

**International Workshop on Methodologies Regarding Free, Prior and Informed
Consent and Indigenous Peoples
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Information Note
by the
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EXECUTIVE SUMMARY

1. The legal protection of traditional knowledge and traditional cultural expressions is the subject of active policy development, norm-building and capacity-building programs at the World Intellectual Property Organization (WIPO). WIPO's work in these areas has included extensive consultations with indigenous peoples and traditional communities in all regions, and involves direct participation by more than 100 non-governmental organizations (NGOs), many of whom represent the interests of indigenous peoples and traditional communities.

2. A principle of 'free, prior and informed consent' (FPIC) has been central to the policy debate on the protection of traditional knowledge and cultural expressions since the commencement of this work at WIPO and is the most widely supported approach in discussions taking place within the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. A FPIC principle is, for example, already implemented in many national and regional *sui generis* protection laws, measures and systems. In addition, existing intellectual property (IP) rights can be used to provide a legal basis for the exercise (or withholding) of FPIC.

3. A FPIC principle could, for example, entail that traditional knowledge and traditional cultural expressions held by an indigenous people or traditional community, and derivatives of such knowledge and expressions, should not be accessed, recorded, adapted, used or commercialized without the prior informed consent of the people or community concerned. It could, it is suggested by some, provide a legal and practical mechanism for negotiation of 'mutually agreed terms' as a basis for benefit-sharing arrangements at the point of access to traditional knowledge and traditional cultural expressions. Compliance with FPIC is also under active consideration in WIPO's work concerning the intellectual property aspects of access to and benefit-sharing in genetic resources.

4. These questions are the focus of intense and ongoing discussion between WIPO's Member States, representatives of indigenous peoples and traditional communities and other stakeholders. These discussions are complex and sensitive, and the legal,

cultural, social, political and economic questions they address are the subject of rapidly-evolving policy and legislative development at WIPO and elsewhere.

5. Whether or not, for example, a FPIC principle is to be applied in all circumstances and to all uses of traditional knowledge and cultural expressions and derivatives thereof, goes to the heart of a complex debate. Diverse stakeholders have identified the need for an equitable balance between the rights and interests of those that develop, preserve and sustain traditional knowledge and cultural expressions, and of those who use and benefit from them, the need to reconcile diverse policy concerns, and the need for specific protection measures to be proportional to the objectives of protection and actual experiences and needs. Conventional IP rights themselves, it is pointed out, are not necessarily exclusive property rights nor are they absolute, as they are subject to various exceptions and limitations.

6. Thus, the WIPO Intergovernmental Committee has adopted a wide-ranging, flexible and comprehensive approach to the protection of traditional knowledge and cultural expressions. Protection should, the Committee has discussed, draw on a comprehensive range of options, combining proprietary, non-proprietary and non-IP measures, and using existing IP rights, *sui generis* extensions or adaptations of IP rights, and specially-created *sui generis* IP measures and systems, including both defensive and positive measures.

7. In November 2004, the Intergovernmental Committee examined draft instruments for recognizing, amongst other things, collective interests in traditional know-how and expressions of traditional cultures which are ‘innovative’ or ‘creative’ and ‘characteristic’ of a distinct cultural identity. These draft proposals, which include compliance with a FPIC principle, are under continuing examination by Member States and other stakeholders.

I. INTRODUCTION

8. The World Intellectual Property Organization (WIPO) is the United Nations agency responsible for the promotion and protection of creative intellectual activity and for the facilitation of the transfer of technology in order to accelerate economic, social and cultural development. Intellectual property (IP) protection is essentially implemented under national, and in some cases regional, laws. Internationally and regionally, existing agreements, conventions and treaties help to establish the framework within which specific national laws operate.¹

¹ International instruments would include many of the treaties administered by WIPO, such as the Paris Convention for the Protection of Industrial Property, 1883, as last revised in 1967; the Berne Convention for the Protection of Literary and Artistic Works, 1886, as last revised in 1971; the Madrid Agreement for the Repression of False and Deceptive Indications of Source on Goods, 1891; the International Convention for the Protection of Performers, the Producers of Phonograms and Broadcasting Organizations (the “Rome Convention”), 1961; the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration, 1958, as last amended in 1979; the WIPO Copyright Treaty, 1996; and, the WIPO Performances and Phonograms Treaty, 1996.

9. This Information Note sets out technical and background information on the principle of free, prior and informed consent (FPIC) in so far as it relates, first, to the participation of indigenous peoples and other traditional communities in consultations, studies, fact-finding and legal-technical assistance projects undertaken by WIPO and, second, to the policy-making and standard-setting discussions taking place between WIPO's Member States concerning improved protection of traditional knowledge and cultural expressions of indigenous peoples and other traditional communities by intellectual property, or intellectual property-type, rights and measures.

