

WIPO



WIPO/GRTKF/IC/6/8

ORIGINAL: English

DATE: December 15, 2003

E

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

Sixth Session
Geneva, March 15 to 19, 2004

DEFENSIVE PROTECTION MEASURES RELATING TO INTELLECTUAL PROPERTY,
GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE: AN UPDATE

Document prepared by the Secretariat

I. OVERVIEW

1. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“the Committee”) has developed and implemented a range of practical mechanisms for the defensive protection of traditional knowledge (TK) and genetic resources. It has also referred proposals to other WIPO bodies which have taken up defensive protection measures relating to TK. At its fifth session, the Committee considered a comprehensive overview of defensive measures, document WIPO/GRTKF/IC/5/6, and noted some points that required clarification. This document supplements and updates the full report in document WIPO/GRTKF/IC/5/6. It gives an update on the practical steps in the development of defensive protection measures. It then clarifies some of the issues raised in the previous document, and in other material and discussions within the Committee.

2. The term “defensive protection,” when applied to TK and genetic resources, refers to measures aimed at preventing the acquisition of intellectual property rights over TK or genetic resources by parties other than the customary custodians of the knowledge or

resources.¹ The development of measures for defensive protection have formed a significant component of the early outcomes of the Committee. An overview of the outcomes produced by the Committee was contained in Annex 1 of document WIPO/GRTKF/IC/5/6.

3. In the work of the Committee, it has frequently been stressed that protection of TK should be undertaken in a comprehensive manner, potentially using both positive and defensive forms of protection. Defensive protection is no substitute for positive protection, and should not be mistaken for the acquisition and active exercise of rights in the protected material. Its impact is limited to preventing other parties from gaining intellectual property (IP) rights, and does not in itself prevent others from using this material. Often, the active assertion of rights (positive protection) is necessary to prevent the unauthorized or illegitimate use of TK. In some scenarios, defensive protection may actually undermine the interests of TK holders, particularly when this involves giving the public access to TK which is otherwise undisclosed, secret or inaccessible. In the absence of positive rights, public disclosure of TK may actually facilitate the unauthorized use of TK which the community wishes to protect.

4. Previous discussion has clarified that defensive protection strategies focussed on the patent system have two aspects:

- a legal aspect, ensuring that information is published or documented in such a way as to meet the legal criteria to be counted as prior art in the jurisdiction concerned (this may include, for instance, ensuring that there is a clear date of publication, and that the disclosure enables the reader to put the technology into effect); and
- a practical aspect, ensuring that in fact the information is available to search authorities and patent examiners, and is readily accessible (such as through being indexed or classified), so that it is likely to be found in a search for relevant prior art.

These two aspects were elaborated fully in the previous survey in document WIPO/GRTKF/IC/5/6.

II. UPDATE ON DEFENSIVE PROTECTION MEASURES

International Patent Classification

5. Paragraphs 44 to 52 of document WIPO/GRTKF/IC/5/6 described the current activities to update and expand the International Patent Classification (IPC) to take better account of TK subject matter, and in particular concerning medicinal products based on plant extracts. It described how a WIPO Task Force on Classification of Traditional Knowledge had developed a new main group for the IPC, designated A61K 36/00, with approximately 200 subgroups, in the field of medicinal preparations containing plants. This should increase the likelihood that patent examiners will locate already published TK that is relevant to claimed inventions in patent applications, without adversely affecting the legal status of TK from the point of view of TK holders.

6. The IPC Revision Working Group, at its tenth session held in Geneva from November 24 to December 5, 2003, approved the revision proposal relating to traditional

¹ See the overview of forms of legal protection provided in document WIPO/GRTKF/IC/5/12, from paragraph 17, and the discussion of defensive protection from paragraph 28.

medicine classifications, with some amendments.² The results of this revision would be ready to submit to the next session of the Committee of Experts for final adoption which is scheduled to take place in February 2004 and would be integrated into the new edition of the IPC that will be published in June 2004 and will enter into force on January 1, 2005.

