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DRAFT TECHNICAL STUDY ON DISCLOSURE REQUIREMENTS RELATED TO GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

Document prepared by the Secretariat

I. OVERVIEW

1. This document concerns a draft technical study on requirements in patent law systems to disclose information about genetic resources and traditional knowledge (TK) relevant to patented inventions. Such requirements have been proposed in a number of international forums in particular as a possible means of strengthening the relationship between the patent system and arrangements for access and benefit-sharing relating to biological resources and associated TK. Existing patent laws contain a range of general disclosure mechanisms, which in some cases have had the effect of disclosing relevant genetic resources and TK. There are a number of proposals and several national laws which establish disclosure obligations specific to genetic resources or TK, or both, with varying legal effect.

2. A study of this issue was requested by the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the Committee") at its third session, building on earlier work within WIPO and responding also to an invitation made by the Conference of Parties (COP) of the Convention on Biological Diversity (CBD). The draft study, which is annexed to this document, is based on an initial report (document WIPO/GRTKF/IC/4/12) that was considered by the Committee at its fourth session.

3. The draft study reviews salient aspects of the patent system and of legal mechanisms concerning access to genetic resources and associated TK, and surveys the responses to a questionnaire circulated to WIPO Member States on patent disclosure requirements. It discusses the range of relevant disclosure mechanisms, noting that these may differ according to the required linkage between genetic resources or TK and the invention, and according to the legal basis for the disclosure mechanism. The study also reviews relevant provisions of WIPO treaties that may be relevant to disclosure requirements. It concludes with a discussion of disclosure methods consistent with general patent principles and WIPO treaties in particular. These are provided as the basis of further policy discussion in this area rather than as a definitive view on treaty compliance.

II. INTRODUCTION

4. The background to this study is discussed in detail in document WIPO/GRTKF/IC/4/11 ("Initial Report on Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge"), which was considered by the Committee at its fourth session.[1] Among the tasks proposed for the Committee at its inception was consideration of intellectual property (IP) questions related to genetic resources, including:

- Contractual agreements for access to genetic resources and benefit-sharing;
- Legislative, administrative and policy measures to regulate access to genetic resources and benefit-sharing;
- Protection of biotechnological inventions, including certain related administrative and procedural issues; and
- Multilateral systems for facilitated access to genetic resources and benefit-sharing.[2]

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[1] See report of the fourth session, document WIPO/GRTKF/IC/4/15, paragraphs 169-174.

[2] See discussion in WIPO/GRTKF/IC/1/3.

5. The Committee's work on IP issues concerning genetic resources has focussed on IP-related provisions in licensing and contractual agreements concerning access to genetic resources and benefit-sharing. The Committee has also received reports on related developments and policy discussions in other fora, such as the adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) under the auspices of the Food and Agricultural Organization (FAO)[3] and certain decisions of the COP of the CBD, which include the adoption of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization ("the Bonn Guidelines").[4]

6. Further, at its third session, the Committee approved an invitation issued to WIPO in paragraph 4 of Section C of Decision VI/24 of the COP and transmitted by the Executive Secretariat of the CBD.[5] The invitation, as accepted by the Committee, was phrased as follows:

> "[The COP] [i]nvites the World Intellectual Property Organization to prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, *inter alia*:
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> (a) Genetic resources utilized in the development of the claimed inventions;
>
> (b) The country of origin of genetic resources utilized in the claimed inventions;
>
> (c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;
>
> (d) The source of associated traditional knowledge, innovations and practices; and,
>
> (e) Evidence of prior informed consent."

7. The Committee agreed upon a work schedule (proposed in document WIPO/GRTKF/IC/3/12) that would permit a technical study to be prepared and consulted upon in time for it to be transmitted as a technical information document to the seventh COP. The work schedule comprises the following steps:

"1. *Intersessional Period between the third and fourth sessions of the Committee* (June to December 2002): A questionnaire could be sent to Committee members regarding the issues identified for study in the invitation contained in paragraph 4, Section C, of Decision VI/24.

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3 See document WIPO/GRTKF/IC/2/INF.2.

4 See document WIPO/GRTKF/IC/3/12.

5 See paragraph 79 of the Report of the Committee's Third Session (WIPO/GRTKF/IC/3/17). The decisions made at the sixth Conference of the Parties to the CBD that are of relevance to WIPO were described in document WIPO/GRTKF/IC/3/12 ("Certain Decisions of the Sixth Conference of the Parties to the Convention on Biological Diversity").

"2. *Fourth session of the Committee* (December 2002): A draft technical study, including a compilation of responses received from Committee members and a draft analysis of those responses, could be presented to the Committee for its consideration and comments.

"3. *Intersessional Period between the fourth and fifth sessions of the Committee* (December 2002 to June 2003): Subject to the decisions of the Committee upon consideration of the draft technical study, the comments received from the Committee members could be incorporated into the draft study in order to produce the revised technical study.

"4. *Fifth session of the Committee* (June 2003): The revised technical study could be presented to the Committee for consideration and for transmission, if agreed, to the Twenty-Ninth Session of the WIPO General Assembly.

"5. *Twenty-Ninth Session of the WIPO General Assembly* (September 2003): The revised technical study, if so agreed by the Committee, could be presented to the General Assembly for its consideration. If so decided by the WIPO General Assembly, the final technical study could be transmitted as a technical information document to the seventh COP of the CBD, which will take place in Kuala Lumpur, Malaysia, in the first quarter of 2004."[6]

8. The Committee also accepted the suggestion made by the delegations of Bolivia, the Dominican Republic, Peru, Sri Lanka, and Venezuela that the questionnaire referred to in step one of the schedule be submitted to Members for comment prior to its general distribution. The Secretariat accordingly engaged in informal consultations with Members on a draft list of questions in July 2002. Following these consultations, the questionnaire was revised and circulated under cover of document WIPO/GRTFK/IC/Q.3, and is provided as Annex II to this document ("the Questionnaire"). Thirty-one responses to the Questionnaire have been received[7] up to April 30, 2003, and have been taken into account in the present draft. The initial report on the development of the draft study (document WIPO/GRTKF/IC/4/11) was considered by the Committee at its fourth session.[8] It was agreed that the comments on the initial report and any further responses to the Questionnaire be submitted to the Secretariat before March 14, 2003, so that the current version could be prepared and circulated in due time to permit its consideration in advance of the fifth session of the Committee.

9. Based on the inputs received, the draft study has been prepared and is attached as Annex I. According to the agreed program, this draft study is to be considered by the Committee with a view to its submission to the WIPO General Assembly, for possible transmission to the Conference of Parties of the Convention of Biological Diversity as a technical background document for consideration in that forum.

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6 Document WIPO/GRTKF/IC/3/12, paragraph 3.

7 Up to April 30, 2003, responses had been received from Argentina, Australia, Burundi, Canada, China, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Kenya, Malawi, Mexico, New Zealand, Niger, Philippines, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Spain, Sweden, Switzerland, Uruguay, United States of America, Viet Nam, the European Commission and the European Patent Office. The responses to the questionnaire are available on the WIPO website at: < http://www.wipo.int/globalissues>.

8 See paragraphs 169 to 173 in the report of the fourth session, document WIPO/GRTKF/IC/4/15.

10. The attached draft technical study has been prepared to contribute to international discussion and analysis of this general issue, and to help clarify some of the legal and policy matters it raises. It has not been prepared to advocate any particular approach nor to expound a definitive interpretation of any treaty. It is therefore suggested that the appropriate status of this document is to be regarded as technical input to facilitate policy discussion and analysis in the CBD and in other fora, and it should not be considered a formal paper expressing a policy position on the part of WIPO, its Secretariat or its Member States.

11. This draft technical study has explored a number of significant issues relevant to the interaction between the patent system and genetic resources and traditional knowledge that are used in the invention. It has not sought to resolve these issues but rather to illustrate and elucidate them. Member States may wish to consider future work in this area within the Committee or elsewhere within WIPO, which may include additional exchange of national experience beyond the responses received so far to the Questionnaire, and the elaboration of case studies and the analysis of some of the specific disclosure scenarios described and discussed in the draft study.

12. The Committee is invited: (i) to consider and comment on the draft technical study as contained in Annex I, and to decide on whether it should be forwarded to the WIPO General Assembly with the recommendation that it be transmitted as a technical reference document to the Seventh Conference of Parties of the CBD; and (ii) to consider possible future work on this issue, including the continued exchange of national experience and case studies, and the development of guidelines and recommendations concerning the interaction between access to genetic resources and patent disclosure.

[Annex I follows]

ANNEX I

DRAFT TECHNICAL STUDY

DISCLOSURE REQUIREMENTS IN PATENT SYSTEMS RELATED TO GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

Paragraphs

I. INTRODUCTION

1. This draft study concerns disclosure requirements in patent law that are relevant to genetic resources (GR) and traditional knowledge (TK) that are used in inventions for which patent protection is claimed.

2. The draft study builds on the work of WIPO concerning the relationship between intellectual property (IP) and GR/TK,[1] including the Working Group on Biotechnology[2], the WIPO Meeting on Intellectual Property (April 2000), and the subsequent work of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the "IGC") which was established by the WIPO General Assembly in 2000.

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[1] For ease of reference, the abbreviation 'GR/TK' in this draft study will refer generally to either genetic resources or traditional knowledge, or the combination of genetic resources and associated TK.

[2] See document WIPO/BIOT/WG/99/1, *Issues for Proposed WIPO Work Program on Biotechnology*, prepared by Dr. Barreto de Castro, Mr. Kushan, Dr. Zaleha and Professor Strauss, paragraph 46.

3. The immediate context for this study is provided by the invitation of the Conference of Parties (COP) of the Convention on Biological Diversity (CBD) for WIPO to:

> "prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, *inter alia*:
>
> (a) Genetic resources utilized in the development of the claimed inventions;
>
> (b) The country of origin of genetic resources utilized in the claimed inventions;
>
> (c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;
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> (d) The source of associated traditional knowledge, innovations and practices; and,
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> (e) Evidence of prior informed consent."

