

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

Fortieth Session
Geneva, June 17 to 21, 2019

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

Document prepared by the Secretariat

Background and Context

1. In relation to genetic resources (GRs) and traditional knowledge (TK), documentation is primarily a process by which information about GRs and TK is generated, identified, collected, recorded, organized or registered in some way, as a means to characterize, maintain, safeguard, preserve, manage, use, disseminate and/or protect GRs and TK (either positively or defensively) according to specific goals. Documentation of TK and GRs in the form of databases and registers, and technical issues surrounding it, have been raised in various contexts during the sessions of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC).

2. More generally, the IGC has discussed both the use of existing intellectual property systems and the possible establishment of a *sui generis* system for the protection of TK and for addressing intellectual property issues related to GRs. Within this context, documentation has been discussed for different purposes and from different perspectives. For example, at IGC 1 (April/May 2001), WIPO Member States discussed, as one of the possible tasks of the IGC, revising existing criteria and developing new criteria which would allow the effective integration of TK documentation into searchable prior art (Paragraphs 78 to 80 of document WIPO/GRTKF/IC/1/3). The IGC has also considered the potential roles and uses of databases, registers and other collections of GRs and/or TK as positive and/or defensive protection tools, whether as stand-alone mechanisms and/or as part of and related to implementation of *sui generis* systems of TK protection (Paragraph 50 of document WIPO/GRTKF/IC/3/8).

3. The early sessions of the IGC addressed two streams of measures relating to the documentation of TK (document WIPO/GRTKF/IC/2/6):

- Measures related to the procedures of patent granting authorities, such as the inclusion of TK in Patent Cooperation Treaty (PCT) minimum documentation (see paragraph 9 below), and the recognition of TK in search and examination procedures for patent examiners and applicants; and
- Measures related to TK documentation projects and initiatives, such as guidelines for IP management during a documentation process, which led, for example, to the development of the TK documentation toolkit (see paragraph 8 below), and interfaces between documentation and the protection of TK, whether positively and/or defensively.

4. Initially, the IGC addressed the documentation of only TK. Regarding GRs, discussions in the IGC on the interface between patents and databases of GRs and associated TK started at IGC 9 (April 2006), where the Delegation of Japan submitted a document (document WIPO/GRTKF/IC/9/13), entitled “The Patent System and Genetic Resources”, in which it proposed the development of a database related to GRs and TK accessible by patent examiners worldwide.

5. A growing number of initiatives seek to use databases, platforms and registries to preserve and protect TK and GRs, whether positively and/or defensively. The WIPO Secretariat (under Program 4 of WIPO) provides, on request, intellectual property-related technical and policy information and assistance concerning the documentation of GRs and/or TK. Most requests concern documentation undertaken for the purposes of facilitating positive protection, defensive protection and/or research and development.

6. 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”.

7. Pursuant to this decision, document WIPO/GRTKF/IC/35/5 was prepared. That document provided a non-exhaustive list of materials available on WIPO’s website relating to “databases”¹, including a summary of publications and activities of the WIPO Secretariat, proposals from Member States, regional and national experiences, and the historical development of the text-based negotiations at the IGC concerning databases relating to GRs and associated TK. The document also covered tools and activities on databases relating to GR, associated TK and TK as such. The same document with a few updates was re-issued for IGCs 36, 37, 38 and 39, and is re-issued for this session as well.

WIPO Publications and Activities

8. Documenting TK can raise important issues, especially as regards intellectual property. **Documenting Traditional Knowledge – A Toolkit** presents a range of easy-to-use checklists and other resources to help ensure that anyone, especially indigenous peoples and local communities, considering a documentation project can address those issues effectively. It provides practical guidance on key issues that need to be thought through before, during and after documenting TK. It is available at <https://www.wipo.int/publications/en/details.jsp?id=4235>. This publication was originally developed under the auspices of the IGC and the proposal on

¹ While there are various forms of documentation, such as registers, databases, platforms, inventories, catalogues, etc., this document uses the term “databases” to cover all various forms of documentation. This document does not address databases, or any other forms of documentation, of traditional cultural expressions.

this publication was considered and approved by the IGC at IGC 3 (June 2002). After several interim drafts, a consultation draft of the Toolkit was published in November 2012 and the final version entitled 'Documenting Traditional Knowledge – A Toolkit' was published in late 2017.