7. The Committee of Experts of the IPC Union has agreed with the suggestion of the Task Force that a more detailed revision could be carried out at a later stage, in the course of the next IPC revision period. This opens up the scope for future development of the IPC to draw on further practical experience in various countries concerning the interaction between TK systems and the patent system, as the IPC system moves towards a more interactive mode of revision and development, based on the separation of the IPC into a relatively stable core level and a dynamic advanced level. The advanced level will always be the current, continuously updated IPC 'edition.'³

8. The Committee of Experts has instructed the Task Force to continue its work on further development of classification tools for traditional knowledge and to investigate possible patent classification aspects relating to components of biodiversity and folklore and requested the Task Force to consider how the future revised IPC could be linked to TK resources classifications which may be developed in various countries, and how to best organize access to TK documentation which was in public domain, including hyperlinking the IPC to TK databases.

9. A work progress report will be submitted by the Task Force to the Committee at its next session which is scheduled to take place from February 23 to 27, 2004.

Revision of the Minimum Documentation under the Patent Cooperation Treaty

10. As document WIPO/GRTKF/IC/5/6 noted, the "Patent Cooperation Treaty (PCT) is a WIPO-administered treaty for international cooperation in the field of patents. One international patent application under the PCT can have the legal effect of simultaneously filing applications in a large number of countries throughout the world. Importantly, from the point of view of the current document, the PCT provides for international coordination with regard to the filing, searching and examination of patent applications and the publication of technical information contained therein. The PCT simplifies and reduces the cost of obtaining patent protection and facilitates public access to a wealth of technical information relating to inventions, including in the field of TK and genetic resources. The international search and examination processes also have significance for defensive protection strategies."

PCT Minimum Documentation

11. Article 15(4) of the PCT provides that in the context of international searches "[t]he International Searching Authority ... shall endeavor to discover as much of the relevant prior art as its facilities permit, and shall, in any case, consult the documentation specified in the Regulations." The "documentation specified in the Regulations" is specified in Rule 34 of the Regulations Under the PCT and is generally referred to as the PCT minimum documentation.

² See the report of this Working Group in document IPC/WG/10/3 Prov.

³ See 'What are the goals of IPC reform?' at http://www.wipo.int/classifications/en/ipc/faq/ipcfaq-ver01.htm#P348_22246

Rule 34 provides that the minimum documentation shall include certain national patent documents, as specified in the Regulations, the published international applications, the published regional applications for patents and inventors' certificates, the published regional patents and inventors' certificates, and "such other published items of non-patent literature as the International Searching Authorities shall agree upon and which shall be published in a list by the International Bureau when agreed upon for the first time and whenever changed."⁴

12. Document WIPO/GRTKF/IC/5/6 (paragraphs 31 to 43) described the work under way to integrate published TK into the PCT minimum documentation, so as to ensure that TK is given greater recognition during the crucial international search and examination processes. This is aimed to increase the likelihood that, even before international patent applications enter the national phase within individual jurisdictions, pre-existing TK that is relevant to the claimed invention can already be cited against the patent application in the preliminary search and examination process, thus ensuring that relevant TK is given full consideration when the application reaches the national level. The process described in the earlier document has now reached a mature stage, and it is expected that changes to the PCT minimum documentation will be agreed in the near future.

13. Specifically, in July 2003, shortly after the fifth session of the Committee, the ninth session of Meeting of International Authorities under the PCT (the MIA) considered the process for enhancing the minimum documentation based on document PCT/MIA/9/4. Circular C. PCT 911 issued on March 28, 2003, had invited members of the PCT Committee for Technical Cooperation (PCT/CTC) to evaluate the Non-Exhaustive Inventory of Traditional Knowledge-Related Periodicals and the Non-Exhaustive Inventory of Traditional Knowledge-Related Databases, attached to the Circular, and to suggest a selection of appropriate periodicals and databases with a view to providing improved access to traditional knowledge documentation for search purposes. On the basis of replies received from 20 PCT/CTC members, the International Bureau had compiled ranked lists of periodicals and databases which included only those periodicals and databases that had been proposed by more than one of the PCT/CTC members (see document PCT/MIA/9/4, Annexes I and II).

