

IGC 36: Informal Information Session

Presentation by the Secretariat

June 13, 2018

Geneva



Welcome and Introduction

Mr. Wend Wendland

Director, Traditional Knowledge Division



Practical arrangements for the *ad hoc* expert group and IGC 36

Mrs. Fei Jiao

**Assistant Program Officer, Traditional Knowledge
Division**



2018

2019

IGC 35
GRs
(March 19
to 23)

Ad hoc
expert
group on
GRs
(June 24)

IGC 36
GRs
(June 25 to
29)
5 days

IGC 37
TK/TCEs
(August 27
to 31)

IGC 38
TK/TCEs
(December
10 to 14)
5/6 days

IGC 39
TK/TCEs

IGC 40
TK/TCEs



Ad hoc expert group on genetic resources (1/2)

- Objective: to address specific legal, policy or technical issues
- WIPO Secretariat invited:
 - Mr. Pedro Roffe, Senior Fellow, International Centre for Trade and Sustainable Development;
 - Ms. Manisha Desai, *Union Chimique Belge* (UCB); and
 - Mr. Paul Oldham, Director, One World Analytics / Senior visiting fellow, United Nations University.



***Ad hoc* expert group on genetic resources (2/2)**

■ Co-Chairs:

- Mr. Pedro Roffe, Senior Fellow, International Centre for Trade and Sustainable Development
- Ms. Krisztina Kovacs, Policy Officer, European Commission

■ Reporting to IGC 36:

- The Co-Chairs will report to the IGC plenary at IGC 36 on the outcomes of the *ad hoc* expert group's work.
- The report will be included in the report of IGC 36.