9. As briefly mentioned above, at IGC 1 (April/May 2001), Member States discussed issues relating to TK documentation and searchable prior art, namely, the lack of availability of databases of non-patent prior art literature with TK documentation data; the unavailability of classification tools for TK which are required in order to integrate TK into existing classifications systems of patent documents; and, a lack of bibliographic details about TK-related gazettes, articles and newsletters in the PCT minimum documentation list (paragraph 79 of WIPO/GRTKF/IC/1/3). At IGC 2 (December 2001), document WIPO/GRTKF/IC/2/6 was prepared on the status of TK as prior art, including practical measures for the improvement of availability, searchability and exchangeability of TK-related non-patent literature. At IGC 3 (June 2002), the Secretariat prepared document WIPO/GRTKF/IC/3/6, entitled "Inventory of Existing Online Databases Containing Traditional Knowledge Documentation Data", which includes experiences from China, India and Venezuela concerning TK databases. This document also includes a non-exhaustive inventory of traditional knowledge-related periodicals with a recommendation that certain periodicals be considered for integration by the International Searching Authorities into the **minimum documentation list under the PCT**. In 2005, the Meeting of International Authorities under the PCT (PCT/MIA) agreed to include some TK related documentation in the PCT minimum documentation (document PCT/MIA/11/5). It also decided to establish a Task Force to undertake a comprehensive review of the PCT minimum documentation, and the review should address both patent documentation and non-patent literature, including TK-related databases (paragraphs 9 to 12 and 18 of document PCT/MIA/11/14).

10. In 2015, India submitted a request to the PCT/MIA to add the Indian Traditional Knowledge Digital Library (TKDL) to the PCT minimum documentation (document PCT/MIA/22/8). The following year, the PCT/MIA referred this matter to the PCT Minimum Documentation Task Force with a renewed mandate (paragraph 85 of document PCT/MIA/23/14). At the PCT/MIA in February 2018, India presented a further working document on the inclusion of the TKDL in the PCT minimum documentation, along with a revised access agreement intending to address concerns that had been raised by some International Authorities during previous discussions of the proposal (document PCT/MIA/25/9). The Indian Patent Office has since shared these documents with the Task Force for consideration as part of its objective to recommend criteria and standards for the review, addition and maintenance of non-patent literature and TK-based prior art under the renewed mandate. As a first step towards achieving this objective, in July 2018, a questionnaire on non-patent literature, TK-based prior art and inclusion of databases in the PCT Minimum Documentation was circulated by the Task Force among the International Searching and Preliminary Examination Authorities². Responses has been received from 15 International Authorities. A full analysis will be provided on the task force wiki and to the PCT Working Group to form the basis of further discussions. An initial review suggested that some of the main concerns related to the fact that the best sources of non-patent literature were constantly changing and difficult to document. Many searches used sources outside the minimum documentation. Accessibility to non-patent literature was sometimes difficult and there were concerns over confidentiality restrictions that might limit the ability of examiners, applicants and third parties to properly evaluate prior art references.³

² C. PCT 1544 of July 9, 2018, available at: <https://www.wipo.int/export/sites/www/pct/en/circulars/2018/1544.pdf>.

³ See PCT/MIA/26/13, para. 76.

11. The WIPO Secretariat has compiled and keeps updating a collection of **online databases and registries of TK and GRs** provided by WIPO Member States and other organizations. The list is accessible at https://www.wipo.int/tk/en/resources/db_registry.html.

Proposals from Member States

12. Since the establishment of the IGC, Member States have submitted a number of proposals on databases relating to GRs and associated TK. Those proposals are as follows, in chronological order.

13. At IGC 1 (April/May 2001), the Delegation of the European Union (EU), on behalf of the EU and its Member States, proposed to examine “how to make more information available on traditional knowledge to patent offices (through databases or registration) so as to allow patent examiners to take them into account as prior art, in order to reduce the risk of abusive patents” (document WIPO/GRTKF/IC/1/8).

14. At IGC 2 (December 2001), the Asian Group and the Delegation of China submitted a position paper (WIPO/GRTKF/IC/2/10) on TK, including suggestions on databases.

15. At IGC 3 (June 2002), the African Group submitted a document (document WIPO/GRTKF/IC/3/15), entitled “The Position of the African Group”, in which it expressed its position on *inter alia* databases and encouraged “African States to establish traditional knowledge databases and make them available, in cases where ‘defensive protection’ of disclosed traditional knowledge is desired”.

16. At IGC 4 (December 2002), the Asian Group submitted a proposal (document WIPO/GRTKF/IC/4/14), entitled “Technical Proposals on Databases and Registries of Traditional Knowledge and Biological/Genetic Resources (Submitted by the Asian Group)”.

17. At IGC 9 (April 2006), the Delegation of Japan submitted a document (document WIPO/GRTKF/IC/9/13), entitled “The Patent System and Genetic Resources”, in which it proposed to develop a database system related to GRs and TK accessible by examiners worldwide. The document was resubmitted at IGC 20 (February 2012) as document WIPO/GRTKF/IC/20/INF/9. At IGC 11 (July 2007), the Delegation of Japan submitted a document (WIPO/GRTKF/IC/11/11), entitled “Additional Explanation from Japan regarding the document WIPO/GRTKF/IC/9/13 on the Patent System and Genetic Resources”, proposing a “one-click database search system” relating to GRs and associated TK. The document was resubmitted at IGC 20 (February 2012) as document WIPO/GRTKF/IC/20/INF/11.