14. According to the report of this session of the MIA (document PCT/MIA/9/6):

"127. The Meeting reiterated the conclusion ... that integration of traditional knowledge documentation into searchable prior art could significantly improve the quality of international searches in areas where traditional knowledge documentation represented a rich source of information (see document PCT/MIA/7/5, paragraph 10).

128. The Meeting agreed that the ranked lists prepared by the International Bureau provided a good basis for selection of the most appropriate periodicals and databases. Criteria for selection of periodicals had been agreed upon by the Meeting at its seventh session (see document PCT/MIA/7/5, paragraph 12). The Meeting noted particularly that selected periodicals and databases would need to contain descriptions of disclosed technical knowledge to a sufficiently practical or technical level to be of relevance when conducting prior art searches. ...

129. Some Authorities expressed the view that providing examiners with access to databases relating to traditional knowledge, for example through the framework of an

⁴ Rule 34.1(b)(iii) of the Regulations Under the PCT.

IPDL, would in general yield more satisfactory results than consultation of periodicals, although the mandatory use of such databases in the examination process was not envisaged.

130. The Meeting concluded that periodicals and databases mentioned in the lists prepared should be further studied in the light of their accessibility, facilities for electronic searching, and technical and geographical coverage. The Meeting requested the International Bureau to prepare revised ranked lists, taking into account the comments and further suggestions made during the session and making a comprehensive check of their conformity with the established criteria. ...”

15. On the basis of this process, a proposal for revision of the PCT minimum documentation is under preparation, and depending on the schedule of meetings, is expected to be considered for possible adoption and implementation early in 2004. The Committee, at its sixth session, will be updated on any further progress achieved by March 2004.

III. COOPERATION ON DEFENSIVE MEASURES

16. This section considers the potential avenues for further cooperation, including between patent search and examination authorities, to promote the development of defensive strategies. This builds on the discussion in documents WIPO/GRTKF/IC/5/6, WIPO/GRTKF/IC/4/14 “Technical Proposals on Databases and Registries of Traditional Knowledge and Biological/Genetic Resources: Document submitted by the Asian Group,” and WIPO/GRTKF/IC/5/13, “Patents Referring to *Lepidium Meyenii* (Maca): Responses of Peru.” Other activities within WIPO and in other fora are also relevant to the international enhancement of defensive measures, and in this regard it should be noted that the General Assembly, in establishing the revised mandate for the Committee, noted that its particular consideration of the international dimension should be “without prejudice to the work pursued in other fora.”⁵ Certain organs of the Convention on Biological Diversity and of the World Trade Organization, and the Working Group on Reform of the PCT,⁶ are considering various proposals relating to enhanced disclosure under the patent system of the source or origin of genetic resources or TK used in a claimed invention (as well as related matters such as the legal circumstances of access to such genetic resources and TK), a matter also considered by the Committee (see documents WIPO/GRTKF/IC/5/10 and the update in document WIPO/GRTKF/IC/6/9).

17. A further legal means of enhancing defensive strategies especially relevant to TK is the recognition of orally disclosed information. Much TK is customarily transmitted orally, and is not normally reduced to a written or fixed form. This has led to concerns that, to the extent that any patent law system specifically recognizes documented or written knowledge when determining the validity of patent claims, there is the possibility of claimed inventions being deemed valid, even when they may involve the appropriation of orally disclosed TK. The concern is that this would prejudice the interests of those communities with a stronger oral tradition. From the legal perspective, it is possible to recognize orally disclosed material as being relevant prior art, and this recognition may be universal, in the sense that knowledge

⁵ Document WO/GA/30/8, paragraph 93.