10. A principle of FPIC may apply in various circumstances to the copying, recording and documentation, adaptation, use and commercialization of traditional knowledge and cultural expressions, and derivatives thereof, as well as to access to and use of genetic resources and associated traditional knowledge. These circumstances, and the legal and policy framework, for the exercise of such a principle are the subject of intense discussion between WIPO's Member States, representatives of indigenous peoples and traditional communities and other stakeholders. These discussions are complex and sensitive, and the legal, cultural, social, political and economic questions they address are the subject of rapidly-evolving policy and legislative development at WIPO and elsewhere. This is also an area where the work of WIPO needs to be responsive to and cognizant of developments in other international forums. One example is the need to respect and ensure consistency with the work undertaken under the auspices of the Convention on Biological Diversity (the CBD) on the principle of prior informed consent as it applies to genetic resources.

11. This Information Note seeks only to provide a brief and technical overview of some of the main contexts in which compliance with a principle of FPIC has arisen in WIPO's work. It does not enter into or pre-empt policy decisions which are within the competence of Member States, nor seek to represent all the views of the diverse stakeholders participating in WIPO's work, including indigenous peoples and traditional communities.

12. The subjects referred to in this Note are extensively and more comprehensively covered in submissions, working documents, studies and other materials prepared by Member States, indigenous peoples and traditional communities, the WIPO Secretariat and other stakeholders. Readers are referred to the WIPO website for further information.² Documents and other publications of direct and particular relevance are: 'Protection of Traditional Cultural Expressions/Expressions of Folklore: Overview of Policy Objectives and Core Principles';³ 'Protection of Traditional Knowledge: Overview of Policy Objectives and Core Principles';⁴ WIPO Technical Study on Patent Disclosure Requirements related to Genetic Resources and Traditional

² <http://www.wipo.int/tk/en/index.html>

³ WIPO/GRTKF/IC/7/3.

⁴ WIPO/GRTKF/IC/7/5.

Knowledge’;⁵ and, Janke, Terri, ‘Case Studies on Intellectual Property and Traditional Cultural Expressions’.⁶

13. We refer also to a facility on the WIPO website specifically dedicated to the submissions and papers of indigenous peoples and traditional communities and other non-governmental participants in WIPO’s work, which contains much valuable information.⁷

II. BACKGROUND

14. The intellectual property-type protection of traditional knowledge and cultural expressions (referred to in some countries and regions as “expressions of folklore”)⁸ is the subject of an active work program at WIPO. This work program includes, in a closely complementary way, legal-technical assistance, capacity-building and policy development and standard-setting. This program has included extensive consultations with indigenous peoples and traditional communities in 28 countries, and involves direct participation by more than 100 NGOs, many of whom represent the interests of indigenous peoples and traditional communities. Member States of WIPO have specifically requested close cooperation in such work between WIPO and the Permanent Forum on Indigenous Issues and other United Nations and intergovernmental agencies and organizations. Further general information on WIPO and on its work on traditional knowledge and cultural expressions is set out in written information notes made available at previous sessions of the Permanent Forum.⁹

15. WIPO Member States have recently called for accelerated progress in this area, stressed the “international dimension” of these questions and emphasized that no outcome of WIPO’s work in this area is excluded, including the possible development of an international instrument or instruments. They have underscored that WIPO’s work should not prejudice developments in other forums.

16. Discussions on these issues between WIPO Member States take place within the frame of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. This Intergovernmental Committee

⁵ WIPO Publication No. 786 E.

⁶ WIPO Publication No. 781 E.

⁷ <http://www.wipo.int/tk/en/igc/ngo/ngopapers.html>

⁸ There is an established approach in WIPO’s work of considering the legal protection of traditional knowledge as such (TK) and expressions of such knowledge and cultures (traditional cultural expressions/expressions of folklore (TCEs/EoF)) in parallel but distinctly. This is because the legal protection of knowledge as such and expressions of knowledge and cultures raise some distinct legal and cultural issues and each require specific solutions. WIPO’s work concerns specific means of legal protection against misuse of traditional materials by third parties beyond the traditional and customary context, and does not seek to impose definitions or categories on the customary laws, protocols and practices of indigenous peoples and traditional and other communities. This approach is accordingly compatible with and respectful and supportive of the traditional context in which TCEs/EoF and TK are often perceived as integral parts of an holistic cultural identity, subject to the same body of customary law and practices.

