Provider country ABS regimes at country level, with sanctions

~40
User country compliance obligations
What are the Risks? How is ABS enforced?

**NGOs: Reputational**
- Third World Network: Ebola
- Public Eye: Stevia
- “Biopiracy”

**Business to Business**
- Compliance with law during transactions, e.g. M&A, R&D, licenses
- Supplier due diligence

**Authorities**
- **Enforcement in Provider countries**: e.g. India, Peru, South Africa, Brazil
- **Inspections in User countries**: e.g. Germany, UK, Switzerland

**ESG Agenda**
- Corporate Sustainability Reporting
- Corporate Sustainability Due Diligence
A hypothetical

- For my lawyerly brain: cows are injected with SARS-CoV-2 spike protein
Obligations in ‘Provider’ Countries

ABS if the biological material originated from Switzerland, South Africa, Brazil, India and France
ABS in Switzerland

Art. 8 Nagoya Ordinance

1 On accessing genetic resources in Switzerland, the user must record and retain the following information and pass it on to subsequent users:
   - a. the name and address of the user;
   - b. description of the genetic resource or subject matter and its utilisation;
   - c. date on which and location where the genetic resource was accessed;
   - d. in the case of direct acquisition of the genetic resource from a third party: the name and address of this person and the date of acquisition;
   - e. in the case of the transfer of genetic resources: the name and address of the subsequent user and the date of the transfer.

3 The user must notify the FOEN of the information specified in paragraph 1 before market approval or, if such approval is not required, before the commercialisation of products developed on the basis of utilised genetic resources.

5 The user receives a register number as evidence of the notification and, on request, an attestation to the effect that the Swiss provisions on access and sharing of benefits have been complied with.
## ABS in Brazil

### Registration upon Access

| What? | • R&D on genetic heritage and associated traditional knowledge; or,  
|       | • Shipping samples outside of Brazil |

| When? | Prior to: (1) shipping abroad, (2) seek IP right, (3) commercialization of finished product or reproductive material, or (4) disclosure of results of R&D |

| How? | SisGen Platform (requires Brazilian partner) |

### Notification to trigger Benefit Sharing

| What? | Benefit-Sharing from finished product for commercialization: 1% annual global net revenue |

| When? | Prior to commercialization |

| How? | SisGen (requires Brazilian partner) |
ABS in South Africa

2004 National Environmental Management: Biodiversity Act (NEMBA)

Applies to “indigenous species” = “a species that occurs, or has historically occurred, naturally in a free state in nature within the borders of the Republic, but excludes a species that has been introduced in the Republic as a result of human activity.”

Two steps:
• Discovery phase on potential commercial product = notification + export permit;
• Commercialization (e.g. clinical trials, seeking market approval) of product = export and bioprospecting permit

Key issues
- When is a resource indigenous?
- Negotiate benefit-sharing with the “provider” of the indigenous resource?
- A foreign legal entity cannot apply, it must be with and through a South African legal entity
- Criminal penalties
Trigger: “obtaining” a resource (also metabolites) from India, including if held in a collection abroad (2023 amendment).

For “Commercial utilization” = “end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention”

There is a strong legal case to be made that India’s ABS rules, including the discrimination between Indian and foreign entities, apply them likely violate India’s obligations under WTO law

If only someone would convince the US Trade Representative to take this up with India and go to WTO

Impact on U.S. companies is real.
Compliance in ‘User’ Countries

Demonstrating compliance with ABS in jurisdictions where the biological material is ‘used’: EU, Germany, Switzerland, UK ...
European Union (EU) Rules Enforcing Compliance with the Nagoya Protocol

Companies doing R&D in any EU country must, under Regulation 511/2014:

Art. 4(1) exercise due diligence that access was in accordance with ABS rules;

Art. 4(2) transfer and utilize Genetic Resources only in accordance with MAT;

Art. 4(3) seek, keep and transfer to subsequent users: date, place, description, source, users, obligations; PIC; MAT;

Art. 4(6) keep that information for 20 years after R&D ends;

Art (4(5) if the information is insufficient, or uncertainties about the legality of access and utilization persist: obtain PIC/MAT or discontinue utilization;

Art. 7 submit a compliance declaration when receiving research funding or prior to commercialization.
Similar rules in ...

**Switzerland**

**Federal Act on the Protection of Nature and Cultural Heritage**

Art. 23a[8]

Notification of compliance with the due diligence requirement must be given to the FOEN before market authorisation has been obtained or, if such authorisation is not required, before the commercialisation of products developed on the basis of utilised genetic resources.

Art. 24e[8]

Any person who wilfully fails to provide information or provides false information under Article 23a shall be liable to a fine not exceeding 100,000 Swiss francs; in cases of negligence, the penalty shall be a fine not exceeding 40,000 Swiss francs. The court may order the publication of the judgment.[89]

**UK**

**Due diligence obligations of the EU Regulation which are subject to civil sanctions**

8.—(1) Subject to paragraphs (2) and (3), civil sanctions may be imposed in relation to a failure to comply with any of the following provisions—

(a) Article 4(1) of the EU Regulation (obligation to exercise due diligence);
(b) Article 4(3) of the EU Regulation (obligation to seek, keep and transfer information and documentation to subsequent users);
(c) Article 7(2) of the EU Regulation (obligation to make a declaration of due diligence).