⁶ Documents PCT/R/WG/5/11 Rev. and PCT/R/WG/4/13, the latter also considered by the Committee itself at its fifth session.

disclosed by any means, in any geographical location, may be considered as prior art relevant to the novelty of a claimed invention.⁷ Recognizing its legal status as relevant to the determination of validity of patent claims would clearly increase the legal basis for defensive protection, without necessarily requiring TK holders to disclose or publish their TK in violation of the principle of prior informed consent. In practice, taking account of orally disclosed TK, including that which is disclosed in foreign jurisdictions, would create some evidentiary issues, precisely because of the lack of documentation.⁸ On the other hand, there is concern that documentation of oral TK, including for the sake of patent procedures, can accelerate or facilitate its misappropriation, including its commercial use by third parties without the prior informed consent of the holders of TK.⁹ The need to respect the wishes, interests and concerns of TK holders suggests that legal recognition of orally disclosed TK as relevant prior art would enhance the impact of defensive strategies, while leaving clearly open the choice to TK holders in practice as to whether, how, and under what conditions they choose to disclose, publish or otherwise make available their TK. The prospects for TK holders to identify and promote their interests in a practical context should be enhanced by capacity-building programs along the lines requested by TK holders during the WIPO Fact-finding Missions,¹⁰ such as the such as the toolkit to identify and protect TK holders' interests during any documentation process.

18. Apart from these proposals, a number of other suggestions have been put forward that may be relevant to increased international cooperation on defensive strategies. The documents submitted to the Committee by the Delegation of Peru and by the Asian Group discuss in detail a range of measures relating to improved documentation of genetic resources and TK, and increased application of such information in patent procedures. This raises the kind of technical matters addressed by the Data Standards adopted by the Committee at its fifth session, but also raises a range of technical-legal questions about how the patent examination process can pay greater heed not merely to the technical content of disclosed TK, but also the background of the TK in a more holistic manner. For instance,

- The Asian Group has proposed that: “The Intergovernmental Committee should explore practical means of integrating into substantive patent examination procedures the teaching of TK systems in such a way that “the person with ordinary skill in the art” who is referenced in the determination of inventive step includes a person with ordinary skill in the relevant TK systems.”¹¹
- The Delegation of Peru has noted that there is a “need to evaluate how it would be possible to organize and systematize much of this information [on genetic resources and TK] and the role that could be played by a national database in that regard. In summary, how is it possible to articulate this database and information

⁷ See, for example, the proposal under consideration by the Standing Committee on the Law of Patents, document SCP/9/2, p. 21.

⁸ Similar considerations have led in the copyright domain, for example, for some jurisdictions to require fixation of works as a prerequisite for their protection; but as discussed in document WIPO/GRTKF/IC/6/3, many jurisdictions do nonetheless protect unfixed literary and artistic works.

⁹ See document WIPO/GRTKF/IC/5/5 and WIPO/GRTKF/IC/5/6

¹⁰ See “Intellectual Property Needs and Expectations of Traditional Knowledge Holders: WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998-1999), publication 768 (E/F/S)

¹¹ Document WIPO/GRTKF/IC/4/14, Annex, p. 4.

with the search procedures and examinations of the main patent offices throughout the world in order to avoid patents being granted on the basis of partial and limited examinations of novelty and inventive step?"

- The Group of Countries of Latin America and the Caribbean (GRULAC) commented that “the Committee could look into ways of devising a means of settling this problem at the international level in such a way as to include within the state of the art also that which has become known through use, traditional marketing, oral disclosure or any other means whereby a product or process has been made known to the public.”¹²

19. Such proposals raise legal-technical questions of how greater understanding of the technological background of and information about innovations within TK systems may be brought to bear during the patent search and examination process. To some extent, this is a legal question. The standard of inventiveness typically hinges on what would appear obvious to the ‘person skilled in the art.’ If a claimed invention is to some extent a hybrid, drawing in part on a TK system and in part on a separate scientific and technological discipline, should the test for non-obviousness consider the person skilled in the relevant background of TK.