18. At IGC 17 (December 2010), the African Group submitted a proposal (document WIPO/GRTKF/IC/17/10) on GRs and future work, in which it suggested that the use of available databases on GRs and/or associated TK could be considered for defensive protection. The document was resubmitted at IGC 20 (February 2012) as document WIPO/GRTKF/IC/20/INF/12.

19. At IGC 20 (February 2012), the Delegations of Canada, Japan, Norway, the Republic of Korea and the United States of America submitted a document (document WIPO/GRTKF/IC/20/9 REV.), entitled “Joint Recommendation on Genetic Resources and Associated Traditional Knowledge”, in which they proposed the use of databases to prevent the erroneous grant of patents and to allow third parties to dispute the validity of a patent. The document was resubmitted at the following IGC sessions: WIPO/GRTKF/IC/23/5, WIPO/GRTKF/IC/24/5, WIPO/GRTKF/IC/26/5, WIPO/GRTKF/IC/27/6, WIPO/GRTKF/IC/28/7, WIPO/GRTKF/IC/29/5, WIPO/GRTKF/IC/30/6, WIPO/GRTKF/IC/31/5, WIPO/GRTKF/IC/32/6,

WIPO/GRTKF/IC/34/9, WIPO/GRTKF/IC/35/7, WIPO/GRTKF/IC/36/7, WIPO/GRTKF/IC/37/12, WIPO/GRTKF/IC/38/10 and WIPO/GRTKF/IC/39/13.

20. At IGC 23 (February 2013), the Delegations of Canada, Japan, the Republic of Korea and the United States of America submitted a “Joint Recommendation on the Use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated with Genetic Resources” as document WIPO/GRTKF/IC/23/7. The proposal was resubmitted at the following IGC sessions: WIPO/GRTKF/IC/24/7, WIPO/GRTKF/IC/26/6, WIPO/GRTKF/IC/27/7, WIPO/GRTKF/IC/28/8, WIPO/GRTKF/IC/29/6, WIPO/GRTKF/IC/30/7, WIPO/GRTKF/IC/31/6, WIPO/GRTKF/IC/32/7, WIPO/GRTKF/IC/34/10, WIPO/GRTKF/IC/35/8, WIPO/GRTKF/IC/36/8, WIPO/GRTKF/IC/37/13, WIPO/GRTKF/IC/38/11 and WIPO/GRTKF/IC/39/14.

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. Question 12 was related to databases. 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 European Union 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 United States of America submitted document WIPO/GRTKF/IC/4/13, entitled “Access to Genetic Resources Regime of the United States of America”, including its experience on databases relating to GRs and associated TK.

23. Document WIPO/GRTKF/IC/5/INF/2 includes the Provisional Measure No. 2.186-16 of August 23, 2001 of Brazil, which contains provisions regarding the establishment of databases on GRs and associated TK.

24. Document WIPO/GRTKF/IC/7/7 provides the experiences of the following databases/registers with intellectual property issues concerning recorded or registered TK: China Traditional Chinese Medicine (TCM) Patent Database, “StoryBase” of the Tulalip Tribes of Washington State, Traditional Knowledge Digital Library of Ayurveda, and Registers of the Collective Knowledge of Indigenous Peoples under Law No. 27811 of Peru. The document was updated at IGC 8 (June 2005) as document WIPO/GRTKF/IC/8/7.

25. At IGC 9 (April 2006), the Delegation of South Africa submitted document WIPO/GRTKF/IC/9/11, entitled “Republic of South Africa: Indigenous Knowledge Systems Policy”, including a policy on the database of indigenous knowledge.

26. 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 summaries of the presentations made. Speakers from China, Peru and South Africa shared their experiences on databases.

27. 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 databases:

- the Delegation of Algeria (document WIPO/GRTKF/IC/16/INF/10);
- the representative of the International Institute for Environment and Development (IIED) (document WIPO/GRTKF/IC/16/INF/13);
- the Delegation of Mexico (document WIPO/GRTKF/IC/16/INF/16); and
- the Delegation of Kenya (document WIPO/GRTKF/IC/16/INF/25).

