

PANEL DISCUSSION: Disclosure Requirement

WIPO Side Event

Geneve - April 23, 2013

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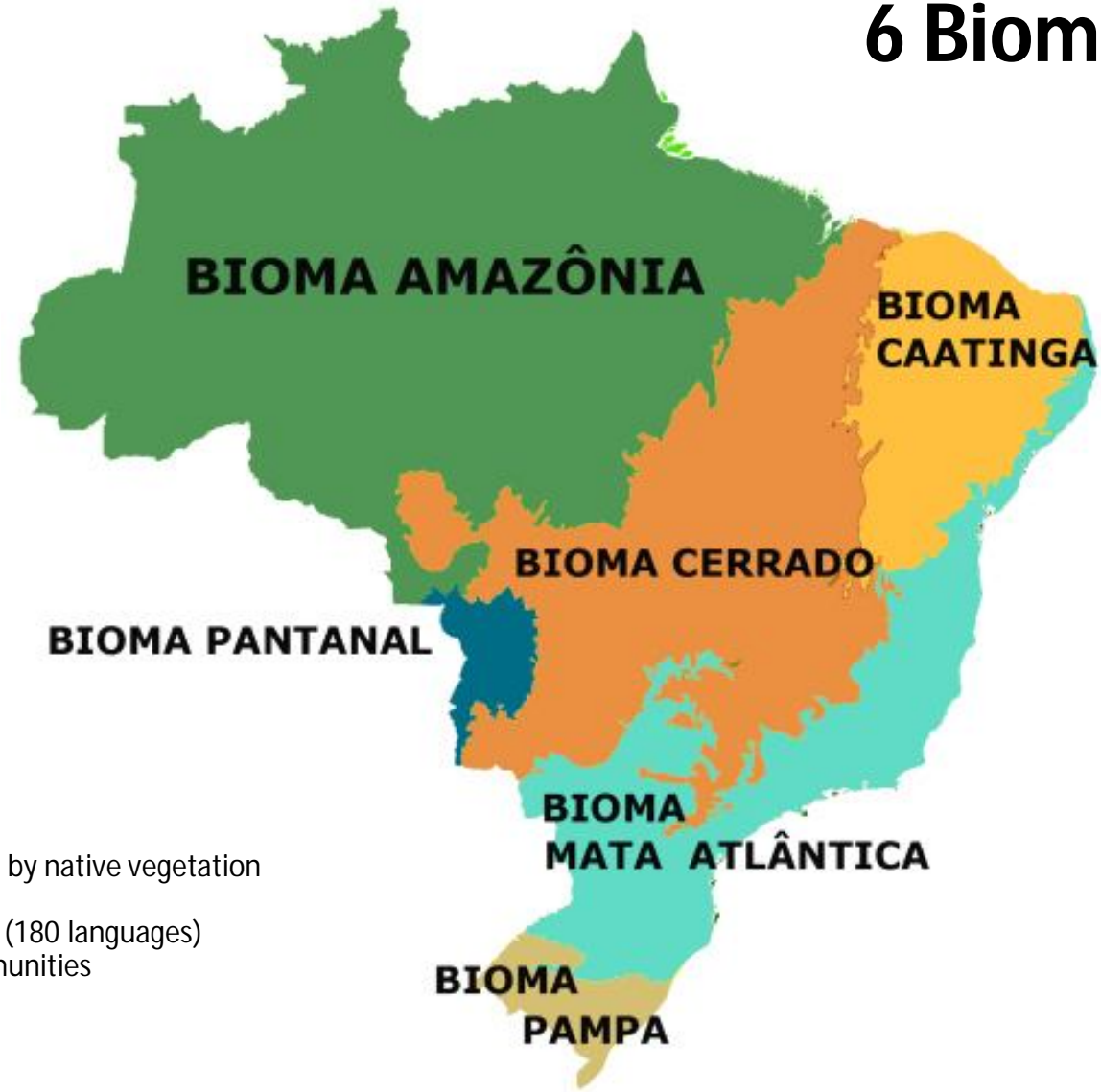
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AGENDA