IGC Bureau

- IGC Chair

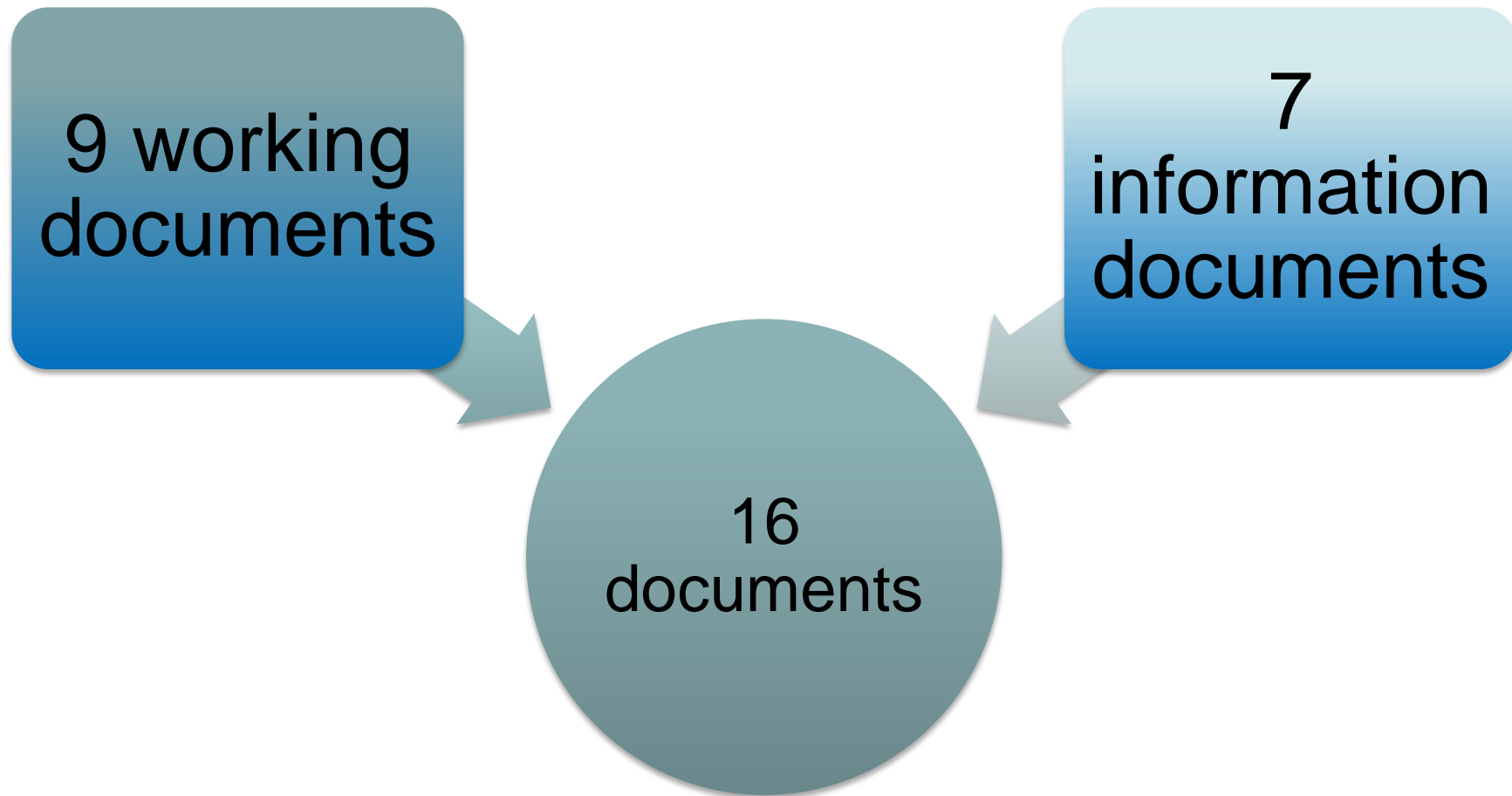
- Mr. Ian Goss of Australia

- IGC Vice-Chairs

- Mr. Jukka Liedes of Finland

- Mr. Faizal Chery Sidharta of Indonesia

IGC 36 documents





Information documents

- WIPO/GRTKF/IC/36/INF/1 (List of Participants)
- WIPO/GRTKF/IC/36/INF/2 (Summary of Documents)
- WIPO/GRTKF/IC/36/INF/3 (Draft Program)
- WIPO/GRTKF/IC/36/INF/4 (Information notes on Voluntary Fund)
- WIPO/GRTKF/IC/36/INF/5 Rev. (Indigenous Panel)
- WIPO/GRTKF/IC/36/INF/6 (Recommendation Adopted by the VF Advisory Board)
- WIPO/GRTKF/IC/36/INF/7 (Glossary)



Working documents

- WIPO/GRTKF/IC/36/1 Prov. 3 (Draft Agenda)
- WIPO/GRTKF/IC/36/2 (Accreditation)
- WIPO/GRTKF/IC/36/3 (Voluntary Fund)
- WIPO/GRTKF/IC/36/4 (Consolidated document Relating to IP and GRs)
- WIPO/GRTKF/IC/36/5 (Report on the Compilation of Materials on Databases Relating to GRs and Associated TK)
- WIPO/GRTKF/IC/36/6 (Report on the Compilation of Materials on Disclosure Regimes Relating to GRs and Associated TK)
- WIPO/GRTKF/IC/36/7 (Joint Recommendation on GRs and Associated TK)
- WIPO/GRTKF/IC/36/8 (Joint Recommendation on the Use of Databases for the Defensive Protection of GRs and TK Associated with GRs)
- WIPO/GRTKF/IC/36/9 (Proposal for the Terms of Reference for the Study by the WIPO Secretariat on Measures Related to the Avoidance of the Erroneous Grant of Patents and Compliance with Existing Access and Benefit-Sharing Systems)
- WIPO/GRTKF/IC/35/2 (Accreditation)

Recall

IGC's Mandate

The Secretariat is requested to produce a report(s) compiling and updating studies, proposals and other materials relating to tools and activities on databases and on existing disclosure regimes relating to GR and associated TK, with a view to identify any gaps.