28. At IGC 29 (February 2016), the IGC decided that “[w]ith regard to resources that Committee participants may wish to use as reference materials in their preparations for Committee sessions: [...] Member States and observers are invited to send to the Secretariat [...] references for any other resources that may be relevant for Committee participants as reference materials, and the Secretariat shall communicate a list of such references, as provided, to the Thirtieth Session of the Committee in an information document.” The Delegations of the Republic of Korea and the United States of America shared their experience on databases (documents WIPO/GRTKF/IC/30/INF/9 and WIPO/GRTKF/IC/31/INF/8).

29. In March 2011, the Government of India and the WIPO Secretariat co-organized an International Conference on Utilization of the Traditional Knowledge Digital Library (TKDL) as a Model for Protection of Traditional Knowledge. Experts from India, the European Patent Office (EPO) and United States Patent and Trademark Office (USPTO) shared their experiences on databases. Their presentations are available at https://www.wipo.int/meetings/en/details.jsp?meeting_id=22423.

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 experiences on databases:

- ARIPO:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ipatk_ge_16/wipo_ipatk_ge_16_presentation_15sackey.pdf;
- EPO:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ipatk_ge_2_15/wipo_ipatk_ge_2_15_presentation_enrico_luzzatto.pdf;
- India:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ipatk_ge_2_15/wipo_ipatk_ge_2_15_presentation_usha_rao.pdf;
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ipatk_ge_2_16/wipo_ipatk_ge_2_16_presentation_12javed.pdf;
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ipatk_ge_16/wipo_ipatk_ge_16_presentation_13dhar.pdf;
- Japan:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ipatk_ge_2_15/wipo_ipatk_ge_2_15_presentation_yoshinari_oyama.pdf;
- Royal Botanic Gardens, Kew:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ipatk_ge_16/wipo_ipatk_ge_16_presentation_17williams.pdf;

- South Africa:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ip tk_ge_2_15/wipo_ip tk_ge_2_15_presentation_yonah_seleti.pdf.

Historical Development of the TK Text

31. 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. TK databases were addressed in the document. 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).

32. 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 one article on the maintenance of registers or other records of TK for transparency, certainty and the conservation of TK. 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 databases.

33. IGC 21 (April 2012) further developed the Draft Articles, which became document WIPO/GRTKF/IC/24/4, and included several provisions regarding databases. 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 and WIPO/GRTKF/IC/40/4).

Historical Development of the GRs Text

34. Upon the request of Member States, the Secretariat, at IGC 11 (July 2007), prepared a list of options, contained in document WIPO/GRTKF/IC/11/8 (A), for continuing or further work on GRs. One option was an “inventory of databases and information resources on GRs” and another one was “information systems on GR for defensive protection”. 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).

35. 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 regarding databases. 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 (documents WIPO/GRTKF/IC/19/11 and WIPO/GRTKF/IC/20/6).

36. IGC 20 (February 2012) developed a “Consolidated Document Relating to Intellectual Property and Genetic Resources” (document WIPO/GRTKF/IC/23/4), which includes provisions on databases. 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 and WIPO/GRTKF/IC/40/6).

Other Materials

37. Upon Member States' request, at IGC 3 (June 2002), the Secretariat prepared document WIPO/GRTKF/IC/3/8, entitled "Elements of a *Sui Generis* System for the Protection of Traditional Knowledge", including a "system of *sui generis* databases". The document was updated and re-issued as document WIPO/GRTKF/IC/4/8.

38. The Delegation of the EU, on behalf of the EU and its Member States, provided its view on databases in document WIPO/GRTKF/IC/3/16.

39. At IGC 5 (July 2003), the Secretariat also prepared document WIPO/GRTKF/5/12, entitled "Overview of Activities and Outcomes of the Intergovernmental Committee", which included a short summary of the discussions at the IGC on databases. At IGC 6 (March 2004) and IGC 11 (July 2007), updated versions of this document (documents WIPO/GRTKF/IC/6/8 and WIPO/GRTKF/IC/11/9) were issued.

40. At IGC 27 (March/April 2014), the Delegations of Canada, Japan, Norway, the Republic of Korea and the United States of America made available a document, entitled "Responses to Questions Regarding National-Level Databases and an International Portal", as an information document (document WIPO/GRTKF/IC/27/INF/11). There were questions that had been asked at the IGC regarding the creation and use of databases for GRs and/or TK. This document compiled the comments of Canada, Japan, Norway, South Africa, the Republic of Korea, Sweden, and the United States of America that responded to those questions. The document was resubmitted at IGC 28 (July 2014) as document WIPO/GRTKF/IC/28/INF/10.

41. 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 experiences on databases:

- Ms. Shelley Rowe:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ip tk_ge_16/wipo_ip tk_ge_16_presentati on_14rowe.pdf; and
- Ms. Aroha Te Pareake Mead:
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ip tk_ge_16/wipo_ip tk_ge_16_presentati on_16mead.pdf.

42. 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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