At its third session in June 2002,[3] the IGC agreed that this study should be prepared and agreed on a timeline for the development and consideration of the study. A questionnaire was circulated to provide input on national laws and practical experience (WIPO/GRTKF/IC/Q.3, following as Annex II). An initial report on the preparation of this study and overview of the questionnaire responses was published in November 2002 (document WIPO/GRTKF/IC/4/11) and was considered by the IGC at its fourth session.[4] The IGC agreed that further responses should be submitted by March 14, 2003 (see document WIPO/GRTKF/IC/4/15, paragraphs 174 and 175(x)). Up until April 30, 2003, responses had been received from Argentina, Australia, Burundi, Canada, China, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Kenya, Malawi, Mexico, New Zealand, Niger, Philippines, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Spain, Sweden, Switzerland, Uruguay, United States of America, Viet Nam, the European Commission and the European Patent Ofice. Further to discussions at the fourth session, this study is based as far as possible on each of these responses.

II. GENERAL APPROACH

4. This draft study concerns two general areas of law and regulation:

- regulation of the access to, use of, and sharing of benefits from genetic resources and associated TK; and
- laws governing the grant of patent rights for eligible inventions.

5. The study deals with the interaction, and potential new forms of interaction, between these two regulatory systems. The laws and administrative mechanisms that apply in these

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[3] Document WIPO/GRTKF/IC/3/17, paragraphs 79-81.

[4] Document WIPO/GRTKF/IC4/15, paragraphs 169-174.

areas have both national and international components (as well as several regional agreements and arrangements). In essence, it is national laws that determine the conditions of access to genetic resources[5] and traditional knowledge, and national laws that provide for the recognition, grant and maintenance of patent rights[6] (several systems also provide for regional patents with the legal effect of patents granted under national law). International law, expressed especially in several key treaties, establishes general principles for the operation of national laws, and also provides for administrative facilitation.

6. This study therefore addresses these issues at both levels – the general principles and administrative systems created at the international level, and the application of these principles through the operation of distinct national laws. There is, however, an additional international issue that this study raises – the possibility that the national legal system of one country should take account of the operation of a different area of law in another country. In particular, the study deals with the possibility that the grant or validity of a patent in one jurisdiction may be dependent on compliance with the laws of another country that establish the conditions for access to genetic resources and TK.

7. The approach that this study takes is to consider first the different relationships that may exist between a patented invention and relevant genetic resources and TK, and consider the implications of each in terms of patent law. It then considers the implications of each of these possibilities in the light of general international patent standards and of specific treaties.

III. BACKGROUND

8. The growing importance of biotechnology and the increasing number of patents granted to biotechnology-related inventions[7] highlight the potential value of genetic resources and associated TK as source material for some biotechnology inventions; yet there is a wide range of technologies that may use genetic resources as inputs and may make use of traditional knowledge, so that their importance and value are not limited to biotechnology as such. At the same time, there have been significant international developments in the legal framework that applies to genetic resources and associated TK, especially the implementation of the CBD and the recent negotiation of the FAO ITPGR. These developments have combined to sharpen concerns that appropriate mechanisms should be established and effectively implemented to regulate access to genetic resources and associated TK, and in particular to provide for prior informed consent regarding access, and to promote the equitable sharing of benefits from the use of these resources and knowledge. At the same

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5 Consistent, for example, with the principles of the "sovereign rights of States over their natural resources" and of "prior informed consent" concerning access (Article 15 of the CBD).

6 Consistent, for example, with the principle of independence of patents under Article 4*bis* of the Paris Convention.

7 A general indication of the increase in relative importance of biotechnology patent activity is suggested by a recent OECD study which concluded that "the absolute number of USPTO and EPO biotechnology patents has grown substantially in comparison with the total number of patents. At the USPTO between 1990 and 2000, the number of biotechnology patents increased by 15%, compared to an increase of just 5% for patents overall. At the EPO, biotechnology patent applications show a very similar trend: between 1990 and 1997, the number of biotechnology patents increased by 10.5%, while total patents rose by 5%," **"**Biotechnology Statistics in OECD Member Countries: Compendium Of Existing National Statistics," STI Working Paper 2001/6, at, p. 10.

time, these developments have underscored the need for effective use of the IP system to promote benefits from the use of genetic resources and TK in line with the international legal and policy framework.

9. There are, in general, distinct national (and in certain cases regional) laws that establish and regulate IP rights and that govern access to genetic resources. These distinct legal systems correspond to distinct international legal frameworks – on the one hand, the CBD and the FAO ITPGR, and on the other, the set of international conventions concerning IP. Yet the two regulatory systems do interact in practice. For instance, IP rights such as patents can be part of the legal and commercial framework that is used to generate benefits from the use of genetic resources, and agreements concerning patent ownership, licensing exploitation can help define how benefits are shared. Hence concerns about access and benefit-sharing can translate into a debate about the interaction between the IP system and the regulation of genetic resources and associated TK.

Access and benefit-sharing for genetic resources and TK – international frameworks

10. The conclusion of the CBD in 1992 was one of the key steps internationally in the articulation of rules governing access to genetic resources and associated TK. The objectives of the CBD are:

> "…the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."[8]

11. Thus the CBD adopts the dual goals of conserving biodiversity and of promoting sustainable use of its components, and specifies that benefits arising from use of genetic resources should be shared fairly and equitably. The CBD articulates the principle that "States have … the sovereign right to exploit their own resources pursuant to their own environmental policies…"[9] It recognizes "the sovereign rights of States over their natural resources," and provides that "the authority to determine access to genetic resources rests with the national governments and is subject to national legislation" and that "[a]ccess, where granted, shall be on mutually agreed terms and subject to [certain] provisions, including that [a]ccess to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party."[10] For the purposes of the CBD, "'genetic material' means any material of plant, animal, microbial or other origin containing functional units of heredity, 'genetic resources' means genetic material of actual or potential value," and "'biological resources' includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity."[11]

12. In the context of measures on *in situ* conservation of biodiversity (Article 8), the CBD requires each State Party "as far as possible and as appropriate" and "subject to its national

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8 CBD, Article 1.
9 CBD, Article 3.
10 CBD, Article 15.
11 CBD, Article 2.

legislation" to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices" (Article 8(j)). In implementing these requirements, consideration also has to be given to related provisions, such as Article 10(c), which refers to customary use of biological resources within the parameters of sustainable use, and Article 18(4) concerning cooperation for the development and use of indigenous and traditional technologies in pursuance of the objectives of the CBD.

13. The CBD provides that each Contracting Party "shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties"[12] and "shall take legislative, administrative or policy measures, as appropriate [and subject to certain conditions] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources."[13] It stipulates that this sharing of benefits "shall be upon mutually agreed terms." Article 19, on "handling of biotechnology[14] and distribution of its benefits," provides among other things that each Contracting Party "shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties" and that this "access shall be on mutually agreed terms." This may in practice entail bilateral agreement between those providing and those making use of resources and associated TK.

14. The adoption in November 2001 of the FAO ITPGR[15] was a further key step in the evolution of international frameworks for access to genetic resources and benefit-sharing. The ITPGR provides for a multilateral approach to access and benefit-sharing, in which sovereign rights of States over their own genetic resources are recognized, and it is agreed, in the exercise of these rights, to establish an open multilateral system of exchange.[16] Such a system is exemplified in the work and functioning of the Consultative Group on International Agricultural Research and is to be established under Part IV of the ITPGR in the form of a Multilateral System of Access and Benefit-sharing (MLS). The MLS will include the plant genetic resources for food and agriculture listed under Annex 1 of the ITPGR and which are under the management and control of Contracting Parties and in the public domain. The MLS will provide for facilitated access in accordance with certain conditions and benefit-sharing through mechanisms of information exchange, access to and transfer of technology, capacity-building, and the sharing of the benefits arising from commercialization. Whereas the CBD defines the term "country of origin of genetic resources" (Article 2), the ITPGR uses the term

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12 CBD, Article 15.6.

13 CBD, Article 15.7.

14 Biotechnology is defined in Article 2 as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."

15 See document WIPO/GRTKF/IC/2/INF.2.

16 See section IV.A.3 in document WIPO/GRTKF/IC/1/3 for further background on multilateral systems.

"center of origin" of plant genetic resources (Article 2), reflecting the fact that for many such resources a single country of origin may not easily be determined.[17] An observer organization at the Committee's fourth session observed that:

> " the FAO ITPGR provides for a multilateral approach to access and benefit sharing but only for a list of phytogenetic resources and solely for food and agriculture purposes, and established a facilitated access mechanism to the listed genetic resources rather than an open exchange mechanism. The CGIAR centers although mentioned the Treaty are at the moment out of its scope. Finally, the facilitated access mechanism does not equal public domain."[18]

National regulation of access to genetic resources

15. A full or authoritative discussion of national regulation of the principles and substantive provisions of the CBD is beyond the scope of this draft study – the policy forums of the CBD itself have explored these issues in detail.[19] Similarly, mechanisms for national implementation of the FAO ITPGR are under consideration within the FAO. It is clear, however, that a variety of existing mechanisms at the level of national law can have the effect of governing access to genetic resources, and setting and enforcing the conditions of access, such as arrangements for sharing benefits, within the bounds of national sovereignty and the general principles of the CBD. These can include property law, environmental and resources law, laws concerning the interests of indigenous people, and specific laws regulating access to categories of genetic or biological resources. There may be a specific legal framework for access to genetic resources, or access may be regulated indirectly through laws concerning rights attached to land ownership or leasehold, through the conditions that apply to access to and exploitation of State-owned land and resources, or through the effect of the law of contract. Government agencies and access providers have used contracts (such as material transfer agreements), licenses and permits, to establish and enforce the conditions of access to genetic resources and associated TK.

