PANEL DISCUSSION: Disclosure Requirement
WIPO Side Event
Geneve - April 23, 2013

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AGENDA

- Brazil and Biodiversity
- Statistics
- Brazilian Legislation
- Procedures for accessing GR/TK
- Downsides and Upsides
- Cases
- Conclusion
2/3 of the country is still covered by native vegetation
20% biodiversity in the world
> 220 native Indian communities (180 languages)
> 20 non-Indian traditional communities

http://nosenossascoisas.wordpress.com/2008/12/22/desconhecida-amazonia/
## CGEN and other governamental entities

<table>
<thead>
<tr>
<th>Period</th>
<th>Description</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004-2011</td>
<td>Granted Authorizations</td>
<td>622</td>
</tr>
<tr>
<td>2004-2011</td>
<td>Approved Agreements</td>
<td>31</td>
</tr>
<tr>
<td>Jan-Oct 2012</td>
<td>Approved and Published Agreements</td>
<td>23</td>
</tr>
</tbody>
</table>

More than 200 requests for authorizations under examination

### PTO

<table>
<thead>
<tr>
<th>Description</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimate number of pending patent applications or granted patents</td>
<td>250</td>
</tr>
</tbody>
</table>

Source: CGEN – Oct 2012
BRAZILIAN LEGISLATION

  - “To preserve the diversity and integrity of the genetic heritage of the country and to control entities engaged in research and manipulation of genetic material” (art. 225)

  - CGEN Resolution 34 (Feb 2009)

  - PTO Resolution 207 (Apr 2009) – renumbered as 692013

- State laws
BRAZILIAN LEGISLATION

- Federal Law 2.186-16
  - It regulates:
    - Access to GRs and associated TK
    - Access authorizations
    - BS agreement on the commercial use of components of the genetic heritage
  - It created the CGEN that stands for Genetic Heritage Management Council:
    - Established in April 2002
    - Representatives of 19 governmental entities
    - Only body granting access authorization to GRs and associated TK with potential commercial use
BRAZILIAN LEGISLATION

- **Federal Law (GR/TK)**
  - The person or institution applying for the IPRs must inform the origin of GR/TK (art. 31)
  - Penalties
    - Seizure of end products
    - Fines up to US$ 25M
  - Sanction: nullity of patent

- **CGEN Resolution**
  - the applicant of the patent application shall inform the Brazilian PTO the origin of GR/TK + number of the access authorization
BRAZILIAN LEGISLATION

- **Patent Law**
  - Non-patentable matter: biological material/molecules of natural origin, even if isolated and/or purified

- **PTO Resolution**
  - Affirmative or negative mandatory declaration regarding the access to GR/TK
  - Origin of the GR/TK + number of authorization access
    - Such information has been requested through publication of official action (deadline: 60-day period of time)
PROCEDURES FOR OBTAINING GR AND TK

Scientific research

1. Authorization for going into the area
2. Collecting information
3. Consent from the provider
4. Protocol before the gov. authority
5. Technical analysis
6. Authorization from gov. authority
7. Access to GR

Techological development

1. Authorization for going into the area
2. Collecting information
3. Previous consent and ABS with the provider
4. Protocol before CGEN
5. Analysis by Executive Secretariat
6. Compliance with office actions
7. Technical analysis
8. Access to GR and/or TK
9. CGEN Authorization
10. Preparation of Executive Secretariat
11. Additional requirements
DOWNSIDES & UPSIDES

- Complicated approval process
- ABS must be executed before access in case of potential economic use
- Very few access authorizations for commercial activities
- Less use of biodiversity = less R&D
- Less filing of patent applications

- Already existing legislation for ABS
**CASES**

- **Fines applied by IBAMA (Governmental Environment Entity):**
  - *Operação Novos Rumos* - Phase I (“New Paths” – Phase I)
    - August 2010
    - 80 entities
  - *Operação Novos Rumos* - Phase II
    - June 2012
    - 70 companies + 30 research institutes
      - Carnauba wax: coating pharmaceutical tablets
    » Results:
      - Fine, loss of investments and development of a new product line
CONCLUSION

- The disclosure requirement in patent cases seeks to identify the detection of the origin of the GR/TK and establishing ABS, however, it is hard to obtain the authorization for accessing GR/TK
- Legal uncertainty under the current legislation
- Ongoing discussions between Government and Industries, Traditional Communities and Academy towards a new Federal Law
THANK YOU!

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