TRADITIONAL KNOWLEDGE AND PATENTS: A BRIEF SUMMARY OF THE EPO'S PERSPECTIVE

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Knowledge of the legal provisions of the European Patent Convention (EPC) relevant to traditional knowledge (TK) is essential to TK holders such as in Pacific Island countries so that they can actively protect in Europe any TK-derived invention they may want to develop. It is also of fundamental importance to be able to properly defend their rights if a European patent application that could be based on their TK is filed without their consent. This paper introduces the role and structure of the European Patent Office (EPO) and basic legal requirements, as set out in the EPC, that are most relevant to TK-related inventions. Examples taken from EPO practice and case law (neem tree, *Pelargonium* species, and *Hoodia*), along with provisions that can be used to prevent misappropriation under European patent law, are discussed to illustrate how the European patent system may affect Pacific Island countries and their traditional knowledge.

Introduction: Patent Grant Procedure at the EPO

THE EUROPEAN PATENT ORGANISATION is an independent intergovernmental international organization with 38 contracting states (including all 28 member states of the European Union). It has two bodies, the European Patent Office (EPO) and the Administrative Council; the latter supervises the office's activities. The EPO is the patent-granting authority for Europe. The legal basis for its activity is set out in the European Patent Convention (EPC).¹

The EPO is also responsible for examining oppositions filed against granted European patents and for deciding on appeals filed against decisions

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of the receiving section and the examining and opposition divisions of the EPO. The EPO's structure is shown in Figure 1. A more detailed explanation of the roles and composition of the boards involved in these tasks is given later in this section.

The European patent grant procedure begins with a formalities examination and a mandatory search of the relevant "state of art" disclosures. The first stage ends with the publication of the European patent application and the search report. The search report lists the documents most relevant to the examination of the patent application, which were retrieved during the search. It is publicly accessible, as are all communications between the EPO and the applicants. This is followed by the second stage, the substantive examination, at the applicant's request. This stage can result either in the refusal of the patent application or in the grant of a patent. The final decision is made by a three-member board called the examining division, consisting of three patent examiners. Within nine months after its grant, a patent may be challenged centrally before the EPO in what are referred to as "opposition proceedings," which are initiated by any natural or legal person who considers that the patent does not comply with specific provisions of the EPC, such as novelty, inventive step (nonobviousness), or reproducibility (the grounds for opposition are listed in art. 100 EPC). The opposition division is made up of three patent examiners, at least two of which, one being the person chairing the division, cannot have taken part in the examination proceedings.

The decision to refuse the patent application and the final decision made at the end of the opposition proceedings may be appealed. Appeal proceedings are separate and independent from the earlier proceedings and are dealt with by the board of appeal.

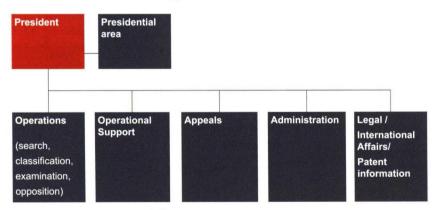


FIGURE 1. Structure of the EPO.



FIGURE 2. Overview of European patent grant procedure (part 1).

The grant procedure is summarized in Figures 2 and 3. As shown in the figures, third parties can file observations immediately after the publication of the application and up to the final decision to grant a patent, or once the opposition procedure is open. Filing these observations is free of charge.

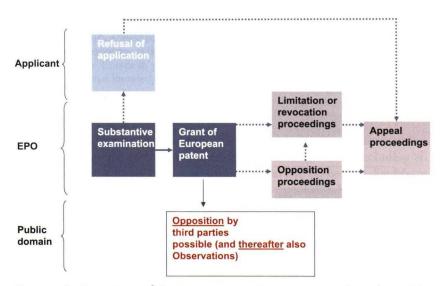


FIGURE 3. Overview of European patent grant procedure (part 2).

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They can be filed by anyone, without limitation, by postal mail or electronically.² All third-party observations submitted are taken into account in the sense that either the documents they quote are admitted into the procedure (if they are more relevant than the documents already available to the EPO) or the division that is involved explains why the quoted documents were not admitted. The third party that files these observations does not become party to the proceedings (art. 115 EPC),³ contrary to what happens to the person filing an opposition.