16. As part of the consideration of the implementation of the CBD, the most recent CBD COP adopted recommendations[20] on access and benefit-sharing, drawing on the recommendations (reported in document WIPO/GRTKF/IC/2/11) of the CBD Ad Hoc Open-ended Working Group on Access and Benefit-sharing. This included the adoption of the Bonn Guidelines, which are voluntary and non-binding but gives an illustration of possible approaches to national regulatory systems in this domain, under the heading "competent authority(ies) granting prior informed consent":

> "26. Prior informed consent for access to *in situ* genetic resources shall be obtained from the Contracting Party providing such resources, through its competent national authority(ies), unless otherwise determined by that Party.

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17 See "Identifying Genetic Resources and Their Origin: The Capabilities and Limitations of Modern Biochemical and Legal Systems," CGRFA, Background Study No. 4, 1994.

18 See the report of the fourth session, document WIPO/GRTKF/IC/4/15, at paragraph 171.

19 Notably the CBD Ad Hoc Open-ended Working Group on Access and Benefit-sharing, and the Conference of Parties (COP) itself, as discussed below.

20 UNEP/CBD/COP/6/20, decision VI/24; see also WIPO/GRTKF/IC/3/12.

> "27. In accordance with national legislation, prior informed consent may be required from different levels of Government. Requirements for obtaining prior informed consent (national/provincial/local) in the provider country should therefore be specified."[21]

17. On the operation of national regulatory systems, the Bonn Guidelines provide under 'process' that:

> "36. Applications for access to genetic resources through prior informed consent and decisions by the competent authority(ies) to grant access to genetic resources or not shall be documented in written form."
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> "37. The competent authority could grant access by issuing a permit or licence or following other appropriate procedures. A national registration system could be used to record the issuance of all permits or licences, on the basis of duly completed application forms."[22]

18. To elicit information about applicable legal regimes in WIPO Member States, Question 1 of the Questionnaire requested details of "national and/or regional laws and/or regulations which regulate access to genetic resources and/or traditional knowledge…" Responses received so far included references to:

- Federal, provincial and territorial legal regimes governing access to land, environmental laws or sectoral laws (such as on forestry or fisheries), and the legal regime governing Aboriginal rights to use natural resources;[23]
- Specific legislation on genetic resources as such, which may also concern associated TK;[24]
- Statutory and customary law regarding real estate and movables, and general property law;[25]
- Property and contract law, regulations concerning Federal National Parks, and state trade secret law applying to TK;[26]
- Use of contracts on access to genetic resources;[27]
- Deposits of biological material for patent purposes;[28]
- Specific rules on genetic resources of animal origin and of plant origin (selection achievements); [29] and
- Regulations under environment protection and biodiversity conservation legislation, involving the issuing of a permit system with distinct benefit-sharing arrangements, monitored by the access provider.[30]

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21 WIPO/GRTKF/IC/2/11, Annex, page 20.
22 WIPO/GRTKF/IC/2/11, Annex, page 21.
23 Response of Canada.
24 Response of Portugal.
25 Response of Switzerland.
26 Response of the United States of America, including also the "Application Procedures and Requirements for Scientific Research and Collecting Permits" from the National Parks Service of the United States Department of the Interior.
27 Response of Mexico.
28 Response of the Republic of Moldova.
29 Response of the Russian Federation.
30 Response of Australia.

19. Several responses noted the role of federal, provincial (state) and local legal systems in the overall governance of access to genetic resources and associated TK, and one response noted the existence of a consultative mechanism aimed at ensuring national consistency between federal and state laws.[31]

20. Most responses so far received indicate that there were no specific laws or regulations in place governing access to genetic resources or TK, and several report on processes that are under way to introduce such a regime. Various contracts, agreements, licensing or permit schemes and similar tools have also been widely employed, and these are discussed in document WIPO/TKGRF/IC/4/10, "Report on Electronic Database of Contractual Practices and Clauses Relating to Intellectual Property, Access to Genetic Resources and Benefit-Sharing" and document WIPO/GRTKF/IC/5/9 "Contractual Practices and Clauses Relating to Intellectual Property, Access to Genetic Resources and Benefit-Sharing."

Intellectual property and access to genetic resources and TK

21. The IP system plays a practical role in promoting the sharing of benefits from access to genetic resources and associated TK. IP rights have arisen in discussion about implementation of the CBD, including within the governance structure of the CBD itself, specifically the CBD COP and subsidiary bodies such as the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, the Ad Hoc Open-ended Intersessional Working Group on Article 8(j) and Related Provisions, and the Subsidiary Body on Scientific, Technical and Technological Advice. This work has led, for instance, to the adoption by the COP of recommendations on the role of intellectual property rights in the implementation of access and benefit-sharing arrangements.[32] The CBD refers explicitly to IP, and patents in particular, only in the context of access to and transfer of technology in Article 16, although elements of this paragraph are also referred to in Article 17 on the exchange of information. Article 16 provides that access and transfer "shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights" when the technology is subject to IPRs. It also provides that Contracting Parties should take certain legislative, administrative or policy measures relating to access and transfer to technology "including technology protected by patents and other intellectual property rights, where necessary." In the provision on access to and transfer of technology, it provides (at Article 16.5) that:

> "The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."

There has also been extensive consideration of the role of IP rights in relation to the provisions of Article 8(j) concerning "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles," and the wider application and

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31 Response of Australia.

32 Within COP Decision VI/24, and based on recommendations of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing.

equitable sharing of benefits; much of the Committee's own work on TK is relevant in this regard.[33]

22. The Bonn Guidelines provide some background to the discussions on the practical interaction between the IP system and the CBD. For instance, the Guidelines suggest that material transfer agreements (MTAs) on genetic resources could include "conditions under which user [of an accessed genetic resource] may seek intellectual property rights";[34] and that non-monetary benefits could include "joint ownership of patents and other relevant forms of intellectual property rights."[35]

23. A number of proposals have been put forward in international discussions that would involve more specific interaction between the IP system and systems for access and benefit-sharing. These proposals would require or encourage patent applicants to furnish information relating to genetic resources and/or TK used in the development of inventions claimed in patent applications. This may include disclosing the source of this material, and providing information about the legal basis of the access to it (such as evidence or an indication of whether prior informed consent was obtained). Proposals with various forms of this general concept have been put forward in the World Trade Organization (WTO);[36] the CBD;[37] the United Nations Conference on Trade and Development (UNCTAD);[38] and WIPO.[39] CBD COP Decision VI/24 invited its Parties and Governments "to encourage the disclosure of the country of origin of genetic resources in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted" and "to encourage the disclosure of the origin of relevant traditional knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity in applications for intellectual property rights, where the subject matter of the application concerns or makes use of such knowledge in its development."

24. These proposals are discussed in greater detail below (see section V especially). While there is a number of diverse proposals, they center around one or both of two general requirements: a requirement on the patent applicant to disclose the origin or source of genetic resources or traditional knowledge used in an invention (or in some way connected with the development of the invention), and a requirement to disclose the legal context in which relevant genetic resources or traditional knowledge were accessed – in a strong form, this may include providing evidence that the access complied with a certain procedure or legal standard (such as criteria for adequate prior informed consent). These proposals may differ in terms of the required linkage between the GR or TK and the invention concerned, the legal basis of the requirement (within or beyond patent law, and potentially applying and interpreting foreign access or contract law), and the exact legal nature of the requirement and the consequences of

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33 See, for example, documents WIPO/GRTKF/IC/5/8, WIPO/GRTKF/IC/5/7, WIPO/GRTKF/IC/4/8, WIPO/GRTKF/IC/3/9 and WIPO/GRTKF/IC/3/7.

34 Bonn Guidelines, Appendix I.

35 Bonn Guidelines, Appendix II.

36 See, *inter alia*, documents IP/C/W/195, IP/C/W/228, WT/GC/W/233, IP/C/M/32, para 128, IP/C/M/33, para 121.

37 See Decision IV/8, paragraph 3 and Annex; Decision V/26, paragraph A.15(d); UNEP/CBD/COP/5/8: paragraph 127.

38 See TD/B/COM.1/EM.13/3, paragraph 17.

39 See SCP/3/10, WIPO/IP/GR/00/2, WIPO/IP/GR/00/4.

non-compliance. For example, the source or origin of genetic resources may be very specific, or may be limited (as in the case of the COP invitation) only to *country of origin of genetic resources*, noting that in the CBD this is defined as "the country which possesses those genetic resources in *in-situ* conditions."

25. Certain concerns have been expressed about practical and legal issues raised by some of these proposals, notably concerning the mandatory disclosure of information on use of genetic resources and TK. These concerns touch on the operation of the patent system and applicable international treaties.[40] Accordingly there is an ongoing international dialogue about the need, value, practical implications and legal basis of mechanisms specifically linking access to genetic resources and TK with the patent system. The CBD Ad Hoc Open-ended Working Group on Access and Benefit-sharing noted "that there is a need for accurate technical intellectual property information and explanation concerning methods for requiring the disclosure within patent applications."[41]

WIPO consideration of disclosure issues

26. Earlier work within WIPO has given some consideration to these issues. A paper prepared for the Working Group on Biotechnology commented that:

> "Certain proposals have been advanced within WIPO and other fora that would envision a requirement that patent applicants disclose certain information relating to biological materials that were used in developing an invention. Some of these proposals appear to be designed to ensure that parties have obtained samples of certain biological materials used in developing an invention legitimately, or seek to require applicants to disclose certain contractual relationships in the patent application. It is unclear, however, whether such a requirement should be dealt with by national laws as being substantive, thus leading to the rejection of the patent application in its absence, or rather a merely procedural one."[42]

27. The Working Group proposed "to undertake an evaluation of practices and means used to identify and protect the interests of the various parties that take part in research and development of biotechnology inventions," including the providers of genetic resources and other biological resources.[43] At its meeting of November 8 and 9, 1999, the Working Group agreed to prepare a list of questions about practices related to the protection of biotechnological inventions under patent and plant variety protection systems or a combination thereof by WIPO Member States. This list included several questions concerning special provisions to ensure the recording of contributions to inventions.