IGC 36 documents

WIPO/GRTKF/IC/36/5
(Report on the Compilation of Materials on Databases Relating to GRs and Associated TK)

WIPO/GRTKF/IC/36/6
(Report on the Compilation of Materials on Disclosure Regimes Relating to GRs and Associated TK)

Content

WIPO Publications and Activities

Proposals from Member States

Regional and National Experiences

Historical Development of the TK Text

Historical Development of the GRs Text

WIPO Studies and Guide

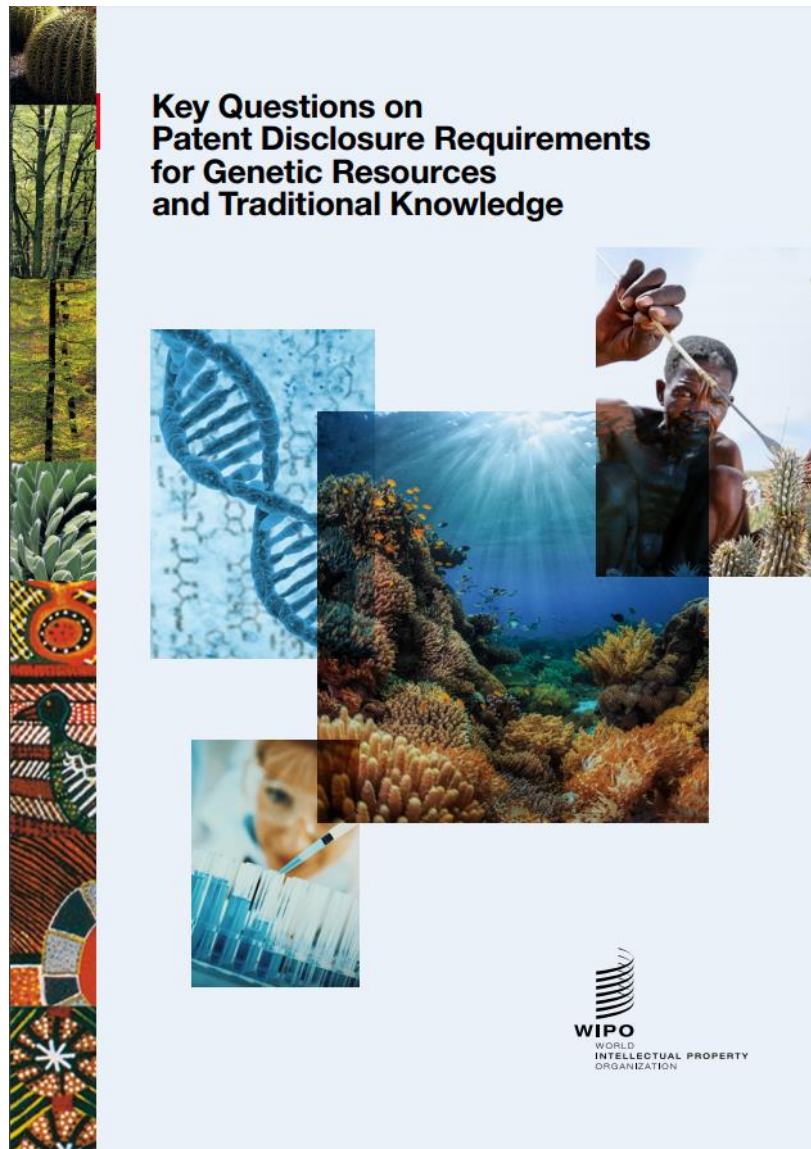
Database on Laws and Regulations

Proposals from Member States

Regional and National Experiences

Historical development of the GRs Text

Resources (1/4)





Resources (2/4)

■ Disclosure Requirements Table

(http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf)

Resources (3/4)



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Home | Policy | Traditional Knowledge | Resources

Regional, National, Local and Community Experiences

This page includes resources available on WIPO's website on regional, national, local and community experiences regarding intellectual property and genetic resources, traditional knowledge and traditional cultural expressions.