EPO's Practice and Legal Provisions Concerning Traditional Knowledge–Related Issues

Genetic resources (GRs) and associated traditional knowledge (TK) have the potential of being translated into substantial commercial benefits. They therefore may represent a valuable source of patentable inventions and benefits to the TK holders. At the international and national levels, requirements for patent applicants to disclose certain information in patent applications ("disclosure requirements") are discussed as a possible means to increase transparency and to prevent "bad" patents, ensuring fair and equitable benefit sharing and allowing developing countries and indigenous and local communities to better control the commercial exploitation of their TK and GRs and thus benefit from the patent system. The scope and modalities of discussed disclosure requirements range from mere encouragements to make information available (e.g., in European Union legislation, described later) to stringent obligations to declare the source, provide evidence of prior informed consent, or both. The sanctions for failing to comply with these obligations vary according to national legislation: for example, the Swiss Patent Act (art. 49a and 81a) foresees a fine in case of willful provision of false information in respect to the source of the GRs or the TK on which the invention is directly based, whereas according to the Norwegian Patents Act (sec. 8b),⁴ the "Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 166.⁵ The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

TK-Related Provisions under the EPC

No Mandatory Disclosure of Origin, Source, or Prior Informed Consent Requirement

The provisions concerning biotechnological inventions are found in a dedicated chapter (titled "Biotechnological Inventions") of the EPC

Implementing Regulations.⁶ Pursuant to rule 26(1) EPC, for European patent applications and patents concerning biotechnological inventions, the relevant provisions of the EPC are applied and interpreted in accordance with the provisions of chapter V of the EPC Implementing Regulations (rules 26 to 34). European Commission directive $98/44/EC^7$ is used as a supplementary means of interpretation. This aims to ensure that the recitals preceding the provisions of the directive are taken into account and that a uniform Europe-wide interpretation of the relevant provisions is promoted.⁸

Recital 27 of directive 98/44/EC says that, 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 and if known, include information on the geographical origin of such material; this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents. The indication of the geographical origin is thus voluntary.

Recital 27 of directive 98/44/EC has to be regarded as encouragement to mention the geographical origin of biological material in the patent application,⁹ along the lines indicated by the Convention on Biological Diversity (art. 16(5)).

To provide such information is thus not an obligation under the EPC. Nor does the failure to provide such information have legal consequences for the processing of patent applications or the validity of rights arising from granted patents. No particular guidelines under the EPC go beyond the stipulations in these provisions.

This legal situation with respect to GRs and TK is in line with the general principle under the EPC that, although applicants are encouraged to provide information on prior art related to the claimed invention, there is no stringent obligation on applicants to acknowledge all prior art known to them. The burden to find the relevant prior art for challenging novelty or inventiveness is in principle on the EPO.

Rule 42(1)(b) EPC provides that the description shall "indicate the background art which, as far as is known to the applicant, can be regarded as useful to understand the invention, draw up the European search report and examine the European patent application, and, preferably, cite the documents reflecting such art." To satisfy this provision, the EPO may invite the applicant to provide information on prior art taken into consideration in national or regional patent proceedings and concerning an invention to which the European patent application relates (art. 124 EPC). If the applicant "fails to reply" within the specified period, the application

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is deemed withdrawn (art. 124(2) EPC). However, "reply" is to be understood in the broadest sense. Under rule 141(1) EPC, an applicant claiming priority of a previous patent application is required to file with the European patent application a copy of the results of any novelty search carried out by or on behalf of the authority with which the previous application was filed. If these search results are not available to the applicant at the time of filing the European patent application, he can file them with the EPO as soon as he receives them. In a case of noncompliance, as defined in rule 71b(1) EPC, the European patent application is deemed to be withdrawn (rule 70b(2) EPC).

The EPC does not foresee a doctrine of inequitable conduct or fraud to the EPO.

No Examination of Lawful Behavior of an Applicant Who Developed or Acquired the Invention

The EPC does not contain any requirement with respect to GRs and associated TK that the applicant give evidence of compliance with the applicable legal requirements in the providing country, such as prior informed consent requirements. In this general context, the EPO does not examine the questions of who is entitled to apply for a patent and of whether the claimed subject matter has been obtained as a result of illegal or unauthorized activities.