⁹ For example, E/C.19/2003/14.

is addressing a number of profound policy questions such as, to whom, if anyone, do or should traditional knowledge and expressions of intangible creativity belong as private property (including collective or communal property)? Who, if anyone, can or should enjoy the exclusive right to commercially exploit intangible traditional know-how and creativity? Should there be legal remedies against demeaning, derogatory or offensive use of or derivations from expressions of traditional cultures? How should such assertions of exclusivity be reconciled with a balanced policy approach that encourages cultural exchange, promotes cultural development, and serves other legitimate goals such as research and education? How should intellectual property mechanisms function to support and complement law and policy initiatives in other related fields, such as the safeguarding of cultural heritage and regulation of access to and use of genetic resources?

17. In November 2004, the Intergovernmental Committee examined specific draft proposals for recognizing, amongst other things, collective interests in traditional know-how and expressions of traditional cultures which are ‘innovative’ or ‘creative’ and ‘characteristic’ of a distinct cultural identity.¹⁰ These draft proposals also incorporate compliance with the FPIC principle, as will be referred to further below. The draft proposals are available on the WIPO website.¹¹

18. With respect to IP and access to and benefit-sharing in genetic resources, WIPO’s work includes examining methods consistent with IP treaties for requiring the disclosure within patent applications of, amongst other things: genetic resources used in the development of the claimed inventions and the country of origin of those genetic resources; associated TK used in the development of the claimed inventions and the source of that associated TK; and, evidence of prior informed consent. This work has in large part been undertaken at the request of the CBD Conference of Parties, and is intended to support the objectives of the CBD.

III. CONSULTATIONS, STUDIES, FACT-FINDING, LEGAL-TECHNICAL ASSISTANCE, CAPACITY-BUILDING

19. In parallel with its policy development and norm-building work (see below), WIPO also undertakes a program of practical activities aimed at consultation, fact-finding, providing legal-technical assistance and capacity-building. Many of these involve representatives of indigenous peoples and traditional communities. A practice of consultation, free, prior and informed consent, and full participation, has been routinely applied in any activity directly involving indigenous peoples and traditional communities. For example:

(i) in 1998 and 1999, WIPO conducted a series of fact-finding missions to 28 countries, during which more than 3000 persons, including mainly representatives of indigenous peoples and traditional communities, were consulted.

¹⁰ See in particular WIPO documents WIPO/GRTKF/IC/7/3 and WIPO/GRTKF/IC/7/5.

¹¹ Regarding TCEs/EoF, as Annex 1 to document WIPO/GRTKF/IC/7/3. Regarding TK in the narrow sense, as Annex 1, document WIPO/GRTKF/IC/7/5.

All visits to indigenous peoples and traditional communities were preceded by their being contacted and their permission for a visit being sought. All persons consulted on the missions received beforehand Terms of Reference for the missions, which set out information on the objectives, activities and outputs of the missions. The Terms of Reference also stated that the missions would only take place with the prior and informed consent of those consulted;¹²

(ii) an indigenous person commissioned by WIPO in 2000 to prepare case-studies of examples of use of IP laws by indigenous peoples in Australia¹³ was, under the terms of her consultancy contract with WIPO, “responsible for informing all persons with whom she consults for purposes of the [case-studies] of the nature, objectives and output of the [case-studies], and for procuring the prior informed consent, for the writing of the [case-studies] and for the publication and use of the [case-studies] by [WIPO], of the Indigenous persons, organizations and communities whose knowledge, innovations, and practices form the subject matter of the [case-studies]. The Contractor shall not include in the [case-studies] any information the publication and use of which by the [WIPO] as contemplated in this agreement has not received such consent”;

(iii) the Terms of Reference for an ongoing WIPO study of the TCEs/EoF of several least-developed countries, which is being undertaken by consultants based in those countries, obliges the consultants to obtain the “prior and informed consent” of communities consulted by them;

(iv) under the aegis of the Intergovernmental Committee, and in cooperation and dialogue with many international, regional and community partners, WIPO is developing a ‘Toolkit’ for managing the IP implications of the documentation of traditional knowledge. In practice, the failure to respect the FPIC principle relating to traditional knowledge can arise at the point when knowledge is documented or otherwise recorded without FPIC and this can have many negative impacts upon the relevant communities. This Toolkit will therefore strengthen the capacity of communities to be fully informed of the IP implications of documenting their knowledge should they wish to do so, supplementing and not detracting from strengthened legal mechanisms.