Table of contents

1. Laws, legislative measures and protocols
2. Fact-finding missions, surveys, submissions by member states and observers
3. Case studies
4. Lectures and presentations
5. Other resources

1. Laws, legislative measures and protocols

- Laws, treaties and regulations relevant to traditional knowledge, traditional cultural expressions and genetic resources
- Disclosure requirements table [PDF](#)
- Codes, guidelines and practices relating to the recording, digitization and dissemination of TCEs

2. Fact-finding missions, surveys, submissions by member states and observers

Report on fact-finding missions

- Intellectual Property Needs and Expectations of Traditional Knowledge Holders (WIPO Report on Fact-Finding Missions) [PDF](#)



Resources (4/4)

- Background Brief on GRs
- The IGC Preparation Kit
 - A one-stop destination for preparatory information, substantive working documents and other materials most directly relevant to each IGC session.
 - Updated with relevant information relating to the 36th session (working documents, background briefs, this briefing, useful links etc.)
- Indigenous Portal
 - Part of the WIPO Secretariat's effort to provide tailored resources for indigenous peoples and promote easy access to information for and about indigenous peoples and local communities.





Indigenous Participation in IGC 36

■ Indigenous Consultative Forum

- Not a formal committee session or official WIPO meeting, but endorsed by the Committee and facilitated by the Secretariat
- Sunday, June 24, 2018, 16h00

■ Indigenous Panel (shortened)

- Monday, June 25, around 11h00
- Theme: “Practical Measures Relating to Intellectual Property and Genetic Resources: Databases and Contracts – Indigenous Peoples’ and Local Communities’ Perspectives”
- Two panelists:
 - Mr. Aleksey Tsykarev, Member and Former Chairperson-Rapporteur of the United Nations Expert Mechanism on the Rights of Indigenous Peoples (Russian Federation)
 - Ms. Sue Noe, Attorney, Native American Rights Fund (United States of America)



To note...

- WIPO Voluntary Fund
 - No money
 - Nominations by Regional Groups for the Advisory Board to please be sent to grtkf@wipo.int by 12pm, Monday, June 25, 2018.



Meeting(s) with the IGC Chair

- Time:
 - 9:30 p.m., Thursday, June 21, 2018
 - 11 a.m., Friday, June 22, 2018 (Provisionally)
- Venue: TBC
- Participation: Regional Coordinators + interested delegates from Member States



Genetic Resources: Issues for IGC 36

Mr. Shakeel Bhatti, Counsellor, Traditional Knowledge Division



Substantive working documents

- WIPO/GRTKF/IC/36/4: Consolidated Document Relating to Intellectual Property and Genetic Resources
- WIPO/GRTKF/IC/36/5: Report on the Compilation of Materials on Databases Relating to Genetic Resources and Associated Traditional Knowledge
- WIPO/GRTKF/IC/36/6: Report on the Compilation of Materials on Disclosure Regimes Relating to Genetic Resources and Associated Traditional Knowledge
- WIPO/GRTKF/IC/36/7: Joint Recommendation on Genetic Resources and Associated Traditional Knowledge
- WIPO/GRTKF/IC/36/8: Joint Recommendation on the Use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated with Genetic Resources
- WIPO/GRTKF/IC/36/9: Proposal for the Terms of Reference for the Study by the WIPO Secretariat on Measures Related to the Avoidance of the Erroneous Grant of Patents and Compliance with Existing Access and Benefit-Sharing Systems

Structure of the Consolidated Document 36/4

- [Preamble]
- [Alternative Preamble]
- [Article 1] Definitions
 - Terms used in the operative articles
 - Other terms
- **[I. [Mandatory] Disclosure]**
- [Article 2] [Objective]
- [Article 3] [Subject matter of instrument]
- [Article 4] [Disclosure requirement]
- [Article 5] [Exceptions and limitations]
- [Article 6] [Sanctions and remedies]
- **[II. Alternatives to Articles 2-6; No New Disclosure Requirements]**
- Alt [Article 2] [Objective]
- Alt [Article 3] [Subject matter of instrument]
- Alt [Article 4] [Disclosure]
- **[III. [Defensive]/[complementary] measures]**
- [Article 7] [Due diligence]
- [Article 8] [[Prevention of the [erroneous] grant of patents and voluntary codes of conduct]
- **[IV. Final Provisions]**
- [Article 9] Preventive measures for protection]
- [Article 10] Relationship with international agreements
- [Article 11] International cooperation
- [Article 12] Transboundary cooperation
- [Article 13] Technical assistance, cooperation and capacity building



