

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

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REPORT ON THE COMPILATION OF MATERIALS ON DISCLOSURE REGIMES RELATING TO GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE

Document prepared by the Secretariat

Background and Context

1. Disclosure is part of the core rationale of patent law. Patent law imposes a general obligation on patent applicants, as referred to in Article 29.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights and Article 5 of the Patent Cooperation Treaty (PCT), to “disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.”

2. In the context of genetic resources (GRs) and associated traditional knowledge (TK), the term “disclosure requirements” is used as a general term to refer to provisions in international, regional and/or national patent law which do or would specifically require patent applicants to disclose several categories of information¹ concerning GRs and/or associated TK when these are used in developing the invention claimed in a patent application.

¹ Three broad disclosures relating to GRs and associated TK have been considered:

- to disclose any GRs/associated TK actually used in the course of developing the claimed invention;
- to disclose the actual source of the GRs/associated TK – this may concern the country of origin or the country from which the resource or knowledge was acquired; and
- to provide an undertaking or evidence of compliance with relevant access and benefit-sharing requirements - this may entail showing that GRs/associated TK used in the claimed invention were obtained with prior informed consent and used in compliance with mutually agreed terms and applicable laws in the country of origin.

3. Since its First Session (April/May 2001), the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC) has discussed possible interfaces between intellectual property protection and access to GRs and associated TK, including possible disclosure requirements in the context of GRs and associated TK.
4. At its First Session (April/May 2001), the IGC examined document WIPO/GRTKF/IC/1/3, prepared by the Secretariat, which had identified four different topics related to GRs with possible tasks which the Member States might consider to set themselves in the IGC. The four different topics were “(i) contractual agreements for access to genetic resources and benefit-sharing; (ii) legislative, administrative and policy measures at the national and regional levels to regulate access to genetic resources; (iii) multilateral systems for facilitated access to genetic resources and benefit-sharing; and (iv) existing intellectual property frameworks for the legal protection of biotechnological inventions.”
5. As one of the possible legislative, administrative and policy measures to regulate access to GRs, the IGC began to discuss at that time the possible establishment of “a requirement that patent documents shall disclose the origin of the genetic resources used in the development of inventions and/or provide evidence that the resource was acquired legally” (Paragraph 44 of document WIPO/GRTKF/IC/1/3). At that same IGC session, the Group of Countries of Latin America and the Caribbean (GRULAC) proposed the adoption of “model provisions with which to control the use and exploitation of genetic and biological resources, and machinery for the equitable distribution of profits in the event of a patentable product or process being developed from a given resource” (Page 6 of Annex II of WIPO/GRTKF/IC/1/5).
6. Since then, some Member States have submitted proposals on disclosure requirements and the IGC has discussed various issues relating to possible disclosure requirements.
7. The WIPO General Assembly in 2017 requested the Secretariat 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.”
8. Pursuant to this decision, document WIPO/GRTKF/IC/35/6 was prepared, providing a non-exhaustive list of materials available on WIPO’s website relating to disclosure regimes in the sense described in paragraph 2 above (from now on in this document, “disclosure regimes” or “possible disclosure requirements” refers to disclosure in this sense). That document included a summary of studies and guides produced by the WIPO Secretariat, proposals from Member States, regional and national experiences, and the historical development of the text-based negotiations at the IGC relating to disclosure requirements. The same document with a few updates was re-issued for IGCs 36, 37, 38, 39 and 40, and is re-issued for this session as well.

WIPO Studies and Guides

9. **Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge – Second Edition** (available at <https://www.wipo.int/publications/en/details.jsp?id=4498>) offers a comprehensive and neutral overview of key legal and operational questions on patent disclosure requirements in relation to GRs and TK, based on the analysis of patent disclosure requirements in force at national and regional levels.
10. **Disclosure requirements table**, updated as of May 2019, (available at https://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf)

comprises a non-exhaustive selection of extracts from existing national and legislative texts providing for a specific disclosure requirement related to GRs and/or TK.

11. Upon the request of the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) at its Sixth Meeting in April 2002, the WIPO Secretariat prepared **the WIPO Technical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional Knowledge** (available at https://www.wipo.int/edocs/pubdocs/en/tk/786/wipo_pub_786.pdf), which was approved by the Thirtieth Session of the WIPO General Assembly (September 2003) (see documents WO/GA/30/7 and WO/GA/30/7 ADD.1) for transmission to the Seventh Meeting of the COP in February 2004. As a first step to develop the technical study, a Questionnaire on Various Requirements for Disclosure relating to Genetic Resources and Traditional Knowledge in Patent Applications (document WIPO/GRTKF/IC/3/Q.3) was sent to WIPO Member States for response. Document WIPO/GRTKF/IC/4/11 contains a compilation of the responses received from Member States to the above questionnaire.