20. As has been pointed out by the Inter-Agency Support Group on Indigenous Issues, “meaningful participation and consultation are seen as key to the principle of free, prior and informed consent.”¹⁴ The WIPO General Assembly and the WIPO Intergovernmental Committee have both emphasized the need for enhanced

¹² The missions are reported on in the WIPO publication No. 768 “Intellectual Property Needs and Expectations of Traditional Knowledge Holders” (WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge (1998 - 1999)). Annex 2 to this publication reproduces the Terms of Reference.

¹³ Ms. Terri Janke “Minding Culture” (Case Studies on Intellectual Property and Traditional Cultural Expressions), Publication No. 781.

¹⁴ Report on Free, Prior and Informed Consent, E/C.19/2004/11.

involvement of representatives of indigenous peoples and local communities in the work of the Committee. Since the inception of the current program in 1998, various steps have already been undertaken to facilitate the participation of indigenous and local communities in the work of WIPO in the Committee, and more generally concerning IP and genetic resources, TK and TCEs/EoF. For example:

(i) A number of Member States have adopted the practice of funding NGO representatives of indigenous and local communities to participate in sessions of the Intergovernmental Committee;

(ii) The funds provided by WIPO to support Member State participation from developing countries in sessions of the Intergovernmental Committee have been used in some cases by such countries to support the participation of leaders of indigenous or local communities;

(iii) Consultations and workshops at the national and regional level and other fora have included representatives of indigenous and local communities as speakers and participants;

(iv) The WIPO web site continues to update its Accredited Observer's web page designed to allow for the submissions of accredited observers on the issues before the Committee.¹⁵ Much of the material on this web page represents the perspectives of indigenous communities;

(v) Specific briefings and consultations for NGO representatives, particularly representatives of indigenous and local communities, have been undertaken in the framework of Committee meetings and in WIPO's broader interaction with stakeholders;

(vi) The Secretariat has continued its practice of consulting with interested representatives of indigenous and local communities on draft documents and other materials being developed for the Committee;

(vii) An informal consultative forum for indigenous communities and holders of TK/TCEs has been established in advance of the sessions of the Committee;

(viii) Steps have also been undertaken to encourage voluntary donors to support the immediate participation of representatives of accredited observers in any such consultative forum and in the Committee's sessions. Furthermore, the Committee has requested the development of a proposal to establish a Voluntary Fund at WIPO to fund the participation of representatives of indigenous peoples and local communities in sessions of the WIPO Committee;

(ix) WIPO has continued to work with the United Nations Permanent Forum on Indigenous Issues, having formally invited it to take part in its work, including the

¹⁵ <http://www.wipo.int/tk/en/igc/ngo/index.html>

WIPO General Assembly and the Committee. WIPO hosted the 2003 meeting of the Interagency Support Group for the Permanent Forum, and took part in the Permanent Forum's meeting in May 2004, where the question of enhanced participation of indigenous communities was explored and recommendations developed;

(x) at its most recent session in November 2004, the WIPO Intergovernmental Committee agreed, amongst other things, that sessions of the Committee should be preceded by panel presentations chaired by a representative of an indigenous or local community.

IV. POLICY DEVELOPMENT AND NORM-BUILDING

21. A principle of 'prior and informed consent' has been central to the policy debate on the protection of TK and TCEs/EoF since the commencement of this work at WIPO and is the most widely supported approach to TK and TCEs/EoF protection in discussions taking place within the WIPO Intergovernmental Committee.

22. Compliance with a FPIC principle is being discussed in relation to most aspects of possible new forms of protection for traditional knowledge and traditional cultural expressions, such as the objectives of protection, the legal basis for protection, the beneficiaries of protection, the management of rights, the scope of protection (for example, which acts would require FPIC), applicable exceptions and limitations, the term of protection, possible formalities, application in time (for example, would any new form of protection cover earlier and ongoing uses of traditional knowledge), mechanisms for regional and international protection and the relationship between such new form of protection and existing IP protection.

23. A FPIC principle could, for example, entail that TK and TCEs/EoF held by an indigenous people or traditional community should not be accessed, recorded, adapted, used or commercialized without the prior informed consent of the people or community concerned. It could, it is suggested by some, provide a legal and practical mechanism for negotiation of 'mutually agreed terms' as a basis for benefit-sharing arrangements at the point of access to TK and/or TCEs/EoF.