- Brazil and Biodiversity
- Statistics
- Brazilian Legislation
- Procedures for accessing GR/TK
- Downsides and Upsides
- Cases
- Conclusion

BRAZIL AND BIODIVERSITY

6 Biomes



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

CGEN and other governamental entities		
2004-2011	Granted Authorizations	622
2004-2011	Approved Agreements	31
Jan-oct 2012	Approved and Published Agreements	23
More than 200 requests for authorizations under examination		
PTO		
Estimate number of pending patent applications or granted patents		250

Source: CGEN – Oct 2012

BRAZILIAN LEGISLATION

- Federal Constitution (1988)
 - *"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)

- Federal Law 2.186-16 (2000)
 - CGEN Resolution 34 (Feb 2009)

- Patent Law 9.279 (1997)
 - 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

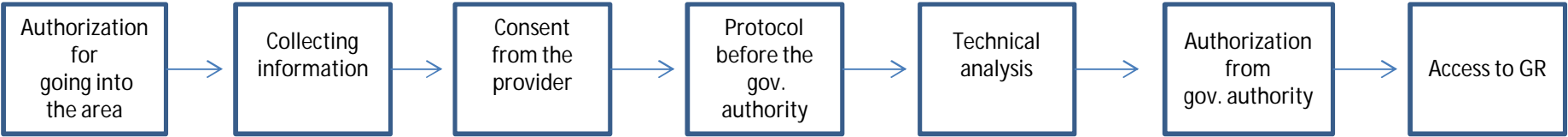
- Patent Law
 - Non-patentable matter: biological material/molecules of natural origin, even if isolated and/or purified

- 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)

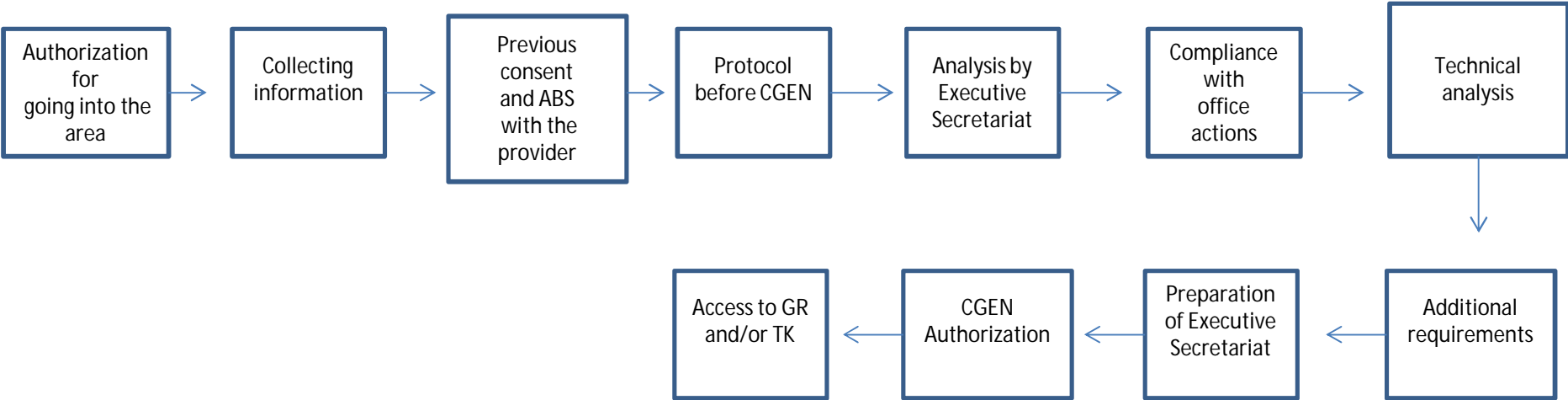


PROCEDURES FOR OBTAINING GR AND TK

Scientific research



Technological development



DOWNSIDERS & 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

- 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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