Database on Laws and Regulations

12. The WIPO Secretariat has developed and keeps updating a searchable database on legal texts relevant to TK, traditional cultural expressions and GRs, including legal texts relating to disclosure requirements. The database is accessible at <https://www.wipo.int/tk/en/databases/tklaws/>.

Proposals from Member States

13. Since the establishment of the IGC, Member States have submitted proposals on disclosure requirements relating to GRs and associated TK. Those proposals are as follows, in chronological order.

14. In May 2003, the Delegation of Switzerland submitted a proposal regarding the declaration of the source of GRs and TK in patent applications to the Working Group on Reform of the Patent Cooperation Treaty (PCT) (see document PCT/R/WG/4/13, and, with identical contents, document PCT/R/WG/5/11). In this proposal, the Delegation suggested to amend the Regulations under the PCT in order to explicitly enable a national legislator to require the declaration of the source of GRs and TK in patent applications. The Delegation of Switzerland submitted document WIPO/GRTKF/IC/7/INF/5 to IGC 7 (November 2004) to present its further observations on the proposal. At IGC 11 (July 2007), the Delegation submitted a proposal (document WIPO/GRTKF/IC/11/10) regarding the declaration of the source of GRs and TK in patent applications, which had been originally submitted to the Working Group on Reform of the PCT in May 2003. The proposal contained in document WIPO/GRTKF/IC/11/10 was re-submitted at IGC 20 (February 2012) as document WIPO/GRTKF/IC/20/INF/10.

15. In March 2004, the African Group submitted a document (document WIPO/GRTKF/IC/6/12), entitled "Objectives, principles and elements of an international instrument, or instruments, on intellectual property in relation to genetic resources and on the protection of traditional knowledge and folklore". It proposed to introduce "a disclosure requirement in patent laws as well as evidence of compliance with national access and benefit sharing laws of the country of origin of genetic resources (disclosure of the source and country of origin of the genetic resource in claimed inventions and of the associated traditional knowledge used in the invention)".

16. In June 2005, The Delegation of the European Union (EU), on behalf of the EU and its Member States, submitted a proposal on disclosure requirements, entitled "Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications".

The proposal was annexed to document WIPO/GRTKF/IC/8/11, which was re-submitted at IGC 20 (February 2012) as document WIPO/GRTKF/IC/20/INF/8.

17. The Delegation of Japan submitted a document (document WIPO/GRTKF/IC/9/13), entitled “The Patent System and Genetic Resources”, in which it expressed its view on disclosure requirements. The document was resubmitted at IGC 20 (February 2012) as document WIPO/GRTKF/IC/20/INF/9.

18. Document WIPO/GRTKF/IC/13/9 contains the proposal of the African Group on the IGC’s work on GRs, including considering the development of disclosure requirements. The document was re-submitted at IGC 14 (June/July 2009) as document WIPO/GRTKF/IC/14/9.

19. The African Group submitted a proposal (document WIPO/GRTKF/IC/17/10) on GRs and future work, including its views on disclosure requirements. The document was re-submitted at IGC 20 (February 2012) as document WIPO/GRTKF/IC/20/INF/12.

20. The Delegations of Canada, Japan, the Republic of Korea and the United States of America submitted a “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” at IGC 23 (February 2013) as document WIPO/GRTKF/IC/23/6. The proposal was re-submitted at the following IGC sessions (WIPO/GRTKF/IC/24/6 REV., WIPO/GRTKF/IC/26/7, WIPO/GRTKF/IC/27/8, WIPO/GRTKF/IC/28/9, WIPO/GRTKF/IC/29/7, WIPO/GRTKF/IC/30/8, WIPO/GRTKF/IC/31/7, WIPO/GRTKF/IC/32/8, WIPO/GRTKF/IC/34/11, WIPO/GRTKF/IC/35/9, WIPO/GRTKF/IC/36/9, WIPO/GRTKF/IC/37/14, WIPO/GRTKF/IC/38/12, WIPO/GRTKF/IC/39/15 and WIPO/GRTKF/IC/40/17), and the Delegation of the Russian Federation became a co-sponsor.