20. A similar issue arises in relation to novelty, and the requirement that an invention not be publicly disclosed before the priority date of a patent. The legal dilemma was set out in a leading decision on patent law, by using an example directly relevant to the traditional knowledge debate:

“The Amazonian Indians have known for centuries that cinchona bark can be used to treat malarial and other fevers. They used it in the form of powdered bark. In 1820, French scientists discovered that the active ingredient, an alkaloid called quinine, could be extracted and used more effectively in the form of sulphate of quinine. In 1944, the structure of the alkaloid molecule (C sub20 H sub24 N sub2 O sub2) was discovered. This meant that the substance could be synthesised.”

“Imagine a scientist telling an Amazonian Indian about the discoveries of 1820 and 1944. He says: ‘We have found that the reason why the bark is good for fevers is that it contains an alkaloid with a rather complicated chemical structure which reacts with the red corpuscles in the bloodstream. It is called quinine’ The Indian replies: ‘That is very interesting. In my tribe, we call it the magic spirit of the bark.’ Does the Indian know about quinine? My Lords, under the description of a quality of the bark which makes it useful for treating fevers, he obviously does. I do not think it matters that he chooses to label it in animistic rather than chemical terms. He knows that the bark has a quality which makes it good for fever and that is one description of quinine.”

“On the other hand, in a different context, the Amazonian Indian would not know about quinine. If shown pills of quinine sulphate, he would not associate them with the cinchona bark. He does not know quinine under the description of a substance in the form of pills. and he certainly would not know about the artificially synthesised alkaloid...”

“The quinine example shows that there are descriptions under which something may in a relevant sense be known without anyone being aware of its chemical composition or

¹² WIPO/GRTKF/IC/1/5, Annex II, page 7.

even that it has an identifiable molecular structure. This proposition is unaffected by whether the substance is natural or artificial. So far I have been considering what it means to know about something in ordinary everyday life. Do the same principles apply in the law of patents? Or does patent law have a specialised epistemology of its own?"¹³

21. Because they entail distinct judgments on the patentability of individual patent claims, such legal questions are ultimately resolved case by case within the framework of national and regional patent systems. Nonetheless, given the interest expressed in promoting international cooperation on such questions, there may be avenues for more focussed work on the questions that have been put to the Committee. For example, there has been considerable practical work undertaken in Latin America,¹⁴ South Asia,¹⁵ China¹⁶ and Africa,¹⁷ as well as other regions, concerning the interaction between various TK systems and the patent system.

22. There is in particular an increasing amount of practical experience in certain patent offices in considering the patentability of TK-based inventions from the specific point of view of the TK systems in which they have been developed. For instance, it is reported that the State Intellectual Property Office (SIPO) of China received 20,864 patent applications in the field of traditional Chinese medicine (TCM) up to 2002, and that SIPO has a team of specialist patent examiners with expertise in the field of TCM.¹⁸ In general, those countries with rich backgrounds in traditional knowledge are likely to develop a strong basis of practical understanding in making judgements about whether claimed inventions are truly novel or inventive, having regard to the standards and conceptual framework of the TK holders and traditional communities themselves. This experience would illustrate how the conceptions of novelty, inventive step, and person skilled in the relevant art, may be adapted and applied most appropriately to innovations based on TK, so as to deal with concerns such as those noted above (in paragraph 18). This could in time lead to the recognition of certain regional or national patent offices in countries which are the source of certain TK systems as having specific expertise in providing at least an initial judgement on the validity of patent claims directed to material using such TK systems.