24. The principle of FPIC has also been discussed within the WIPO Committee in relation to the nature and boundaries of the so-called 'public domain'. The term 'public domain' is used here in the sense in which the term is used in the IP context and it refers to elements of IP that are ineligible for private ownership and the contents of which any member of the public is legally entitled to use.¹⁶ The 'public domain' is often characterized as a construct of the IP system, which does not take into account

¹⁶ Litman, J., The Public Domain, quoted in Bragdon, Susan, "Rights and Responsibilities for Plant Genetic Resources: Understanding the role of the public domain and private rights in the production of public goods", draft paper delivered at First Meeting of the Advisory Committee for IPGRI project on the public domain, Portland Oregon, November 14-15, 2002. See also Coombe, R., 'Fear, Hope, and Longing for the Future of Authorship and a Revitalised Public Domain in Global Regimes of Intellectual Property,' 52 *DePaul L. Rev.* 1171, 2003.

private domains established by customary and indigenous laws. Representatives of indigenous peoples and traditional communities within WIPO's discussions have pointed out, for example, that their TK and TCEs/EoF could not be said to have entered the 'public domain' without their FPIC, and, therefore, that any new forms of protection should also apply retroactively to TK and TCEs/EoF that had previously entered the 'public domain' without the requisite FPIC.

25. A FPIC principle in relation to the protection of TK and TCEs/EoF is already variously effected through common-law decisions concerning confidentiality and fiduciary relationships,¹⁷ implied in the provisions of international legal instruments,¹⁸ implemented in many national *sui generis* TK and TCE protection laws, measures and systems,¹⁹ proposed in several working documents submitted by regional groups to the Committee,²⁰ recommended in numerous policy statements by Committee members,²¹ and referred to in a number of responses on national TK and TCEs/EoF protection in response to WIPO questionnaires on TK and TCEs/EoF.²² Many of the existing laws, measures and systems contain detailed procedures and mechanisms for obtaining FPIC.

¹⁷ *Foster v. Mountford and Rigby* (1976) 29 FLR 233.

¹⁸ Such as Article 8(j), CBD and Section IV. C of the Bonn Guidelines.

¹⁹ See, for example, the African Model Law, the laws of Brazil, Costa Rica, India, Peru, the Philippines, South Pacific Regional Model Law, Panama and Portugal (WIPO Publication 'Consolidated Analysis of the Legal Protection of Traditional Cultural Expressions/Expressions of Folklore (Pub. No. 785 E) and WIPO document WIPO/GRTKF/IC/5/INF/4, Annex 1.)

²⁰ See the submissions of the African Group (WIPO/GRTKF/IC/1/10, Annex, page 6, Proposals 3.3(c) and 3.4(d)) and GRULAC (WO/GA/26/9, Annex I, page 2, and Annex II, page 4).

²¹ See African Group (WIPO/GRTKF/IC/1/13, para. 154, referring to WIPO/GRTKF/IC/1/10), Andean Community (WIPO/GRTKF/IC/3/17, para.240), Brazil (WIPO/GRTKF/IC/5/15, paragraph 86, WIPO/GRTKF/IC/4/15, paragraph 103, WIPO/GRTKF/IC/2/14, Annex, para. 15), Canada (WIPO/GRTKF/IC/5/15, para. 92), Colombia (WIPO/GRTKF/IC/3/17, para. 222), Cuba (WIPO/GRTKF/IC/5/15, para. 97), Egypt (WIPO/GRTKF/IC/5/15, para. 96, 127 and WIPO/GRTKF/IC/4/15, para. 153), the European Community and its Member States (WIPO/GRTKF/IC/3/16, page 5, and WIPO/GRTKF/IC/1/8, Annex III, para. 34), Islamic Republic of Iran (WIPO/GRTKF/IC/5/15, paragraph 119), Kenya (WIPO/GRTKF/IC/5/15, para. 69 and WIPO/GRTKF/IC/4/15, para. 111), Mexico (WIPO/GRTKF/IC/5/15, para. 70, and WIPO/GRTKF/IC/4/15, para. 97), Panama (WIPO/GRTKF/IC/3/17, para 226), Peru (WIPO/GRTKF/IC/4/15, paras. 96, 127, and WIPO/GRTKF/IC/3/17, para. 221), the Philippines (WIPO/GRTKF/IC/5/15, para. 85), Turkey (WIPO/GRTKF/IC/4/15, para. 109), the United States of America (WIPO/GRTKF/IC/4/13, para. 8), Venezuela (WIPO/GRTKF/IC/4/15, para. 94, and WIPO/GRTKF/IC/3/17, para. 132), Zambia (WIPO/GRTKF/IC/3/17, para.213), and the Pauktuutit Inuit Women's Association, the Canadian Indigenous Biodiversity Network and the Kaska Dena Council (WIPO/GRTKF/IC/5/15, para. 75), Tebtebba Foundation (WIPO/GRTKF/IC/5/15, para. 77), Indian Movement Tupaj Amaru (WIPO/GRTKF/IC/5/15, para. 80), the Pauktuutit Inuit Womens Association on behalf of the Arctic Athabaskan Council, the Assembly of First Nations, the Call of the Earth Circle, the Canadian Indigenous Biodiversity Network, the Indigenous Peoples Biodiversity Network, the Kaska Dena Council, the Pauktuutit Inuit Women's Association, and the Tulalip Tribes of Washington (WIPO/GRTKF/IC/5/15, para. 172), Mejlis of the Crimean Tartar Peoples (WIPO/GRTKF/IC/4/15, para. 162).