Regional and national experiences

21. At its meeting in November 1999, the WIPO Working Group on Biotechnology agreed to prepare a list of questions about practices related to the protection of biotechnological inventions under patent and plant variety protection systems or a combination thereof by WIPO Member States. Questions 8, 9 and 10 were related to possible disclosure requirements. 56 Member States (Australia, Austria, Bangladesh, Belarus, Belgium, Benin, Brazil, Bulgaria, Cameroon, Canada, China, Colombia, Cuba, Cyprus, Republic of Korea, Denmark, Ecuador, El Salvador, Estonia, Ethiopia, Finland, Germany, Guatemala, Hungary, Iceland, India, Ireland, Italy, Japan, Kazakhstan, Lithuania, Madagascar, Malaysia, Mexico, Netherlands, New Zealand, Norway, Panama, Philippines, Poland, Portugal, Russian Federation, Saudi Arabia, Slovakia, Slovenia, Sri Lanka, Sweden, Switzerland, Thailand, The Former Yugoslav Rep. of Macedonia, United Kingdom, United States of America, Uruguay, Uzbekistan, Venezuela and Zambia) and the EU responded to the list of questions as a whole. Documents WIPO/GRTKF/IC/1/6 and WIPO/GRTKF/IC/1/6 Corr. reflect, in a synoptic manner, the information received.

22. The Delegation of the EU, on behalf of the EU and its Member States, submitted document WIPO/GRTKF/IC/1/8, including three annexes relating to disclosure requirements, entitled “Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions”, “Explanatory note on recital 27 of the above Directive concerning the indication of the geographical origin of biotechnological inventions”, and “Communication by the European Union and its Member States on the relationship between the CBD and the TRIPS Agreement”.

23. The Delegation of Spain submitted document WIPO/GRTKF/IC/2/15, expressing its views on “patents using biological sources material” and presenting some examples of the “mention of

the country of origin in patents using biological source material” in Spain, France, Belgium, Germany, the United States of America, Canada, Australia and China.

24. The Delegation of Peru submitted the following three documents:

- to share its experience on the fight against biopiracy, including its view on disclosure requirements (document WIPO/GRTKF/IC/8/12);
- to analyze potential cases of biopiracy, including a proposal of the inclusion of requirements on disclosure of the origin and legal source of such resources and knowledge as part of the process of revising Articles 27 and 29 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (document WIPO/GRTKF/IC/9/10); and
- to share its experience on combating biopiracy, including its view and experience on disclosure requirements (document WIPO/GRTKF/IC/11/13).

25. The Delegation of Indonesia submitted a report on the Asian-African Forum on Intellectual Property and Traditional Cultural Expressions, Traditional Knowledge and Genetic Resources, held in Bandung from June 18 to 20, 2007. This report is contained in document WIPO/GRTKF/IC/11/12 and includes a summary of the presentation made by Ms. Inger Holten on Norway’s views on disclosure requirements.

26. At IGC 15 (December 2009), Member States and observers were invited to “make available to the Secretariat papers describing regional, national and community policies, measures and experiences regarding intellectual property and genetic resources”. The following Member States and observers shared their policies, measures or experiences regarding disclosure requirements:

- the Delegation of Brazil (document WIPO/GRTKF/IC/16/INF/9);
- the Delegation of Norway (document WIPO/GRTKF/IC/16/INF/12);
- the Delegation of Switzerland (document WIPO/GRTKF/IC/16/INF/14);
- the Delegation of the European Union and its Member States (document WIPO/GRTKF/IC/16/INF/15);
- the Delegation of Mexico (document WIPO/GRTKF/IC/16/INF/16);
- the representatives of the Biotechnology Industry Organization (BIO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) (document WIPO/GRTKF/IC/16/INF/21); and
- the Delegation of China (document WIPO/GRTKF/IC/16/INF/27).

27. The Delegation of Norway submitted document WIPO/GRTKF/IC/23/INF/10, describing disclosure requirements in its Patent Act and Plant Breeder’s Act and some preliminary findings from an ongoing review of disclosure requirements.