28. Responses were collated in Document WIPO/IP/GR/00/3 Rev.1, "Information Provided by WIPO Member States Concerning Special Provisions to Ensure the Recording of Some

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40 See, for example, the summary of the debate about such proposals relating to the TRIPS Agreement provided in *The Relationship between the TRIPS Agreement and the Convention on Biological Diversity: Summary of Issues Raised and Points Made*, WTO document IP/C/W/368, paragraphs 20 to 28.

41 Reported to the Committee in document WIPO/GRTKF/IC/2/11, page 35.

42 Document WIPO/BIOT/WG/99/1, *Issues for Proposed WIPO Work Program on Biotechnology*, prepared by Dr. Barreto de Castro, Mr. Kushan, Dr. Zaleha and Professor Strauss, paragraph 46.

43 Document WIPO/BIOT/WG/99/1, paragraph 48.

Contributions to Inventions," considered by the WIPO Meeting on Intellectual Property and Genetic Resources which met on April 17 and 18, 2000, and were provided to the Committee itself with document WIPO/GRTKF/IC/1/6, "Information Provided by WIPO Member States concerning Practices related to the Protection of Biotechnological Inventions." Of the 57 Member States that had responded to the questions, five gave affirmative answers to the question whether their included "any special provisions to ensure the recording of contributions to inventions (such as the source of government funding, the source of genetic resources that originate or are employed in biotechnological inventions, the grant or prior informed consent to have access to those resources, etc.)?" Another three indicated that legislation was planned to introduce such provisions. Two indicated that "failure in disclosing such contributions will bar the patent from being granted and/or will constitute grounds for its invalidation or revocation."

29. The Committee has also considered document WIPO/GRTKF/IC/1/3, which discusses among other issues the "recording of ownership interests in inventions which arise from access to or use of genetic resources," and pointed out that "aspects for further discussion may include: (i) whether the proposed requirement would also apply when the invention, for which the application is filed, concerns synthesized substances that were isolated or derived from active compounds of an accessed genetic resource and, if so, what is an agreed definition of "derived"; (ii) whether and how the requirement would apply for genetic resources accessed from multilateral systems for facilitated access to genetic resources, which may be established in the agricultural sector; and (iii) what would be the consequences of non-compliance with the requirement, ranging from a fine to invalidation or revocation of the patent." It commented that "from the intellectual property point of view, existing standards on the availability, scope and use of patents, such as those set out in Articles 27, 29, 32 and 62 of the TRIPS Agreement, may afford some guidance as to how those WIPO Member States which are also WTO Members may address this concept."

IV. ASPECTS OF INTELLECTUAL PROPERTY SYSTEMS

30. This section highlights aspects of the patent system that may be relevant to requirements on patent applicants to disclose certain information, illustrated with reference to Member States' responses to the Questionnaire and noting some relevant provisions of the key treaties administered by WIPO with bearing on the patent system, notably the Paris Convention,[44] the Patent Cooperation Treaty (PCT),[45] and the Patent Law Treaty (PLT).[46] A number of Questionnaire responses also refer to microorganism deposit systems that give effect to the system of international recognition established under the Budapest Treaty.[47] This study also cites various elements of the WTO TRIPS Agreement, since it is an important expression of some of the key concepts under discussion, but does not seek to make authoritative interpretations of TRIPS and of the nature of the obligations it imposes.

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44 The Paris Convention for the Protection of Industrial Property, as revised at Stockholm on July 14, 1967.

45 Patent Cooperation Treaty (PCT), done at Washington on June 19, 1970.

46 Patent Law Treaty, adopted at Geneva on June 1, 2000 (*not yet in force*).

47 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977).

31. While international treaties set general legal standards that apply to patent laws, and provide for administrative facilitation, actual patent rights are defined, granted, exercised and regulated under national (and some regional) laws. Patent rights are granted to the actual inventor (or his or her successor in title, typically the inventor's employer) on the basis of applications submitted to national or regional authorities. The PCT system provides for a single international patent application that has the legal effect[48] of separate applications in each of the countries and regions that are designated in the international application.

Information requirements for patent applications

32. Patent applications contain a combination of technical, legal and administrative information. Under national and regional patent law and related laws (and in line with established international standards), patent applicants are typically required to furnish information in four general areas:

(a) Information that enables a person skilled in the art to carry out the claimed invention, and in some laws the disclosure of the best mode of carrying out the invention known by the inventor at the relevant date.[49] For inventions involving a new microorganism, the disclosure obligation may also entail deposit of the microorganism itself;[50]

(b) information that defines the matter for which protection is sought (a claim or claims);

(c) other information relevant to the determination of novelty, inventive step or non-obviousness, and capability of industrial application or utility of the claimed invention, including search reports, and other known prior art;[51]

(d) administrative or bibliographic information relevant to the claimed patent right, such as the name of the inventor, address for service, details of priority documents, etc.

These requirements are generally characterized as 'formal' or 'substantive,' and there is a distinction in the PCT and PLT systems between substantive patent law and requirements concerning the 'form or contents' of an application (see discussion below from paragraph 168). This is an important distinction in the context of the current discussion, and a distinction that is not always clearly articulated. A reference to 'formality requirements' may apply to the need to disclose information (such as names of inventor(s) and addresses) or to the need to submit certain documents (such as priority documents – i.e. copies and translations of foreign patent applications that form the basis of a claim to priority); 'formality requirements' may also refer to the physical format (layout on the page, size of

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48 See PCT, Article 11(3).

49 For example, TRIPS Article 29.1 provides that: "[WTO] Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application."

50 See the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977); this requirement applies in some countries to biological resources in general – see the discussion below in paragraph 45.

51 TRIPS Article 29.2 provides that "Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants."

paper, etc.). 'Substantive requirements' generally refers to the actual nature of the invention as such, and whether it meets the standards set for patentability ('substantive' law may also be relevant, however, in determining such questions as inventorship, entitlement to apply for or to be granted a patent, and other interests in a patent right, quite apart from the qualities of the invention as such). The distinction between substantive and formal requirements is often considered in terms of consequences of non-compliance (in particular, failure to comply with substantive requirements such as novelty renders a patent invalid), failure to meet certain formality requirements may nonetheless be fatal for a patent application, especially if it is not rectified in time.

33. The obligation on an applicant to provide information can therefore be considered under two aspects – compliance with formal requirements, and compliance with substantive requirements. For example, where a patent application is required to identify the inventor or inventors, this may be considered as a formality requirement (in that an application will generally not be accepted if there is no mention of a claimed inventor), but determining the identity of the inventor also entails a substantive legal judgement, and indeed forms the basis of the entitlement to a patent right. An incorrect or incomplete indication of the inventor may lead to transfer or invalidation of the patent right. Similarly, it is also a formal requirement that a patent application should include a description of the invention, but this description must also meet specific substantive standards if the patent application is to be accepted (or if a granted patent is to be valid).

34. International standards that apply to the patent system have bearing both on formalities and substantive aspects of the requirements placed on an applicant. This distinction can be illustrated by reference to the requirements specified for applications to be accorded a filing date by the patent authority receiving the application. Such requirements are considered to be 'formalities' rather than substantive requirements. For instance, it is generally mandatory to submit an apparent description of the invention before a filing date is accorded to a patent application; at this stage no judgement is made as to the substantive content of the description, but the application is accepted for processing because it meets the formality requirement when it simply appears that a description has been submitted. Patent applications may subsequently be examined to assess whether the application accords with substantive requirements, such as the requirement that the invention as claimed be novel, involve an inventive step (or be non-obvious), and be industrially applicable,[52] and the requirement that the description be sufficient and the claims be supported by it. At this stage, the description may be assessed as to its substantive compliance with legal requirements, as against formal compliance.

35. For instance, in relation to descriptions, the PLT (Article 5(1)(a)) identifies, as a formality requirement, 'a part which on the face of it appears to be a description' as one of the elements that forms part of an application sufficient to establish a filing date. The PCT Article 3(2) similarly requires that an international application shall contain a description, among other elements required for establishing a filing date, but it also sets a substantive standard for the description, specifying that it "shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." (Article 5) This substantive requirement is mirrored in TRIPS, Article 28, which makes it mandatory for WTO Members to "require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a

[52] PCT Article 33(1) and TRIPS Article 27(1).

person skilled in the art…" Some international standards are permissive rather than mandatory, in other words clarifying optional requirements that may be imposed on a patent applicant. Hence TRIPS indicates that WTO Members "may require the applicant to indicate the best mode for carrying out the invention known to the inventor," leaving this in effect as an optional additional requirement for a patent application to meet. The PCT Regulations (Rule 5.1(v)) provides that the description should: "set forth at least the best mode contemplated by the applicant for carrying out the invention claimed; this shall be done in terms of examples, where appropriate, and with reference to the drawings, if any; where the national law of the designated State does not require the description of the best mode but is satisfied with the description of any mode (whether it is the best contemplated or not), failure to describe the best mode contemplated shall have no effect in that State."

36. Concerning formalities more generally, TRIPS provides that "[WTO] Members may require, as a condition of the acquisition or maintenance of the intellectual property rights [including patent rights], compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement."[53] The PLT also provides for requirements concerning the form and contents of patent applications, specifying in effect (subject to other provisions) that requirements on form and contents should not be different from or additional to the requirements of the PCT system.

Information requirements in national law

37. To illustrate the approaches taken in national law, Question 2 of the Questionnaire requested WIPO Member States to "itemize the information that a patent applicant is required to provide in the course of gaining a patent." In general terms, most responses referred to requirements to disclose information in each of the following broad categories:

- An indication that the grant of a patent is sought (a request or petition);
- The name and address of applicants, inventors and/or patent agents/legal representatives;
- The title of the invention;
- One or more claims;
- Information relevant to assertion of claims of priority (either a corresponding foreign application as the basis of a priority right under the Paris Convention, or an earlier application in the same jurisdiction, in the case of a divisional application, continuation-in-part or the like);
- An abstract; and
- A description of the invention (and drawings if necessary).