According to art. 60(3) EPC, "In proceedings before the European Office, the applicant shall be deemed to be entitled to exercise the right to a European patent." The applicant is regarded as the entitled party by virtue of a fiction, without this entitlement being examined by the EPO. The reason for this is that the EPO is not in a position to appreciate substantive entitlement to a patent under the respective national laws. It has to rely on final decisions by the competent national judicial bodies (art. 61 EPC).

Likewise, the questions of whether the knowledge or elements that contributed to the invention have been lawfully acquired and of whether the applicant needs authorization by the providers of the technology that the invention is building on to exploit the patent are presumed to be dealt with by national authorities outside the European patent grant procedure.

Safeguards against Misappropriation under European Patent Law

Two aims of a disclosure of origin requirement would be to prevent (or at least to render difficult) the acquisition of patent rights over GRs or TK by

parties without the prior informed consent of their customary custodians and to avoid granting a patent on subject matter that was well known by TK holders' communities and part of the state of the art.¹⁰ As explained earlier, there are no mandatory disclosure requirements under the EPC. However, various provisions in the EPC indirectly serve these purposes, as explained in next section.

Prior Art Concept. The concept of absolute novelty adopted under the EPC lays the basis for preventing misappropriation of GRs or TK already in the public domain. An invention is considered new if it does not form part of the state of the art. The "state of the art," comprises everything made available to the public by means of a written or oral description, by use, or in any other way before the date of filing of the European patent application (art. 54(1) and (2) EPC). There are no restrictions as to the geographical location or the language or manner in which the relevant information was made available to the public; also, no age limit is stipulated for the documents or other sources of the information. However, to obtain the revocation of a patent on the basis of prior use, the prior use must be proved beyond reasonable doubt, and this requires conclusive evidence.¹¹ The same applies to oral disclosures.¹²

This same concept of state of the art applies to the "inventive step" requirement: any disclosure, including through use, at any time and anywhere in the world may be sufficient to challenge the inventiveness of an application. However, just as in other fields of technology, patents can be granted if an application demonstrates inventiveness, for instance, by showing significant improvements, compared to the prior art (use of) GRs and relevant TK.

Prior Art Access or Accessibility. The access of examiners to prior art information on GRs and associated TK is a huge challenge, because TK is often undocumented ("noncodified") or, if documented, is unlikely to be easily accessible to a patent examiner located in Europe.¹³ The EPO strives to continuously enhance the coverage of documented TK. For instance, since February 2009 examiners at the EPO have had access to the Traditional Knowledge Digital Library developed by Indian government organizations, and since 2006 they have had access to the Traditional Chinese Medicine patent database. Dedicated TK portals (e.g., the Korean Traditional Knowledge Portal¹⁴) and TK-related databases are also easily accessible to EPO examiners.¹⁵ Moreover, the EPO is interested in acquiring new TK-related databases and is ready to provide technical assistance to help set them up. This could be of relevance to the Pacific region.

The importance that TK databases have for the examination work is highlighted by the standard of proof applicable to oral disclosures, which requires, as indicated earlier, that the content of any oral disclosure be proved in principle beyond reasonable doubt. Hence, it may be difficult to establish that TK that was only transmitted orally belongs to the state of the art. The recording of this oral tradition in a database comprising clear information as to the date wherein it was first made publicly available would avoid such difficulty. Third parties are also constantly encouraged to submit observations and relevant information and documentation in all pending proceedings.

Opposition Procedure. Improved access of examiners to background information on GRs and associated TK at an early stage of patent examination should help reduce the need for opposition procedures. As indicated earlier, these are at the disposal of any third party, including the custodians of GRs and TK who consider that the patent has been wrongly granted. Whereas the information submitted as "third parties' observations" under art. 115 EPC may or may not be admitted into the proceedings, that submitted by the party or parties filing the opposition ("opponent/s") at the beginning of the opposition proceedings are *de jure* part of the proceedings and must be taken into account by the EPO. This guarantees that prior art that anyone in the public considers relevant and that has not been retrieved during the search stage is brought to the attention of the EPO and duly considered when assessing the compliance of the granted patent with the relevant provisions of the EPC.