28. The Delegation of the United States of America submitted a document (document WIPO/GRTKF/IC/30/9), entitled “Seeking a Better Understanding of Switzerland’s Federal Act on the Protection of Nature and Cultural Heritage and Federal Act on Patents for Inventions by Hypothetically Applying them to U.S. Patent Number 5,137,870”. In response to this document, the Delegation of Switzerland submitted a document (document WIPO/GRTKF/IC/31/8), entitled “The Declaration of the Source of Genetic Resources and Traditional Knowledge in the Swiss Patent Act and Related Swiss Regulations on Genetic Resources – Submission by Switzerland in Response to Document WIPO/GRTKF/IC/30/9”.

29. The Delegation of Switzerland submitted a document (document WIPO/GRTKF/IC/41/12), entitled “An International Disclosure of Source Requirement for Genetic Resources and

Associated Traditional Knowledge in Patent Applications – A Contribution to the Evidence-Based Approach”.

30. In 2015, 2016 and 2017, the WIPO Secretariat organized several Seminars on intellectual property and GRs/TK. The speakers from the following countries shared their national experiences on disclosure requirements:

- Brazil:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ip tk_ge_16/wipo_ip tk_ge_16_presentati on_8pinto.pdf;
- China:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ip tk_ge_16/wipo_ip tk_ge_16_presentati on_9yang.pdf;
- Peru:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ip tk_ge_15/wipo_ip tk_ge_15_presentati on_silvia_solis.pdf;
- Romania:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ip tk_ge_16/wipo_ip tk_ge_16_presentati on_11gorgescu.pdf; and
- Switzerland:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ip tk_ge_15/wipo_ip tk_ge_15_presentati on_martin_girsberger.pdf.

Historical development of the GRs text

31. Upon the request of Member States, the WIPO Secretariat, at IGC 11 (July 2007), prepared a brief list of options, contained in document WIPO/GRTKF/IC/11/8 (A), for continuing or further work on GRs, including work in the areas of disclosure requirements and alternative proposals for dealing with the relationship between intellectual property and GRs. The document was updated and re-issued several times at the following IGC sessions (WIPO/GRTKF/IC/12/8 (A), WIPO/GRTKF/IC/13/8 (A), WIPO/GRTKF/IC/16/6, WIPO/GRTKF/IC/17/6, WIPO/GRTKF/IC/18/10, WIPO/GRTKF/IC/19/7 and WIPO/GRTKF/IC/20/5).

32. The Third Intersessional Working Group (IWG 3) met from February 28 to March 4, 2011 to discuss GRs. IWG 3 prepared document WIPO/GRTKF/IC/18/9, entitled “Draft Objectives and Principles relating to Intellectual Property and Genetic Resources”, which included principles on possible disclosure requirements. This draft was discussed further at IGCs 19 and 20 (documents WIPO/GRTKF/IC/19/6 and WIPO/GRTKF/IC/20/4). The Like-Minded Countries also submitted a contribution to document WIPO/GRTKF/IC/18/9, which was issued as document WIPO/GRTKF/IC/19/11 and was later re-submitted as document WIPO/GRTKF/IC/20/6.

33. IGC 20 (February 2012) developed a “Consolidated Document Relating to Intellectual Property and Genetic Resources” (document WIPO/GRTKF/IC/23/4). This document includes draft provisions addressing disclosure requirements. The IGC further discussed and advanced the text in the following IGC sessions (WIPO/GRTKF/IC/25/5, WIPO/GRTKF/IC/26/4, WIPO/GRTKF/IC/28/4, WIPO/GRTKF/IC/29/4, WIPO/GRTKF/IC/30/4, WIPO/GRTKF/IC/34/4, WIPO/GRTKF/IC/35/4, WIPO/GRTKF/IC/36/4, WIPO/GRTKF/IC/40/6 and WIPO/GRTKF/IC/41/4).

34. In April 2019, Mr. Ian Goss, the Chair of the IGC for the 2018-2019 biennium, prepared a text of a *Draft International Legal Instrument Relating to Intellectual Property, Genetic*

Resources and Traditional Knowledge Associated with Genetic Resources, which includes provisions on disclosure requirements. The text is included in WIPO/GRTKF/IC/41/5.

Historical Development of the TK Text

35. Upon the request of Member States, the Secretariat, at IGC 7 (November 2004), prepared an overview of policy objectives and core principles on the protection of TK, contained in document WIPO/GRTKF/IC/7/5, for the IGC to use in developing substantive standards of the protection of TK. The document was revised and re-issued several times at the following IGC sessions (WIPO/GRTKF/IC/8/5, WIPO/GRTKF/IC/9/5, WIPO/GRTKF/IC/16/5, WIPO/GRTKF/IC/17/5 and WIPO/GRTKF/IC/18/5). Disclosure requirements were addressed in the document.