38. Some responses made specific mention of other elements (which does not preclude the possibility that these requirements may apply in other responding Member States), for instance:

- Information on corresponding applications or patent rights in other jurisdictions, or prior art known to the applicant which is relevant to understanding of the invention or examination of the claims;

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[53] TRIPS Article 62.1.

- Documents concerning any search made for the purpose of examining a foreign application;[54]
- Indication of the scope of technology or field of the invention, or International Patent Classification data;
- Shares of ownership/entitlement to the patent right;[55]
- Deed of assignment; and
- Special provisions concerning description or deposit of microorganisms or biological materials.

Requirements for disclosure of the invention

39. Question 2 also asked Member States to "indicate the requirements for disclosure of the invention in a patent application." Apart from uniformly indicating that descriptions of the invention were required as part of the formality requirements, responses highlighted the substantive requirement that descriptions should "disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." A number of responses reported that the additional, optional standard of 'best mode' had also been applied.[56] The substantive requirements for disclosure can be generally characterized by reference to two general objectives:

(i) to ensure that there is sufficient information in the public domain to enable any suitably skilled person to put the invention into effect, because of the fundamental principle in patent law that a patent right is based on discharging the obligation to inform the public how to carry out the claimed invention (sometimes characterized as the obligation to 'teach' the invention) – this is extended in some legal systems to include an obligation to disclose the best mode known to the applicant of carrying out the invention; and

(ii) to provide a basis for judging whether the claims that define the patent right have the right scope, since a patent claim that goes beyond the scope of what is described to the public may be considered too broad, and thus fail to comply with the same general principle (sometimes described as 'sufficiency' or 'fair basis'). The sufficiency of disclosure may be assessed on the basis of the application as a whole, including the description, claims and drawings if any.[57]

To achieve these objectives in relation to inventions involving the use of microorganisms and biological materials, many responses referred to a system for the deposit of microorganisms for the purposes of patent procedures, dealing with the situation where a microorganism cannot be fully described in writing.

40. The response of the United States of America provides a detailed explanation of the substantive disclosure requirements under US law, distinguishing three specific requirements as follows:

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54 See the response of China.

55 See the response of Hungary.

56 Including Argentina, Australia, Hungary, New Zealand, Republic of Moldova, and United States of America.

57 See for example EPO Guidelines for Examination, paragraph C.II.4.1

"Written Description Requirement: The basic inquiry of the written description requirement is whether one skilled in the art would reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claim is not explicitly described in the specification, then the requirement for an adequate written description is met."

"Enablement: An invention is considered enabled if the specification teaches one skilled in the art how to make and how to use the invention without undue experimentation. Undue experimentation is determined based on a weighing of several factors. These are: the nature of the invention, the breadth of the claims, the state of the art, the level of skill in the art, the predictability or unpredictability of the art, the amount of direction or guidance provided in the specification, the presence or absence of working examples provided in the specification and the quantity of experimentation necessary to make the claimed invention."

"Best Mode: The description of an application must set forth the best mode of the invention. The best mode requirement is a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure as required by the statute. There are two distinct analyses under best mode. The first, a subjective requirement of whether, at the time the inventor filed his patent application, he knew of a mode of practicing the claimed invention better than any other. Secondly, if the inventor in fact contemplated such a preferred mode, whether the disclosure by applicant enabled one skilled in the art to practice the best mode or, whether the inventor concealed the preferred mode from the public. Deficiencies related to disclosure of the best mode for carrying out the claimed invention are not usually encountered during examination of an application because evidence to support such a deficiency is seldom in the record."

41. In some instances, it is specified that the substance of the required description of the invention must be within the patent document itself and not implied or cited indirectly. Hence the response of the Russian Federation noted that: "it shall not be permitted to replace the description section with a reference to the source containing essential information (literary source, description in a previously filed application, description attached to a protected document, and so on)."

Prior art and corresponding applications

42. Apart from the disclosure that is required in relation to the claimed invention itself, applicants in some national laws are required to advise the patent authorities of further information that may be useful in assessing the validity of patent claims or that may otherwise be useful in understanding the invention. Accordingly, there may be requirements to disclose known prior art or to provide information about corresponding patent proceedings in other jurisdictions. Disclosure of known prior art may be within the description itself, or by reference to relevant documents. At the international level, the Regulations under the PCT provide that the description should include "the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the

invention, and, preferably, cite the documents reflecting such art."[58] There is reference in TRIPS to the option of requiring "information concerning the applicant's corresponding foreign applications and grants."[59]

43. Responses to the Questionnaire providing information in this area included that of Hungary, which advised that there was a requirement for an "indication of the background art by describing the solutions which are closest to the invention and by citing, where possible, the documents reflecting such art, as well as the description of deficiencies the improvement of which is aimed at by the invention." Mexico, Spain and Uruguay reported on similar requirements. Therefore, some jurisdictions require the applicant to provide information on known prior art, including references to documents, with the need for such material being defined in terms of necessity to understand the invention or for the task of examination of the patent claims. The United States of America described this obligation in the following terms:

> "37 C.F.R. 1.56 requires a duty to applicants and their representatives for candor, good faith, and disclosure. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the USPTO, which includes a duty to disclose to the Office all information known to that individual to be material to patentability…."[60]

44. The same response cites a series of cases in which patent rights have been held invalid or unenforceable through failure to disclose known prior art, such as prior art cited against corresponding foreign applications[61] and failure to translate material portions of documents in foreign languages.[62] The response notes that it "may be desirable to submit information about prior uses and sales even if it appears that they may have been experimental, not involve the specifically claimed invention, or not encompass a completed invention."[63] The response notes that other applications should desirably be brought "to the attention of the examiner even if there is only a question that they might be 'material to patentability' of the application the examiner is considering."

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58 Rule 5.1(a)(ii).

59 TRIPS, Article 29.2.

60 37 C.F.R. 1.56 also provides that "the Office encourages applicants to carefully examine: (1) Prior art cited in search reports of a foreign patent office in a counterpart application, and (2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office." The same provision specifies that information is material to patentability "when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability." [Secretariat footnote, not in original text].

61 Gemveto Jewelry Co. v. Lambert Bros., Inc., 542 F. Supp. 933, 216 USPQ 976 (S.D. N.Y. 1982).

62 Semiconductor Energy Laboratory Co. v. Samsung Electronics Co., 204 F.3d 1368, 54 USPQ2d 1001 (Fed. Cir. 2000).

63 See Hycor Corp. v. The Schlueter Co., 740 F.2d 1529, 1534-37, 222 USPQ 553, 557-559 (Fed. Cir. 1984). See also LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n, 958 F.2d 1066, 22 USPQ2d 1025 (Fed. Cir. 1992).

Microorganisms and biological material

45. A number of responses referred to specific disclosure obligations concerning either microorganisms only, or biological material more broadly.[64] These generally required that details be provided of the deposit of a sample of a microorganism (or biological material) required to implement the invention when it cannot be described in writing (they may also further require that the sample be reasonably available to the public), or related to specific requirements for the identification or description of biological material.

46. For example, the response of France advised that "when the invention concerns the use of a microorganism to which the public does not have access, the description is not considered as disclosing the invention sufficiently if a sample of the microorganism has not been the object of a deposit with a designated body." The European Patent Office response advised that in accordance with EPC Rule 28 "if an invention involves the use of or concerns biological material and this biological material isnot available to the public and cannot be described in such a manner as to enable the invention to be carried out by a person skilled in the art, reference needs to be made to the deposit of this biological material."

47. The Republic of Korea advised that "a patent application of an invention relating to microorganisms shall provide detailed information about any microbial material used in the development of the invention so that a person skilled in the art could easily carry out the invention." The Australian response described the disclosure requirements for biological material: "if the starting point is biological material, this requirement could be met by a full description of the material in words including where to find the material and how to recognize it. For example, full description of a microorganism means the full morphological, biochemical and taxonomic characteristics of the microorganism known to the applicant. There must be sufficient detail in the specification for a person skilled in the art to distinguish, identify and repeat the invention. Therefore, most commonly, where an invention relates to biological material, this material would be deposited in an International Depositary Authority pursuant to the Budapest Treaty."

48. The Russian Federation reports that "in a claim characterizing a strain of a micro-organism, the cell cultures of plants and animals shall comprise the generic and specific name of the biological subject in Latin with an indication of the surname(s) of the inventor(s) of the type and, if the strain has been deposited, the name or abbreviation of the collection-depositary, registration number attributed by the collection to the deposited subject, and the designation of the strain." Moldova requires the applicant "to disclose in an application referring to a biological material the information concerning the cultural-morphological, physiological- biochemical, hemo- and geno- taxonomical, cariological and biotechnological characteristics of the material; the characteristic of the pattern material; the hybridization principle; the genealogy of colonies; the conditions of cultivation and other characteristics, as well as the process of production of the said material."

49. Several responses also noted that there were specific requirements for listings of nucleotide and amino acid sequences relevant to the invention[65] (including in computer

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64 For instance, the response from Sweden advised that it was broadening its requirement.

65 Response from the Russian Federation.

readable form[66]). For instance, the response of China noted that "where a patent application contains disclosure of one or more nucleotide and/or amino acid sequences, the description shall contain a sequence listing in compliance with the standard prescribed by the State Intellectual Property Office (SIPO). The sequence listing shall be submitted as a separated part of the description, and a copy of the said sequence in machine-readable form shall also be submitted."