EPO's Case Law Concerning TK

The Neem Case

A prominent example of a patent that has been opposed and eventually revoked is the neem oil case (European Patent EP-B-0436257). Neem is an evergreen tree endemic to the Indian subcontinent. Neem oil has an extensive history of human use in India and surrounding regions for a variety of therapeutic purposes. Traditional Ayurvedic uses of neem include the treatment of fever, leprosy, malaria, ophthalmia, and tuberculosis. Neem has also been traditionally used as a parasiticide and an insecticide.

During the examination procedure, following novelty objections of the examining division based on prior art citations from the search report, the applicant restricted the scope of the application to the fungicidal use of neem oil obtained by hydrophobic extraction of neem seed. The patent was granted. Oppositions were filed based *inter alia* on the following:

- Lack of novelty or inventive step (based *inter alia* on a prior use in India)
- Insufficient disclosure
- Noncompliance with the provisions of EPC art. 53(a) (going against morality, because the patent rights could jeopardize the life of the Indian neem gatherers)

The opposition division considered that the prior use had been sufficiently established and therefore decided to revoke the patent for lack of novelty over this prior use. The revocation was confirmed by the board of appeal with the decision T416/01¹⁶; however, this was done on the basis of a different ground, namely, lack of an inventive step in view of a document introduced by the opponents at the beginning of the opposition procedure and published in 1981. Given that the patent was revoked on another ground, the board of appeal did not take a position either on the prior use or on the art. 53(a) EPC objection. Concerning the former issue, the board stated,

To prove the alleged public prior use, the respondents put forward affidavits A2, A7, A13 and the testimony of Mr A. D. Phadke. The appellant has disputed the validity of the evidence brought forward inter alia on the grounds that it casts doubt on the credibility of the evidence. This doubt was based on the long period which had elapsed between the actions and the affidavits and testimony. The appellant's main argument was that the recollection of dates and numerals was uncertain for most people and hence some supporting documents, such as laboratory books or notebooks, were required. However, there is no dispute between the parties concerning the existence of the prior art document (8) as part of the state of the art within the meaning of Article 54(2) EPC. In the board's view, document (8) is highly relevant for the ruling of the present case. Thus, it can be left open whether or not the prior use is proven as the case can be decided on the basis of document (8) alone.

The Pelargonium Case

The *Pelargonium* species (*P. sidoides* and *P. reniforme*), which were the object of patent EP-B-1429795, are native and endemic of southern Africa. They are traditionally used by local ethnic communities in the treatment of respiratory tract infections.

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The patent claims were directed to a method for producing an extract from two *Pelargonium* species. Oppositions were filed on the grounds *inter alia* of the following:

- Lack of novelty and inventive step
- Insufficient disclosure
- Noncompliance with art. 53(a) EPC (going against morality) because of noncompliance with the Convention on Biological Diversity provisions relating to prior informed consent and to an agreement as to the term of access to GRs and benefit sharing

The opposition division revoked the patent for lack of inventive step in view of two prior art documents introduced by the opponents.¹⁷ Concerning the art. 53(a) EPC objection, the opposition division held that the disclosure of prior informed consent and the access to GRs and benefit sharing are not linked to the patentability requirements and thus their absence is not a ground for revocation under the EPC. The patent proprietor did not file an appeal against this decision, and the decision of the opposition division became therefore final.

The Hoodia Case

Hoodia is a genus of plants that grow naturally in South Africa and Namibia. The appetite suppressant activity of the plants' flesh has been known for centuries by indigenous populations of southern Africa, such as the San people.

Patent application EP-A-98917372.9 relating to an extract of *Hoodia* comprising an appetite-suppressant agent was refused by the examining division for lack of novelty and lack of inventive step (the latter ground concerned a more restricted version of the claims than those originally filed and was limited to the medical use of *Hoodia* extracts as an appetite suppressant).