Possible future directions

23. As discussed in document WIPO/GRTKF/IC/5/6, at the practical level, planning and implementation of defensive protection strategies would be assisted by the compilation of information about the criteria that apply to the determination of relevant prior art in various jurisdictions, so that where defensive publication is made for patent purposes, it would achieve the intended objectives. This information could be compiled on the basis of a questionnaire concerning key aspects of prior art (such as the nature of disclosure, including enablement, the nature of public access required, criteria concerning the medium, location,

¹³ *Merrell Dow Pharmaceuticals Inc. v. H.N. Norton & Co. Ltd.*, [1996] RPC 76, at 88 (per Lord Hoffmann)

¹⁴ For example, the working group reported in document WIPO/GRTKF/IC/5

¹⁵ Including the work of the SAARC Documentation Centre (SDC), and the TK Digital Library and Health Heritage database that are accessible at <http://www.wipo.int/tk/en/databases/tkportal/index.html>

¹⁶ See China TCM Patent Database, at <http://www.wipo.int/tk/en/databases/tkportal/index.html>

¹⁷ <http://www.biosafetynews.com/feb02/story15.htm>

¹⁸ Beijing Round Table on Traditional Chinese Medicine, November 14, 2003.

written or oral character, and documentation of the date of disclosure); such a compilation would be a practical tool for defensive protection activities.

24. Another possibility would be to prepare recommendations or guidelines for national patent offices concerning searches in the area of inventions linked to TK (within specific technical fields) or genetic resources, with the goal of ensuring that patent authorities with little background in traditional knowledge systems are better equipped to base decisions on a clearer understanding of the manner in which TK is maintained and developed within the traditional context. This could put into practical effect the developments outlined above concerning the IPC and PCT minimum documentation. Recommendations could call for search and examination to take into account disclosed genetic resources and TK as prior art, and could set out suggested approaches to ensuring that disclosed genetic resources and TK are given full weight in practice as prior art. This could draw on studies and practical examples such as document WIPO/GRTKF/IC/5/15, and draw on the practical experience of those offices with specific expertise in certain traditional knowledge systems linked to their own region, to illustrate for the benefit of patent examiners with little exposure to traditional knowledge systems how questions of patentability can be assessed in a manner that reflects the original context of TK. Such guidelines would recognize and give broader influence to the expertise and perspectives of those patent offices, generally in developing countries, which are more familiar with customary TK systems.

IV. CONCLUSION

25. The practical activities adopted by the Committee focussed on enhanced defensive protection measures have all either been delivered or are currently in the final stages of completion, including through other relevant WIPO bodies for further implementation, such as the PCT/MIA and the PCT/CTC. The Committee's initial work program on defensive protection can be seen as successfully carried out. There remain, however, some possibilities for future work to improve the defensive protection of TK and genetic resources. In particular, there is scope for broader application of the practical lessons learned from ensuring defensive protection of TK and genetic resources. The expertise and experience of those countries which are rich in TK backgrounds and in genetic diversity could provide insight and guidance to those in other regions, so as to strengthen the understanding of how TK systems can be weighed appropriately within the overall framework of patent law.

26. Any work on defensive approaches should, however, be undertaken within the context of a comprehensive approach to the protection of TK, which takes account of the needs, widely expressed, for more effective positive protection and for any holders or custodians of TK to be fully informed of the consequences of making any disclosure of their TK, especially when disclosure leads to publication of the TK or its more ready access by members of the public.

27. The Committee is invited: (i) to call for further responses to be submitted on the Questionnaire on Databases and Registries Related to TK and Genetic Resources (WIPO/GRTKF/IC/Q.4); (ii) to consider practical steps to promote further use and development of the technical proposals contained in document WIPO/GRTKF/IC/4/14 and adopted at its fifth session; and (iii) to consider future work including a questionnaire on prior art criteria and development of draft recommendations to authorities responsible for patent search and examination to take greater account of traditional knowledge systems.

[End of document]