Disclosure of inventor/inventorship

50. According to the Paris Convention, "[t]he inventor shall have the right to be mentioned as such in the patent,"[67] even though the inventor or joint inventor may not be entitled to the patent itself. Patent applicants are also generally required to provide certain information about the invention and other administrative information – for instance an address for service within the jurisdiction of the patent authority.[68] While it is convenient, broadly speaking, to distinguish between the formalities that are required in the patent application process, and the substantial requirements, some apparently "formality" requirements can entail substantive legal considerations, with significant implications. The declaration of the identity of the inventor or inventors can involve a crucial assessment of which individuals substantially contributed to the claimed invention, and forms the basis of the legitimacy of the patent application and any patent right granted. Identifying the inventor or inventors is fundamental as the patent right is derived, directly or indirectly, from the act of invention. An applicant who does not have the required relationship with the actual inventor or inventors (e.g. as the inventor, as the inventor's relevant employer, or otherwise as successor in title) is not entitled to a patent right, even if the patent is otherwise fully valid on substantive grounds (novel, inventive, and industrially applicable) – so this apparent formality may also be a significant assertion of a legal entitlement, and failure to disclose an actual inventor (including one of the joint inventors) may prejudice the patent right. Otherwise, the origin or basis of the patent right may be required to be declared. The Swiss response notes the requirement of the European Patent Convention (Article 81) that "(t)he European patent application shall designate the inventor. If the applicant is not the inventor or is not the sole inventor, the designation shall contain a statement indicating the origin of the right to the European patent."

51. If a patent is based on another person's knowledge (whether traditional or not), to the extent that this knowledge forms a substantive part (or all) of the invention, and that person is not identified as an inventor, this could have substantial legal implications. It could form the basis of a claim that this person is entitled to a partial or full share of ownership of the patent or form the basis of invalidation or revocation of the patent.[69] If the knowledge had been disclosed to the public (for instance by the TK holder) prior to the patent's priority date, then it could also invalidate the claimed invention owing to lack of novelty.

52. Requirements to disclose the inventor are directly relevant to the debate about misappropriation of TK, in view of the concerns expressed that some claimed inventions may incorporate TK without authorization of its provider. There is a great deal of case law in

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66 Response from Canada.

67 Article 4*ter*; cf PCT Article 4(1)(v).

68 Patent Law Treaty, Article 8(6); PCT Article 27(7); TRIPS, Article 3.2.

69 Attachment to the Australian response: grounds for revocation include "that the patentee is not entitled to the patent" and "that the patent was obtained by fraud, false suggestion or misrepresentation."

patent law concerning 'inventive contribution,' in other words, on how to determine what kind of contribution to the development of an invention amounts to substantial inventorship (including co-inventorship). According to one authority on United Kingdom patent law, "the generation of the idea or avenue for research, that is the formulation of the problem to be addressed, has also been treated as inventive" citing a case[70] in which "it was held that a person (A) was a joint inventor of a new method of securing electric cables, where it was unlikely that the main inventor (B) would have turned his mind to the question without having been prompted by (A) … [the tribunal] was influenced by the fact that the principal inventor, who did not work in the field, was only alerted to the possibility of the improvement by A."[71] On the other hand, "the decision to pursue a particular goal is unlikely to be treated as being sufficiently creative for it to be recognized as an inventive contribution." Where the inventive activity of a patent applicant uses the TK as a lead or a hint, and the TK is not part of the inventive process as such, then TK holders or TK providers may not be considered a co-inventor as such. Outcomes in this area and the distinctions between inventive and non-inventive contribution may also vary according to the way general principles are applied in respective national legal systems. Potentially, what is considered an inventive contribution in one jurisdiction may not be considered as such in another jurisdiction, meaning that the obligation to identify each inventor could in some borderline cases differ in different countries – cases in which TK provided a directly relevant lead or constituted the first step of the inventive process could figure among such borderline cases. This eventuality is illustrated by Rule 4.6 (c) of the Regulations under the PCT, which provides for the possible need for a request filed with an international application to "indicate different persons as inventors where, in this respect, the requirements of the national laws of the designated States are not the same."

Specific measures relating to genetic resources or TK

53. Questions 3 to 10 of the Questionnaire concerned any '*specific* requirement' for a patent applicant to disclose certain information concerning genetic resources or TK. Apart from responses to these questions, a number of responses dealt with specific requirements for the disclosure of biological resources (as noted above). Most responses to Question 3 indicated that none of the specific forms of disclosure mentioned were present in applicable laws. Earlier material submitted to the Committee for consideration have also referred to such mechanisms.[72]

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70 *Staeng's Patent* [1996] RPC 183.

71 L. Bently & B. Sherman, "Intellectual Property Law," Oxford, 2001, p. 476.

72 For instance, Document WIPO/GRTKF/IC/1/11 submitted by the Member States of the Andean Community contains as Annexes III and IV unofficial translations of "Decision 391 – Common Regime on Access to Genetic Resources," and "Decision 486 – Common Intellectual Property Regime;" Article 26 of the latter decision incorporates a requirement for "a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or byproducts originating in one of the Member Countries;" and "if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations."

54. The response of the European Commission indicated that:

> "There is no article in the directive 98/44 [on the legal protection of biotechnological inventions] which is devoted to this issue. However, recital 27 (which is not legally binding) of this directive lays down 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, include information on the geographical origin of such material, if known; (…) this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."
>
> "This has to be regarded as being an encouragement to mention the geographical origin of biological material in the patent application, along the lines indicated by Article 16(5) of the Convention on Biological Diversity. However, to provide such information is not an obligation under Community law. Nor does the failure to provide such information have, as such, any legal consequences for the processing of patent applications, or on the validity of rights arising from granted patents."

55. The German response noted that "there is no such specific requirement in our national law. Disclosure of origin is stipulated in the preamble of the EC Directive 98/44/EC on the legal protection of biotechnological inventions, although without making it a binding requirement." Sweden reports that a government memorandum on the implementation of the EC-Directive (98/44/EC) proposes a draft new Rule 5(a) of the Patents Decree. The draft Rule mainly reiterates paragraph 27 of the Preamble of the EC-Directive and contains provisions on the disclosure of the geographical origin of biological material as follows:

> "If an invention is based on biological material of plant or animal origin or if it uses such material, the patent application shall include information on the geographical origin of such material, if known. If the origin is unknown, this shall be said. Lack of information on the geographical origin or on the knowledge of the applicant in this respect is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

56. Concerning TK, Romania cited a pending amendment to its patent law providing that "when the state of the art includes also traditional knowledges they shall be clearly indicated in the description including their source, when known."

Actual disclosure of relevant information under general patent law

57. Question 12 of the Questionnaire concerned whether conventional patent disclosure requirements had actually obliged, or may potentially oblige, an applicant to disclose any of the categories of information set out in questions 3(a) to (f), and information about any such cases. In addition to the Questionnaire responses, the Committee has earlier received information relevant to this question. In particular, document WIPO/GRTKF/IC/1/13,[73] on the basis of a survey of relevant patents, commented that "of all the patents using biological source material, such as plants, fungi, animals, microorganisms, firstly we are going to focus

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[73] "Patents Using Biological Source Material and Mention of the Country of Origin in Patents Using Biological Source Material" (submitted by the Delegation of Spain).

on patent applications related to plant extracts which are the most numerous within this sector. As a general rule, when the plant(s) is (are) well-known and widespread … the place of origin is not specified in the patent application. On the other hand, when the object of the patent application is a "rare" or "exotic" plant extract, the application provides information relating to the country/countries of origin in the description and the traditional use(s) of the plant(s) as far as it is known to him." The Spanish response to the Questionnaire provides some further examples, and makes similar observations to the effect that disclosure requirements may entail disclosing the geographical origin of plant or animal biological material, when that is endemic to a specific location. Apart from the distinction between "rare or exotic" plants and "well-known and widespread" plants, there is a possible third category, for which the country of origin cannot be specified, for instance if the concept of a center of origin applies (see the discussion above, in paragraph 15).

58. The response of Germany contained the similar observation that "in general an indication of the origin etc. is not necessary to enable a person skilled in the art to carry out the invention; this might be different, where the source is unique and essential to put the invention into practice." The response of Burundi confirmed that such information was required in the case of an invention on traditional medicine. It cited the case of a traditional healer who had submitted a patent application to protect his knowledge. When the competent authorities had requested him to describe the method of production of his medicines, he had refused to disclose them, and the patent application was declined.

59. The response of Switzerland commented that:

> "The invention must be disclosed in a manner sufficiently clear and complete to enable a person skilled in the art to carry out the invention. If any information about the genetic resource or traditional knowledge is indispensable in this regard, it must be disclosed. In particular, this may be the case if a genetic resource used in an invention only occurs in a particular location…. We are not aware of any such particular cases. In this regard … the number of patent applications deposited according to the provisions of the [Federal Patent Law] that concern inventions that are based on or use genetic resources is very small. We have no information about any such patent applications that concern inventions that are based on or use traditional knowledge."

60. Similarly, the European Patent Office confirmed that "categories of information as set out in Question 3 are sometimes disclosed in relevant EP applications," the United States of America reported that "based on experience, the USPTO is aware that patent applicants, at times, provide information about the genetic resources used in their invention, including the source of origin, in order to meet the written description, enablement or best mode requirement," and Viet Nam advised that:

> "There are not any particular regulations that oblige applicants to disclose any of the categories. However, in fact, in order to make the applications clearly and completely disclose the content of the inventions, the applicants are required to disclose categories of information set out in question 3 (d) to (f). Applications regarding to genetic resources could be taken as examples where the applicants did so to meet conventional patent disclosure requirements."

61. The response from France commented that "in theory, it is not excluded that the requirement for sufficiency of description may oblige an applicant to disclose some of the information listed in Question 3(a) to (f). For example, the composition or the structure of the

genetic resource is indispensable for the precise description of the object of the patent," and Moldova indicated that "in order to comply with the requirement for an invention to be disclosed in a manner sufficiently clear and complete, the applicant should furnish also information containing in questions 3(a), (b), and (d), the last point - only where the isolation or the distinguish of the biological material can not be disclosed otherwise."

62. The European Community draws attention to the relevance of specific disclosure requirements concerning biological resources:

> "Article 13(1)(b) of Directive 98/44/EC states that where an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered inadequate for the purpose of patent law unless the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited."