During the appeal proceedings, a modified version of the claims was filed by the applicant. The board of appeal considered this claim to comply with the requirements of the EPC and ordered the grant of a patent on its basis. In its decision,¹⁸ the board of appeal took a position on the available information about TK relative to *Hoodia*'s uses:

The Board is aware that the traditional knowledge of the original inhabitants of the Kalahari desert, like the San people, is the subject of a large number of publications. Many thereof have been published on the Internet. However, most of these documents have been published after the filing date of the present patent application and there is no convincing evidence on file that this post-published information, about what was known before the filing date, reflects reality. Therefore, the Board will not take into account post-published documents relating to traditional knowledge allegedly available to the public before the filing date, and consider only those documents which have been published before said date and which refer to different uses of plants of the genera Trichocaulon and Hoodia." (emphasis added)

The problem the board of appeal encountered in assessing the documents was the lack of convincing evidence that the relevant information had been made available to the public prior to the filing date of the patent application. The mere fact that some documents state certain information was known to the public prior to a certain date is not always legally sufficient to prove it. The timing of evidence may, therefore, be crucial.

Patents Relating to Materials Obtained from Species Common in Pacific Island Countries or to Their Uses

Various patent applications relating to species common in Pacific Island countries (e.g., kava, ngali nut, mamala, and coral) have been filed, and some patents on these subject matters have been granted by the EPO. Some of these patent applications were withdrawn after having received a negative search report, a negative opinion from the examining division, or both. For some patents, opposition proceedings have been initiated, third-party observations have been filed, or both.

In the case of a patent for the medical use of ngali nut oil (EP-B-1083914), the prior art search did not disclosed any document that could have been used as a basis for a novelty or an inventive step objection by the examining division. The patent was granted and was not opposed. However, if anyone anywhere in the world, for instance, an indigenous community in Pacific Island countries, could have proved use of ngali nut oil as a medicament or that its medical properties were available to the public before the first filing (priority) date (e.g., by having the prior use or prior knowledge recorded in a database with the clear indication of the relevant dates), they could have filed third-party observations and eventually an opposition before the EPO based on this prior use. The proven prior use or prior knowledge could have led to the revocation or the limitation of the patent by the EPO. Therefore, it is important that records be made of prior art, including prior use, regarding TK.

Even once a European patent has been granted by the EPO and the opposition period has elapsed, the patent can always be challenged at the national level on the same grounds as in an opposition before the EPO.

Conclusions

Discussions at the international level about TK, GRs, and intellectual property have been going on for decades and are ongoing. The World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was set up in 2000 and is expected to finalize documents to be approved by a diplomatic conference in the near future. The EPO is following these discussions with great interest, being well aware of the relevance of the problem.

Notwithstanding the ongoing discussions and different views on the role of intellectual property with respect to TK and GRs, a clear understanding of the legal and procedural framework within which the EPO works is pivotal to ensure that TK is appropriately protected and that it is not unduly exploited by seeking protection for something that is already part of the state of the art.

At the national level legislation often differs from one country to another; for instance, some countries may grant to TK a *sui generis* protection (e.g., some Pacific Island countries), and some may require mandatory disclosure of the origin or source of the GR or TK on which the patent is based (e.g., Norway and Switzerland). Regardless, patent applications at the EPO are examined at all stages solely under the requirements of the EPC. It is therefore essential, in particular for TK holders, such as the Pacific Island countries, to be aware of these requirements to actively protect in Europe any TK-derived invention they may want to develop and to be able to properly defend their rights if a European patent application that could be based on their TK is filed without their consent. This paper describes the most relevant requirements with respect to TK, which, in view of the foregoing analysis of the EPC and of the relevant case law, can be summarized as follows:

 The lack of disclosure of origin or source is not a ground for refusing a patent application or revoking a granted patent. The same applies to the lack of a declaration that the prior informed consent was obtained or that an agreement about access to TK and GRs and benefit sharing was signed.