²² See WIPO/GRTKF/IC/3/7, WIPO/GRTKF/IC/3/10, WIPO/GRTKF/IC/4/7 and WIPO/GRTKF/IC/5/7.

26. In addition, a range of IP or IP-related legal mechanisms can be used to provide the legal basis for the exercise (or withholding) of FPIC. For example, the protection of confidential information as an aspect of suppressing unfair competition²³ has been used to give indigenous communities the right to prevent unauthorized use of traditional knowledge that has been kept within the community or which is subject to customary law restrictions on its use.²⁴ In the domain of copyright and related rights, there is an existing range of legal rights that can give creators and performers within traditional communities the entitlement to prevent unauthorized recording, copying and use of cultural expressions, and to prevent degrading use and the failure to acknowledge source (so-called ‘moral rights’). One example is the right of performers of traditional cultural expressions (or expressions of folklore) to prevent the unauthorized recording of performances such as traditional songs, chants, oral narratives and recitals, and to exercise control over whether and how such recordings are distributed, circulated and commercialized (if at all).²⁵

27. Building upon and extending this existing legal basis, FPIC is a key component of the most recent draft proposals for the protection of TK and TCEs/EoF referred to above and discussed by the WIPO Committee in November 2004. For example, the draft proposals currently provide *inter alia* that in respect of TK:

“1. The principle of prior informed consent should govern any direct access or acquisition of traditional knowledge from its traditional holders, subject to these principles and relevant national laws.

2. Legal systems or mechanisms for obtaining prior informed consent should ensure legal certainty and clarity; should not create burdens for traditional holders and legitimate users of traditional knowledge; should ensure that restrictions on access to traditional knowledge are transparent and based on legal grounds; and should provide for mutually agreed terms for the equitable sharing of benefits arising from the use of that knowledge.

3. The holder of traditional knowledge shall be entitled to grant prior informed consent for access to traditional knowledge, or to approve the grant of such consent by an appropriate national authority, as provided by applicable national legislation.”

28. A further context in which FPIC arises is in relation to the identification of the beneficiaries of protection and to the related question of the management of rights. Many WIPO Committee participants have emphasized, for example, that TCEs/EoF are generally regarded as collectively originated and held, so that any rights and

²³ Paris Convention, Article 10bis; TRIPS Agreement, Article 39.

²⁴ *Foster v. Mountford*, note 15 above.

²⁵ The WIPO Performances and Phonograms Treaty, 1996 (WPPT) defines performers as ‘actors, singers, musicians, dancers, and other persons who act, sing, deliver, declaim, play in, interpret, or otherwise perform literary or artistic works or expressions of folklore’ and accords a range of rights to such performers, including the right to withhold authorization of the recording (or ‘fixation’) of the performance of an expression of folklore. As noted above, ‘expression of folklore’ is used synonymously with ‘traditional cultural expression.’

interests in this material should vest in communities rather than individuals.²⁶ On the other hand, most national laws which already provide *sui generis* protection for TCEs/EoF vest rights in the State or a statutory body, or at least provide that the rights should be managed and exercised by the State. In most of these cases, proceeds from the granting of such rights are applied towards national heritage, social welfare and culture-related programs. The African Group has suggested in a submission to the WIPO Committee that it is necessary to ‘(r)ecognize the role of the State in the preservation and protection of traditional knowledge and expressions of folklore.’²⁷ The relationship between communities and the State, and the role and implementation of FPIC therein, raises several complex questions which Member States and other participants are considering. The draft proposals referred to earlier contain preliminary provisions on this matter which seek to take into account actual experiences to date and address a wide range of concerns. For example, in the draft proposals concerning TCEs/EoF, the following is currently suggested for discussion concerning ‘Beneficiaries’ and ‘Management of Rights’:

“Beneficiaries

Measures for the protection of TCEs/EoF should be for the benefit of the indigenous peoples and traditional and other cultural communities:

- (i) in whom the custody and protection of the TCEs/EoF are entrusted in accordance with the customary law and practices of that community; and
- (ii) who maintain and use the TCEs/EoF as being characteristic of their traditional cultural heritage.