63. The Republic of Korea similarly draws attention to the requirement that "a patent applicant of an invention relating to microorganisms shall provide detailed information about any microbial material used in the development of the invention so that a person skilled in the art could easily carry out the invention." And Australia notes that disclosure requirements would apply in the case of information in Questions 3(a) and (b) "if the invention is for a microorganism and the patent applicant does not use the Budapest Treaty to meeting their requirements to provide a full description of the invention." Annexed to the response of Australia is an excerpt from a decision relating to the statutory requirement that microorganisms be 'reasonably available' for "inventions which involve microorganisms *per se* or their use, modification or cultivation."[74]

64. New Zealand commented on the application of another patentability criterion in this regard, and cited a particular case:

> "Under section 17 of the Patent Acts 1953, the Commissioner of Patents may refuse a patent application where the use of the invention is contrary to morality. Where an invention is either derived from or uses TK, or relates to an indigenous flora or fauna, or products extracted therefrom, applicants are asked to provide an indication or evidence of prior informed consent being given by a relevant Maori group. This requirement is not specifically included in the Patents Act, but is required as a matter of internal office procedure.
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> "These issues have been argued in respect of only one application (NZ 501679). The case concerned an application to use oil extracted from kiwi (a rare indigenous flightless bird, and a national icon) to manufacture insect repellent. In that case the patent attorney for the applicant argued that use of kiwi to manufacture insect repellent was not culturally offensive, and declined to seek consent from any Maori tribe. The application was, however, later amended with all reference to kiwi being deleted from the patent specification."

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[74] *Commonwealth Scientific and Industrial Research Organisation v. Bio-care Technology Pty. Ltd.* (45 IPR 483), 492-3.

Detailed provisions of specific disclosure requirements

65. Questions 4 to 10 concern the detailed operation of specific disclosure requirements mentioned in Question 3, such as the field of application, guidelines on the relationship that should exist between the invention and the genetic resource or TK, territorial application, the form of evidence of prior informed consent required, consequences of failure to comply and the timeframe, and publication requirements.

66. Romania notes that information requirements about genetic resources used in the invention "apply to patent applications for any inventions, regardless of the technology involved" and equally to applications by domestic and foreign nationals.

67. Sweden notes that the proposed information requirements "would apply to patent applications for any inventions based on biological material of plant or animal origin or using such material, regardless of the technology involved. The requirements would apply equally to patent applications by domestic and foreign nationals" and "regardless of where the biological material was obtained." There would be "no consequences for the patent applicant or patent holder of any failure to meet the requirements of disclosure of the geographical origin of the biological material." As to publication, "the information on geographical origin would be available to anyone when the patent was granted (or when 18 months had passed from the filing date or from the date from which priority was claimed). Information which does not concern the invention for which patent is sought or has been granted and which regards business secrets could however on request be kept secret."

Failure to comply with information requirements, or provision of false information

68. Questions 2 and 13 respectively cover the implications of failure to meet information requirements, and the consequences of providing information in a patent application that is false or misleading. The implications of failing to meet one of these requirements under national law can vary considerably: for example, if disclosure is inadequate, or omits important information, failure to discharge the obligation may in some cases lead to rejection of a patent application or invalidation of a patent; failure to identify the true inventor may in some cases lead to loss or transfer of the patent right; administrative shortcomings such as failure to provide an updated address for service are often corrected or remedied routinely. The response of the EPO made the distinction as follows:

> "On the one hand mechanisms exist for the correction of obvious errors. On the other hand false or misleading information in the description or with respect to the deposit of biological material may lead to non-compliance with the requirements for European patent applications (Article 83 EPC: lack of sufficiency of disclosure)."

69. The linkage between false and misleading information and the requirement of sufficiency of disclosure was addressed in several responses, such as that of France, which noted that "the requirement of sufficiency of description is sanctioned by invalidity of the patent. Hence, when information contained in the patent is false or ambiguous, and it is therefore not sufficient for a person skilled in the art to carry out the invention, the patent can be invalidated." The response of Sweden indicated that "false or misleading information could probably lead to the rejection of an application or the invalidation of a granted patent. The reason for rejection or invalidity would then however be that the criteria for patentability

not were met, not the fact of false or misleading information as such." A number of other responses reported on specific remedies in national patent law that did address the provision of false or misleading information as such.

70. Among the specific elements of national patent laws provided in responses to Question 13 were:

- a distinction between false information in general, and false information relevant to the requirements for patentability, with a mechanism for the intervention of third parties to make observations on the patentability of the claimed invention;[75]

- provision for revocation of the patent if the inventor named is not the true inventor;[76]

- more general sanctions, such as the application of criminal law for instance relating to forgery of documents,[77] and legal provisions on falsification of public documents;[78]

- law concerning fraud, inequitable conduct, candor and good faith, including patent laws that impose a duty on applicants and their representatives for candor, good faith and disclosure;[79]

- provisions for patent authorities to require additional information and evidence where there is reasonable doubt about the veracity of any information provided by the applicant;[80] and

- specific measures under patent law, such as criminal penalties under patent legislation for certain acts relating to knowing falsification or provision of false information,[81] provision of false or misleading information as grounds for opposition to grant or for revocation,[82] payment of damages in addition to invalidity or loss of right,[83] and revocation on the grounds that a patent was "obtained by misrepresentation," when the misrepresentation "does not have to be a deliberate misrepresentation" but when "any representation that was material to the … decision to grant the patent … was in fact not true."[84]

71. The response of Hungary advises in detail on the implications of false information concerning inventorship:

> "Under Hungarian patent legislation there is no expressed provision concerning the legal consequences of false or misleading information in a patent application in general. However, where such information relates to the inventor, provisions on moral rights of the inventor and provisions on the right to a patent apply. It is to be pointed out that

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75 Response of Argentina
76 Response of Switzerland
77 Response of Switzerland
78 Response of Spain
79 Response of the United States of America, noting the effect of 37 C.F.R. 1.56, cited also in paragraph 43 above.
80 Response of the Republic of Moldova
81 Response of Canada
82 Response of New Zealand; similar provision also in the response of Uruguay
83 Response of Italy
84 Response of Australia

> unless a final court decision rules to the contrary, the person mentioned as such in the application filed at the accorded filing date is deemed to be the inventor, and that the right to a patent belongs to the inventor or his successor in title. Therefore, if false information is given on the inventor in the patent application, this necessitates the initiation of court proceedings for a party to have such false indication corrected in the patent documents and, as the case may be, thus also establish his/her right to the patent. A similar legal presumption relates to the shares of authorship of a joint invention being those as stated in the application filed at the accorded filing date; consequently if such indication is false, its correction necessitates court proceedings. Also, where the subject matter of a patent application or a patent has been taken unlawfully from the invention of another person, the injured party or his successor in title may claim a statement to the effect that he is entitled wholly or partly to the patent and may claim damages under the rules of civil liability. In other words remedies are *de iure* available under existing patent provisions to TK holders who are not mentioned in a patent application relating to relevant TK, whose shares of authorship is falsely indicated, or whose TK has been misappropriated."

72. As far as the specific measures are concerned (those that relate to genetic resources and TK especially), the general pattern reported was that no sanctions applied. Sweden advises in relation to its draft measure that "there would be no consequences for the patent applicant or patent holder of any failure to meet the requirements of disclosure of the geographical origin of the biological material." Romania advises that "there are no consequences in case of non-compliance" in relation to its draft measure on TK disclosure. The European Commission comments in relation to the preambular reference in the Directive 98/44:

> "This has to be regarded as being an encouragement to mention the geographical origin of biological material in the patent application, along the lines indicated by Article 16(5) of the Convention on Biological Diversity. However, to provide such information is not an obligation under Community law. Nor does the failure to provide such information have, as such, any legal consequences for the processing of patent applications, or on the validity of rights arising from granted patents."

Other forms of registered industrial property rights

73. Question 11 concerned the possibility of analogous requirements for other registered industrial property rights, such as utility models, petty patents, trade marks, or industrial designs. In most cases, the answer was no. Romania foreshadowed a possible future provision for industrial designs. Moldova noted that for appellations of origin "the applicant shall indicate the geographical origin and area of production of the raw material, the existence of some particular conditions for its production and the description of the method of production of the said product." New Zealand reported that "a new Trade Marks Bill, however, currently before Parliament, will provide an absolute ground for not registering a trade mark where the use or registration of the trade mark is, or is likely to be, offensive to a significant section of the community include Maori."

Registration of interests in patents and other IP rights

74. Another disclosure mechanism that has been raised in this discussion is the provision for the registration of ownership interests and other interests in IP rights. For example, the Patent Law Treaty refers to the "recordation of a license or a security interest" under Article 14(1)(b)(iii) as one element which the Regulations under the Treaty may provide for.

The PLT Regulations (Rule 17) provide for the specific material that may be required in relation to a recordal of a license or security interest. The explanatory notes illustrate that a security interest may include "an interest in a patent or application, acquired by contract for the purpose of securing payment or performance of an obligation, or indemnifying against loss or liability." This reflects the practice in a number of jurisdictions under which non-ownership interests in a patent may be recorded, either in the patent register or in other general commercial registers that record security interests in intangible assets. Patent systems also provide for registration of shared ownership in patent rights. The Bonn Guidelines suggest that "the possibility of joint ownership of intellectual property rights according to the degree of contribution"[85] be considered a guiding principle in relation to contractual agreements concerning access and benefit sharing. "Joint ownership of patents"[86] may be considered as a form of "non-monetary benefit" in relation to access and benefit-sharing under the CBD and other relevant forms of intellectual property rights

75. Registration of licenses, security interests or ownership can arise when there is a contractual relationship between the innovator and another party who has provided non-inventive input to the innovation – for instance, a funding agency or financier may require certain undertakings as to ownership or licensing of IP rights that are derived from the financed research. For example, if a research agreement stipulates that the research outcomes should be owned to the funding agency, then that agency has an entitlement to have its ownership share recorded on the basis of this agreement. Similarly, if the funding agency requires a license to any research outcomes, then this license may be recorded in some national systems. Another scenario arises when a patent is relied upon as a security in relation to a loan or other commercial obligation.