Two broad approaches in the current version of the consolidated document

■ **Disclosure Requirement:**

Inclusion of a disclosure requirement within IP/patent legislation relating to the disclosure of information in applications, where the subject matter includes utilization of, or is directly based on, GRs or TK associated with GRs. Within this approach, defensive measures are considered complementary measures and not an alternative approach to addressing policy objectives.

and/or

■ **Defensive Measures:**

This approach incorporates measures such as databases, voluntary codes and guidelines for IP/patent offices, third party dispute mechanisms and due diligence regimes within patent offices under national laws.

[Definitions]

■ Terms used in the operative articles

- Genetic material
- Genetic resources
- [TK associated with GR]
- [Country of origin]
- [Country providing/providing country]
- [Erroneous grant/granting of patents]
- [[Invention] directly based on]
- [Source]
- [Utilization]

■ Other terms

- In-situ conditions
- Ex-situ conditions
- [Biotechnology]
- [Country providing genetic resources]
- [Derivatiative]
- [misappropriation]
- [[Physical] access]
- [Protected genetic resources]
- [Sources of TK associated with GR]
- [unauthorized use]



[Objectives]

In relation to **disclosure requirements**, the following objectives have been identified:

- ensure mutual supportiveness with international agreements;
- enhance transparency in the IP/Patent system; and
- ensure the access to the appropriate information so as to prevent misappropriation.



[Subject matter of the instrument]

- Consideration whether, in addition to GRs, the text should also apply to TK associated with GRs
- TK is not always associated with a GR
- disclosure requirement provisions are currently included in the TK text before the IGC
- may wish to discuss whether disclosure requirements in the GRs text should also apply to TK associated with GRs



[Disclosure requirement]

a) Voluntary disclosure

European Union:*

- In its Preamble, the Directive encourages applicants to mention the geographical origin of biological material in the patent application:
- “(26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law.
- “(27) Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.”

*(Directive 98/44/EC on the Legal Protection of Biotechnological Inventions of July 6, 1998)**

* examples are without prejudice to any Member States' positions



[Disclosure requirement]

b) Mandatory disclosure

Norway:*

- “If an invention concerns or uses biological material or [TK], the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of [TK] shall be subject to prior consent, the application shall state whether such consent has been obtained. [...] Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 221. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.” ”

(Section 8(b) of the *Patents Act No. 9 of December 15, 1967 (consolidated version of 2016)*)

* examples are without prejudice to any Member States' positions

[Disclosure requirement]

c) Mandatory disclosure requirement of substantive nature

Andean community:*

- “The application for a patent shall be filed with the competent national office and shall contain the following: [...] (h) where applicable, a copy of the access contract where the products or processes for which a patent is sought have been obtained or developed from [GRs] or products derived therefrom of which any of the member countries is the country of origin; (i) where applicable, a copy of the document accrediting the licensing or the authorization of the use of the [TK] of the indigenous Afro-American or local communities of member countries where the products or processes for which protection is sought have been obtained or developed from such knowledge of which any of the member countries is the country of origin, in accordance with the provisions of Decision 391 and such of its amendments and implementing regulations as are in force.”

(Article 26 of *Decision No. 486 Establishing the Common Industrial Property Regime* (2000))

* examples are without prejudice to any Member States' positions



[Disclosure requirement] - content

■ **Three categories** of information have been proposed:

- (1) the country of origin;
- (2) the source of the GRs and/or TK; and
- (3) information regarding compliance with access and benefit-sharing requirements including prior informed consent.

(the definitions of “sources” and “country of origin” are relevant)

[Disclosure requirement] - trigger

Two options:

■ “utilization of”:

India: “Every complete specification shall [...] disclose the source and geographical origin of the biological material in the specification, when used in an invention.”