Management of rights

(a) To ensure the effectiveness of protection of TCEs/EoF, a responsible authority, which may be an existing office or agency, should be tasked with awareness-raising, education, advice and guidance, monitoring, dispute resolution and other functions.

(b) Authorizations required to exploit TCEs/EoF should be obtained either directly from the community concerned or the authority acting on behalf of and in the interests of the community. Where authorizations are granted by the authority:

- (i) such authorizations should be granted only after appropriate consultations with the relevant indigenous people/s or traditional or other community/ies, in accordance with their traditional decision-making and governance processes;
- (ii) such authorizations should comply with the scope of protection provided for the TCEs/EoF concerned and should in particular provide for the equitable sharing of benefits from their use;
- (iii) uncertainties or disputes as to which communities are concerned should be resolved as far as possible with reference to customary laws and practices;

²⁶ GRULAC (WIPO/GRTKF/IC/1/5, Annex II, p. 5), SAARC (WIPO/GRTKF/IC/1/13, para. 26), Indonesia (WIPO/GRTKF/IC/1/13, para. 29).

²⁷ WIPO/GRTKF/IC/6/12.

(iv) any monetary or non-monetary benefits collected by the authority for the use of the TCEs/EoF should be provided directly by the authority to the indigenous people or traditional or other community concerned;

(v) enabling legislation, regulations or administrative measures should provide guidance on matters such as procedures for applications for authorization; fees, if any, that the authority may charge for its services; public notification procedures; the resolution of disputes; and the terms and conditions upon which authorizations may be granted by the authority.”

29. These proposals were commented on by the WIPO Committee in November 2004 and are open for further comments by the Committee before February 25, 2005. Revised proposals, prepared in the light of comments received, will be published for discussion by the Committee at its eighth session in June 2004.

30. With respect to access to and benefit-sharing in genetic resources and associated TK, a disclosure of origin requirement in patent applications, referred to above, is regarded by many States and others as an instrument to ensure the traceability of genetic resources and associated TK, and to support compliance with FPIC and fair and equitable benefit-sharing, in furtherance *inter alia* of the objectives of the Convention on Biological Diversity (the CBD). FPIC is already a common feature of laws governing access to genetic resources and associated TK, and its application has been further elaborated in the Bonn Guidelines established under the CBD. WIPO cooperates closely with the Secretariat of the CBD in relation to these questions.

31. These subjects are presently under active Member State consideration. There are a variety of views as to in which circumstances FPIC should be a mandatory requirement in respect of the protection TK and TCEs/EoF, as there are diverse approaches towards establishing a disclosure requirement in patent applications for inventions based upon, derived from or otherwise linked to genetic resources and associated TK (see, for example, the WIPO Technical Study on Patent Disclosure Requirements related to Genetic Resources and Traditional Knowledge²⁸, prepared by WIPO at the request of the Conference of the Parties (COP) to the CBD and submitted to the COP in 2004). A number of processes, within WIPO and elsewhere, are underway in which these complex and sensitive questions are being discussed by Member States, indigenous peoples and traditional communities and other stakeholders.²⁹

²⁸ WIPO Publication No. 786 E.

²⁹ Within WIPO, this issue has been mainly considered by the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC), the Standing Committee on the Law of Patents, and the Working Group on PCT Reform. In early June 2005, a special one-day ad hoc meeting will be convened by WIPO to discuss a further invitation received from the Conference of the Parties of the CBD to examine issues concerning the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications. Proposals in this regard are currently available at <http://www.wipo.int/tk/en/genetic/proposals/index.html>

32. Whether or not, for example, a FPIC principle is to be applied in all circumstances and to all uses of TK and TCEs/EoF and derivatives thereof, goes to the heart of a complex debate. Some stakeholders taking part in this debate have identified the need for an equitable balance between the rights and interests of those that develop, preserve and sustain TK and TCEs/EoF, and of those who use and benefit from them, the need to reconcile diverse policy concerns, and the need for specific protection measures to be proportional to the objectives of protection and actual experiences and needs. Conventional IP rights themselves, it is pointed out, are not necessarily exclusive property rights nor are they absolute, as they are subject to various exceptions and limitations.