36. The Second Intersessional Working Group (IWG 2) met from February 21 to 25, 2011 to discuss TK. IWG 2 prepared document WIPO/GRTKF/IC/19/5, entitled “The Protection of Traditional Knowledge: Draft Articles”, which included disclosure requirements. This draft was discussed further at IGC 21 (document WIPO/GRTKF/IC/21/4). The Like-Minded Countries also submitted a contribution to document WIPO/GRTKF/IC/18/9, which was issued as documents WIPO/GRTKF/IC/19/11 and WIPO/GRTKF/IC/20/6. This contribution included provisions on disclosure requirements.

37. IGC 21 (April 2012) further developed the Draft Articles, which became document WIPO/GRTKF/IC/24/4, and included several provisions regarding disclosure requirements. The IGC further discussed and advanced the text in the following IGC sessions (WIPO/GRTKF/IC/25/6, WIPO/GRTKF/IC/27/4, WIPO/GRTKF/IC/28/5, WIPO/GRTKF/IC/31/4, WIPO/GRTKF/IC/32/4, WIPO/GRTKF/IC/34/5, WIPO/GRTKF/IC/37/4, WIPO/GRTKF/IC/38/4, WIPO/GRTKF/IC/39/4, WIPO/GRTKF/IC/40/4 and WIPO/GRTKF/IC/40/18).

Other Materials

38. At IGC 2 (December 2001), the Executive Secretary of the CBD submitted to the IGC the report of the CBD’s Ad Hoc Open-ended Working Group on Access and Benefit-Sharing (document WIPO/GRTKF/IC/2/11). The report includes some recommendations on disclosure requirements.

39. At IGC 13 (October 2008), the Biotechnology Industry Organization (BIO) provided its view on disclosure requirements in document WIPO/GRTKF/IC/13/8(C).

40. At its 11th session, the United Nations Permanent Forum on Indigenous Issues (UNPFII) requested the WIPO Secretariat to commission an independent technical review within the framework of indigenous human rights of the draft texts developed by the WIPO IGC. Professor James Anaya prepared the requested report independently, which was submitted to IGC 29 (February 2016) as document WIPO/GRTKF/IC/29/INF/10. The report includes his view on disclosure requirements from an indigenous perspective. The report was made available at the following IGC sessions (WIPO/GRTKF/IC/30/INF/10, WIPO/GRTKF/IC/31/INF/9, WIPO/GRTKF/IC/32/INF/8, WIPO/GRTKF/IC/33/INF/9, and WIPO/GRTKF/IC/34/INF/8).

41. At IGC 36, the Delegation of the United States of America submitted “The Economic Impact of Patent Delays and Uncertainty: U.S. Concerns about Proposals for New Patent Disclosure Requirements”, which was annexed to document WIPO/GRTKF/IC/36/10. It was resubmitted with a few updates at IGCs 37, 38, 39 and 40 as documents WIPO/GRTKF/IC/37/15, WIPO/GRTKF/IC/38/15, WIPO/GRTKF/IC/39/10 and WIPO/GRTKF/IC/40/11.

42. At the Seminars on intellectual property and GRs/TK organized by the WIPO Secretariat in 2015, 2016 and 2017, the following speakers shared their personal views on disclosure requirements and their presentations are available at:

- Mr. Pierre Du Plessis:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_iprk_ge_15/wipo_iprk_ge_15_presentation_pierre_du_plessis.pdf;
- Ms. Larisa Simonova:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_iprk_ge_15/wipo_iprk_ge_15_presentation_larisa_simonova.pdf;
- Mr. Paul Oldham:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_iprk_ge_15/wipo_iprk_ge_15_presentation_paul_oldham.pdf;
- Professor Ruth Okediji:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_iprk_ge_16/wipo_iprk_ge_16_presentation_10okediji.pdf; and
- Mr. Dominic Muyldermans:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_iprk_ge_16/wipo_iprk_ge_16_presentation_12muyldermans.pdf;
https://www.wipo.int/edocs/mdocs/tk/en/wipo_iprk_ge_15/wipo_iprk_ge_15_presentation_dominic_muyldermans.pdf.

43. The Committee is invited to take note of this document, and provide comments, including identifying any gaps, as it may wish.

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