(2) There is no failure to comply with the provisions referred to in paragraph (1) if the Secretary of State is satisfied that the user has shown that they have effectively implemented best practice recognised under Article 8(2) of the EU Regulation.

(3) There is no failure to comply with Article 4(3) of the EU Regulation if the Secretary of State is satisfied that—

(a) the user is considered to have exercised due diligence under Article 4(4) of the EU Regulation (use of the Plant Treaty’s Standard Material Transfer Agreement for material not listed in Annex 1 to that Treaty);
(b) the user is considered to have exercised due diligence under Article 4(7) of the EU Regulation (users obtaining material from a registered collection, or
(c) the use is in accordance with Article 4(9) of the EU Regulation (use of pathogen for the purpose of public health emergency preparedness).

**Korea**

**National Institute of Biological Resources**

ABSCH Genetic Resources Information Center

**Report compliance**

- Integrated Reporting Service
- Guide
- Report compliance

How to report procedural compliance for foreign genetic resources

- How to report procedural compliance for foreign genetic resources

- Fill in form
- Submit form
- Forms received (Request to modify if needed)
- Report accepted

**Japan**

**Chapter 2 Measures for promoting compliance with legislation in provider countries**

**No. 1 Report concerning the lawful access to genetic resources**

1. Report by acquirers

If a person has obtained access to genetic resources to which legislation in the provider country applies (excluding genetic resources, etc. to which the Protocol does not apply; the same applies hereinafter) and imported them into Japan (hereinafter referred to as an “acquirer”) and an internationally recognized certificate of compliance concerning the said
The future

Other ABS instruments are under way
Digital sequence information on genetic resources

16. **Decides** to establish, as part of the post-2020 global biodiversity framework, a multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including a global fund;¹

17. **Also decides** to establish a fair, transparent, inclusive, participatory and time-bound process to further develop and operationalize the mechanism, as outlined in paragraphs 18 and 20 to 22 below, to be finalized at the sixteenth meeting of the Conference of the Parties;

18. **Establishes** an ad hoc open-ended working group on benefit-sharing from the use of digital sequence information on genetic resources to undertake further development of the multilateral mechanism, including the elements identified in the annex, and to make recommendations to the Conference of the Parties at its sixteenth meeting.
The Future: Pathogens, Marine, and IP Disclosure

Diplomatic Conference on Intellectual Property and Genetic Resources

On July 21, 2022, the WIPO General Assembly decided to convene a Diplomatic Conference to conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources no later than 2024.

AGREEMENT ON MARRAKECH

ARTICLE 3
DISCLOSURE REQUIREMENT

3.1 Where the claimed invention in a patent application is [materially/directly] based on GRs, each Contracting Party shall require applicants to disclose:

(a) the country of origin of the GRs, or,

(b) in cases where the information in sub paragraph (a) is not known to the applicant, or where sub paragraph (a) does not apply, the source of the GRs.

Intergovernmental conference on an international legally binding instrument under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction

Resumed fifth session
New York, 20 February – 3 March 2023

MARINE GENETIC RESOURCES, INCLUDING QUESTIONS ON THE SHARING OF BENEFITS

Article 7
Objectives

The objectives of this Part are:

(a) The fair and equitable sharing of benefits arising from marine genetic resources of areas beyond national jurisdiction for the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction;

World Health Organization

THIRD MEETING OF THE INTERGOVERNMENTAL NEGOTIATING BODY TO DRAFT AND NEGOTIATE A WHO CONVENTION, AGREEMENT OR OTHER INTERNATIONAL INSTRUMENT ON PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE

Article 9. Fair, equitable and timely access and benefit-sharing

1. The Parties [shall]/[should] develop provisions on access and benefit-sharing to promote rapid and transparent sharing, in a safe and secure manner, of pathogens with pandemic potential and genetic sequence data on the one hand, and fair and equitable access to benefits arising from such sharing on the other, by establishing a comprehensive system for access and benefit-sharing, taking into account relevant elements of the Convention on Biological Diversity and its Nagoya Protocol, including by building upon or adapting mechanisms and/or principles contained in existing or previous instruments, such as, but not limited to, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and the WHO Pandemic Influenza Preparedness Framework.
Thank you

Contact me at
Bvanvooren@cov.com
About me & ABS

**Bart (first name) Van Vooren (last name) =**
- A life sciences regulatory lawyer (i.e. deep life sciences industry knowledge);
- Who has worked on ABS / Nagoya for 10 years;
- For food, pharma, cosmetics, biotech and agricultural clients;
- On a breadth of ABS-related assignments, including:
  - ABS public policy support at national, EU and international level
  - Trainings and organize compliance programs for startups and multinationals
  - ABS due diligence of specific biological assets, R&D projects and during M&A
  - In-depth advice on key ABS laws, including permit negotiations in *e.g.* France, South Africa, Viet Nam
  - Drafting ABS clauses in a range of contracts, *e.g.* material transfer, R&D collaboration
  - Engage during enforcement actions in provider and user countries
  - Litigation

**Email:** bvanvooren@cov.com
Panel Discussion

Wednesday September 13, 12:00 PM – 1:00 PM ET