33. Thus, a principle of FPIC is only one aspect of the forms of protection being considered by the Intergovernmental Committee, which has adopted a wide-ranging, flexible and comprehensive approach to the protection of TCEs/EoF and TK. Protection should, the Committee has discussed, draw on a comprehensive range of options, combining proprietary, non-proprietary and non-IP measures, and using existing IP rights, *sui generis* extensions or adaptations of IP rights, and specially-created *sui generis* IP measures and systems, including both defensive and positive measures.

34. Another key consideration has been the need to consider the customary law and practices of traditional communities. These can form the initial legal basis for the entitlement to exercise or withhold FPIC relating to TK and TCEs. Customary law has also been recognized as an important mechanism for establishing appropriate procedures for consulting upon and affirming FPIC. It has been suggested that laws providing for FPIC may need to take full account of customary law and practices in establishing the entitlement to grant or withhold FPIC, and in defining the appropriate procedures.

35. In this context, a range of possible legal bases for TK and TCEs/EoF protection is being considered, which are, in sum:

(a) **exclusive property rights**, giving the right to authorize or prevent others from undertaking certain acts in relation to TCEs/EoF. An exclusive rights approach would be one way of giving effect to a principle of ‘prior informed consent’;

(b) the application of the **principle of prior informed consent**: this approach provides TK holders and TCEs/EoF custodians with the entitlement for prior informed consent for the use, reproduction or commercial exploitation of their TK and TCEs/EoF, and provides for benefit-sharing arrangements to be established as a condition of access. As noted above, measures applying the PIC principle to TK are often part of a regime regulating access to genetic or biological resources;

(c) entitlements under a scheme for **equitable remuneration/compensatory liability**, providing for some form of equitable return to the rights holders for use of their TK or TCEs/EoF, without creating an exclusive right as such in the TK or TCEs/EoF;

(d) a **moral rights** approach, normally providing the rights: of attribution of ownership; not to have ownership falsely attributed; not to have the protected materials subjected to derogatory treatment; and, at least in some jurisdictions, the right to publish or disclose (the right to decide if, when and how the protected materials ought to be made accessible to the public).;

(e) an **unfair competition** approach, providing a right to prevent various acts that constitute ‘unfair competition’ broadly speaking, such as misleading and deceptive trade practices, unjust enrichment, passing off and taking of undue commercial advantage;

(f) a **penal sanctions** approach, where certain acts and omissions are treated as criminal offences.

36. These various options are not necessarily mutually exclusive, and could be combined, in conformity with a principle of flexibility and comprehensiveness. One option may, for example, be more relevant or suited for a particular form of TCEs/EoF and TK than another.

V. LESSONS AND CHALLENGES

37. As already noted, the protection of TK and TCEs/EoF, and the relationship between IP and access to and benefit-sharing in genetic resources, and in particular the role of FPIC, are the subject of rapidly-evolving policy development. There is as yet little reported experience on how a principle of FPIC which is already contained in several national and regional laws as noted earlier, is being implemented in practice and what lessons and challenges there may.

38. Drawing, however, upon ongoing discussions between WIPO’s Member States and other stakeholders, it would seem that practical application of FPIC in the IP area may present raise several of the conceptual and procedural challenges that have already been identified in other policy areas and processes.³⁰ These would include:

- (a) clarifying the meaning of ‘free, prior and informed consent’ and in which circumstances it applies;
- (b) determining from whom FPIC should be obtained, particularly in respect of TK and TCEs/EoF and derivatives thereof common to more than one country, region, community or culture;
- (c) identification of the appropriate representative/s with whom to consult and obtain FPIC;
- (d) determination of the role of governmental or quasi-governmental bodies which are in many national laws tasked to manage rights on behalf of indigenous peoples and traditional communities;

³⁰ See ‘Free and Informed Prior Consent’, Tebtebba Foundation, paper prepared for Working Group on Indigenous Populations, 22nd Session, July 19 to 23, 2004; Inter-Agency Support Group on Indigenous Issues Report on Free, Prior and Informed Consent (E/C.19/2004/11).

- (e) providing policies and mechanisms to respect the interests of those who take reasonable steps to obtain FPIC from one source community but are subsequently challenged by the same or other communities;
- (f) determining the scope and reach of FPIC concerning downstream, collaborative, derivative or cumulative uses of knowledge or expressions;
- (g) identifying the applicability of FPIC relating to the rights and responsibilities of dispersed or urbanized traditional communities; and,
- (h) establishing mechanisms to use traditional procedures or customary protocols within a framework of FPIC, the equitable sharing of benefits, and related dispute settlement.

39. This is by no means an exhaustive list of issues that require further examination, and the WIPO Secretariat looks forward to continuing to participate in the further consideration of this important question.