- 2. Public prior use, irrespective of the place where it occurred, is part of the prior art under the same circumstances as any written document. If prior use is established as required under the applicable standard of proof, it may lead to the revocation of a patent. The same applies to oral disclosures.
- 3. The development of TK-related databases that provide a clear indication of the information disclosed (e.g., scientific name of the plants or animals referred to in the disclosure) and of the date of its first public disclosure represent an important tool for the EPO (and patent offices worldwide) to further limit the risk of granting a patent for known subject matter. TK holders, like the Pacific Island countries, would certainly help to further limit this risk by creating databases of this kind and allowing access to them by EPO and other patent office examiners.
- 4. Third-party observations are free-of-charge, easy-to-use, and powerful tools that can bring to the EPO's attention any prior art disclosure considered relevant to the examination of the patent or patent application.

In a sensitive field such as inventions related to TK, GRs, or both, even a single patent that turns out to have been unduly granted (i.e., where relevant prior art was missed or not properly taken into account) can create mistrust and a negative perception of the patent system in general and of the EPO as the involved granting authority in particular. All efforts must be made to avoid this, not least because patent rights could represent one of the opportunities for TK holders to obtain those benefits to which they are entitled, as clearly stipulated in the Convention on Biodiversity and the Nagoya Protocol. As stated in the foreword of WIPO and United Nations Environment Programme Study 4, "The patent system ... recognizes innovations based on genetic resources and provides a framework for investment in the development of valuable new products and processes. It therefore offers the potential to yield the desired benefits from access to genetic resources." The study further highlights "the need, when genetic resources are first accessed, for a clear understanding of intellectual property issues."19

It is hoped that the information provided in this paper may help increase this understanding.

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NOTES

1. The complete text of the EPC is available at http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/index.html.

2. Form available at http://tpo.epo.org/tpo/app/form/.

3. The text of article 115 is available at http://www.epo.org/law-practice/legal-texts/ html/epc/2010/e/ar115.html.

4. The text of the relevant section of the Norwegian Patent Act is available at http:// www.patentstyret.no/en/For-Experts/Patents-Expert/Legal-texts/The-Norwegian-Patents-Act/#Chapter 2.

5. "Any person who gives false testimony in court or before a notary public or in any statement presented to the court by him as a party to or legal representative in a case, or who orally or in writing gives false testimony to any public authority in a case in which he is obliged to give such testimony, or where the testimony is intended to serve as proof, shall be liable to fines or imprisonment for a term not exceeding two years."

6. The text of the EPC Implementing Regulations is available at http://www.epo.org/ law-practice/legal-texts/html/epc/2010/e/rcii_v.html.

7. The text of the EC Directive is available at http://eur-lex.europa.eu/LexUriServ/ LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF.

8. See the Official Journal of the EPO 8-9 (1999): 573, 587, and "Guidelines for Examination in the EPO" (2012), G-II, 5.2.

9. The text of the directive is available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_1/wipo_grtkf_ic_1_8-annex1.pdf.

10. See, e.g., WIPO, "Technical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional Knowledge," http://www.wipo.int/tk/en/publications/technical_study.pdf.

11. A discussion on this topic and references to the relevant decisions of the EPO Boards of Appeal are available at http://www.epo.org/law-practice/legal-texts/html/caselaw/2010/e/clr_vii_d_2_3_4_a.htm and http://www.epo.org/law-practice/legal-texts/ html/caselaw/2010/e/clr_i_c_1_9_3.htm.

12. A discussion on this topic and references to the relevant decisions of the EPO Boards of Appeal are available at http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_iv_7_3.htm.

13. See the distinction between codified and noncodified TK given, e.g., at http://www.wipo.int/edocs/mdocs/sct/en/wipo_grtkf_ic_17/wipo_grtkf_ic_17_inf_9.pdf.

14. http://www.koreantk.com/en/JZ0100.jsp.

15. Accessible, e.g., via the Epoxy portal at https://epoxy.epo.org/.

16. The complete text of this decision is available at http://www.epo.org/law-practice/case-law-appeals/recent/t010416eu1.html#q=.

17. The complete text of this decision is available at https://register.epo.org/espacenet/application?number=EP02777223&lng=en&tab=doclist.

18. The complete text of this decision is available at http://www.epo.org/law-practice/ case-law-appeals/recent/t040543eu1.html.

19. http://www.wipo.int/tk/en/publications/769e_unep_tk.pdf, p 4.