(Section 10 of the *Patents (Amendments) Act 2002*)*

■ “directly based on”:

Switzerland: “For inventions based on [GRs] or [TK] the patent application must contain information concerning the source:

(a) of the [GRs] to which the inventor or the applicant had access, when the invention is based directly on that resource;

(b) of [TK] of indigenous or local communities related to the [GRs] to which the inventor or applicant had access, when the invention is based directly on that knowledge.”

(Article 49 of the *Amendment of Patent Law of June 2, 2007, RO 2008 2551*)*

* examples are without prejudice to any Member States' positions



[Sanctions and remedies]

- inclusion of an administrative mechanism option at IGC 35, focused on ensuring transparency within the IP/patent system
- Open questions:
 - do pre-grant and post-grant measures need to be described in detail?
 - should non-compliance affect validity of a granted patent and, if so, what would permissible condition(s) for revocation be?



Defensive/complementary approaches

Existing views:

- defensive measures only, without any additional disclosure requirements, would be the best way to achieve the objectives.
- disclosure requirements could be complemented by defensive measures.



Alternative to Articles 2-6: No new disclosure requirement

■ [Article 2 - Objective]

[The objective of this instrument is to prevent the grant of patent rights on inventions that are not novel, non-obvious, and industrially applicable.]

■ [Article 3 – Subject matter of instrument]

This instrument [shall]/[should] apply to patent applications for inventions directly based on genetic resources and traditional knowledge associated with genetic resources.]



Alternative to Articles 2-6: No new disclosure requirement

■ [Article 4 – Disclosure]

4.1 Patent applicants may only be required to state where the GR can be obtained if that location is necessary for a person skilled in the art to carry out the invention. Therefore no disclosure requirements can be imposed upon patent applicants or patentees for patents related to GRs and [TK associated with GRs], for reasons other than those related to novelty, inventive step, industrial applicability and enablement.]

...

4.5 [The disclosure of the [geographic location] where the genetic material was obtained [shall]/[should]/[may][does] not place an obligation on the patent office to verify the contents of the disclosure. But patent offices [shall]/[should] provide guidance to patent applicants on how to meet the disclosure requirement as well as an opportunity for applicants or patentees to correct any disclosures that are erroneous or incorrect.

...



III. Defensive measures

[Article 7 - Due diligence]

[Member States]/[Parties] [shall]/[should] encourage or establish a fair and reasonable due diligence system to ascertain that [protected] GRs have been accessed in accordance with [applicable] [access and benefit-sharing] legislation or regulatory requirements.

- (a) Optional establishment of a database
- (b) Database should be accessible to potential patent licensees [and potential investors]]



Prevention of erroneous grant of patents

- Provide legal, policy or administrative measures
 - to prevent patents from being granted erroneously
 - to allow third party to dispute validity of a patent
- Develop and use voluntary codes of conduct and guidelines for users regarding protection of GRs
- Facilitate the creation, exchange, dissemination and access to, databases of GRs



Prevention of erroneous grant of patents (2)

■ Database Search System

- Members are encouraged to facilitate the establishment of databases of GR, [their derivatives] and [TK associated with GRs] for the purpose of search and examination of patent applications

■ WIPO Portal Site

- Member States shall/should establish a database search system (the WIPO Portal) that links databases of WIPO members that contain information on GRs within their territory.



Other useful information sources

- Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, <http://www.wipo.int/publications/en/details.jsp?id=4194>;
- Disclosure Requirement Table, http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf;
- Brief 10: Intellectual Property and Genetic Resources, <http://www.wipo.int/publications/en/details.jsp?id=4011>;
- Regional, National, Local and Community Experiences, http://www.wipo.int/tk/en/resources/tk_experiences.html;
- Lectures and presentations on the selected topics, http://www.wipo.int/tk/en/resources/tk_experiences.html#4



Discussion and Closing Remarks

**Facilitated by Mr. Edward Kwakwa, Senior Director,
Department for Traditional Knowledge and Global
Challenges, Global Issues Sector, WIPO**



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“IGC Preparation Kit”.