76. The implications of failure to record these interests vary. For example, a patent owner may need to be recorded as such in order to be able to enforce a patent. Alternatively, ownership resulting from assignment may need to be proven in order to enforce a patent: in this case, recordation establishes this proof and prevents transfer from occurring subsequent to recordation. Equally, an exclusive licensee may not be able to enforce their interests in a patent against an infringer without being recorded. An unregistered security interest may be unenforceable, or have no effect, in the event of bankruptcy or default, if it has not been perfected.

77. These mechanisms for recording interests in patents may be relevant in the case of innovations based on access to GR or TK. For instance, a provider of genetic resources or TK may enter into a legal agreement (such as a licence, or material transfer agreement) which requires the person receiving this material to share ownership of IP rights resulting from research on this material, or to enjoy a license to ensure access to IP-protected technologies derived from this research. An example from the WIPO GR contracts database (see document WIPO/GRTKF/IC/5/9) is a provision that indicates that "if the Company or any of its licensees do not take up the manufacture of chemical products on the basis of the natural constituent(s) selected within the Project within 10 (ten) years after execution of the grant, the exclusive right of commercialisation … shall lapse and the respective industrial property

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[85] paragraph 41(d).

[86] Appendix II, paragraph 2(p).

rights applied for in the name of the Company will be offered for assignment to the University free of charge."[87]

78. In other cases, an IP title, such as a patent, may be pledged as security in relation to a loan or another commercial transaction. To take one possible scenario, as a condition for gaining access to GR or TK, a party undertakes to make certain payments in relation to this access, subject to the transfer of patent rights in default of payment (similarly, the party giving access could acquire a security interest over patents as an asset in the event that the party gaining access goes bankrupt).

79. Therefore, there are potential situations where access to GR/TK access could create relevant legal obligations that can be expressed as either recordal of ownership (or part-ownership), or the recordal of security interests or licenses. In other words, the circumstances of access to GR or TK may create either an obligation or an option to record ownership, licensing or security interests.

V. INTERACTION BETWEEN GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND PATENTS

80. This section reviews the nature of the kinds of relationship that may exist between genetic resources or traditional knowledge on the one hand, and patents on the other. This is undertaken for two reasons:

(i) some understanding of the linkage between GR/TK and the patent is necessary so as to analyze what triggers a disclosure requirement; and

(ii) a review of the range of ways of characterizing the possible linkages will illustrate the degree to which disclosure requirements work within or separate from patent law.

Whether, and how, a particular disclosure requirement draws on, applies or extends existing patent law mechanisms are central questions – both in terms of how disclosure requirements would work in practice, and in terms of their compatibility with current international patent standards. The nature of the relationship that is considered relevant in the policy debate in turn may shape and define the legal tools that are necessary.

81. There has been very extensive discussion on the possible linkages between genetic resources and TK and the patent system, both as a means of "improving benefit-sharing by creating a positive link between … patent legislation and … legislation governing access to genetic resources"[88] and as a means of policing restrictions on use of genetic resources and TK. The objectives for clarifying and strengthening this linkage have variously been defined as transparency and monitoring, and as enforcing compliance with legal obligations governing access. One CBD study summarized the proposals made as follows:

(i) patent applicants to disclose the country of origin of biological samples used in research leading to the invention in the normal invention description to be submitted to the patent office;

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87 Agreement for the Testing of Plant Extracts between the Company and the University (Sri Lanka), dated January 1st, 2000.

88 Knowledge, Innovations and Practices of Indigenous and Local Communities, UNEP/CBD/SBSTTA/2/7, 10 August 1996, paragraph 93.

(ii) applicants to state what part, if any, existing rural, local and indigenous knowledge, innovations or techniques played in identifying the properties and location of relevant samples, including samples that were helpful in the research even though these do not form the basis of the final product or process;

(iii) applicants to enclose an undertaking confirming that to the best of their knowledge, all national laws relating to access to genetic resources, conservation and use of natural resources, customary laws of rural and indigenous peoples and any biodiversity prospecting arrangements entered into by the prospective patentee have been complied with;

(iv) that if no such laws exist, applicants should be required to give an undertaking that any collection was done in compliance with an internationally recognised code, such as the FAO's Code of Conduct for Plant Germplasm Collecting and Transfer or its Code of Conduct on Biotechnology;

(v) that failure to fulfil these requirements should bar the grant of a valid patent and subsequent discovery of false or negligent information should invalidate a patent and lead to appropriate legal proceedings against the patent-holder; and

(vi) that upon receiving adequate documentation, and as a normal part of their scrutiny of patent applications, patent offices should inform designated authorities in the country of origin and any local communities of the pending application concerning them. Countries of origin and local communities should have an opportunity to oppose the grant of a patent and to undertake investigations into whether or not a patentee has fulfilled any relevant code of conduct or biodiversity prospecting arrangements.[89]

82. While these proposals go well beyond current patent law principles and procedure, some studies have focussed on the possibility of measures that build on existing patent procedures to enhance disclosure of the origin of genetic resources and TK used in developing the invention:

> "Some evidence suggests that such disclosures are already common practice in filing patent applications. The disclosure might also include the "certification of prior approval of the use by the source party or community." There have been proposals that the requirement of disclosure might be enforced by making it a condition of approval of an application, and providing for the revocation of a patent where a disclosure was shown to be fraudulent. In some instances, disclosure of the use of traditional biodiversity-related knowledge may provide grounds for not granting a patent. The patenting process normally requires the description of the invention and the background knowledge it was based on. Thus, where traditional biodiversity-related knowledge is used, this should be disclosed, irrespective of whether there is specific reference to traditional biodiversity-related knowledge in the relevant statute. Patent examiners could reject a patent application if it were found that previous knowledge in the area showed the invention was not novel. This practice would prevent others from profiting from the use of the knowledge, but would not necessarily lead to a benefit-sharing arrangement for the knowledge-holders. Another strategy suggested is that indigenous and local communities might form corporations that could then apply for and hold

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89 *loc. cit*.

> patents as legal entities in much the same way as corporations in developed countries do under the relevant national laws."[90]

83. A number of specific proposals to this effect have been proposed in relation to the WTO TRIPS Agreement, for instance a recent proposal that:

> an applicant for a patent relating to biological materials or to traditional knowledge shall provide, as a condition to acquiring patent rights: (i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention; (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes; and (iii) evidence of fair and equitable benefit sharing under the national regime of the country of origin.[91]

84. Consideration of mechanisms for disclosure relating to genetic resources and TK would be facilitated by understanding about the relationship of such mechanisms with established patent law, both at the level of policy principle and at the level of consistency with current standards. As several responses have illustrated, there is an overlap in practice (with several examples being cited) of existing, well established requirements resulting in the disclosure of relevant information concerning both genetic resources and TK. As was noted in an earlier document submitted to the Committee:

> "The applicants of patents using biological source material, when dealing with 'exotic' or 'rare' material, which is therefore not easily accessible, are aware that for their applications to comply with such requirements they must mention the country of origin of the material. Failure to do so would make it difficult for the person skilled in the art to carry out the invention. There are thousands of different species, and with new ones being discovered everyday, it becomes impossible for the person skilled in the art to know the country (countries) where to find the raw material to carry out the invention in the case of exotic or rare species. Moreover, in order to comply with the requirement of indicating the background which, as far as known to the applicant, he usually mentions the traditional uses of such material which are, almost always, common public knowledge in the country where the species is found."[92]

85. One key factor that determines whether, and how, the reported disclosure requirements apply to relevant information is in fact the relationship between the invention itself and the genetic resources or traditional knowledge. This emerged in the above review of national legal mechanisms in various ways:

(i) If access to a genetic resource is required to enable a person skilled in the art to carry out the invention (or to carry out the best known mode where applicable), and it is not readily available to that person (for instance, as a plant variety well known to researchers in

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90 "Legal and other Appropriate Forms of Protection for the Knowledge, Innovations and Practices of Indigenous and Local Communities Embodying Traditional Lifestyles Relevant for the Conservation and Sustainable Use of Biological Diversity," UNEP/CBD/WG8J/1/2, paragraph 8.

91 "The relationship between the TRIPS Agreement and the Convention on Biological Diversity and the protection of traditional knowledge," communication from Brazil on behalf of the delegations of Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Peru, Thailand, Venezuela, Zambia and Zimbabwe, WTO document IP/C/W/356.

92 WIPO/GRTKF/IC/1/13.

the field), then there may be an obligation to disclose its source, because it may otherwise be impossible for third parties to carry out the invention.

(ii) If, however, the genetic resource is readily available to third parties who are skilled in the relevant art, then established disclosure requirements may not necessarily create an obligation to identify the specific source (the nature of the genetic resource must however be fully described).

(iii) If, on the other hand, the genetic resource is so remote from the claimed inventive concept, as not to be needed in carrying out the invention, then it may not be relevant to the enablement or best-mode test (where applicable) for disclosure; in this case it would be necessary to clarify how the claimed invention could be determined to be based on or derived from the genetic resource.

(iv) If TK (known to the applicant) is so close to the claimed invention that it has bearing on the assessment of the validity of the application (e.g. in assessing whether the invention is truly novel and non-obvious), or so that it is necessary for the understanding of the inventive concept, then established obligations to disclose known prior art may apply in systems where there is a duty to disclose known prior art.

(v) If TK (known to the applicant) is so close to the claimed invention that it is in fact intrinsic to it under the legal doctrine that determines "inventive contribution" in the jurisdiction concerned, then it may be necessary either to declare the provider of the TK as a joint inventor (or indeed as the sole inventor, where the TK in itself provides the inventive concept of the claimed invention), or to amend the claimed invention to exclude the TK element (in which case it is likely to be highly relevant prior art, and thus may need to be disclosed in any case)

(vi) If TK (known to the applicant) is so remote from the claimed inventive concept that it is neither relevant to the assessment of validity or determination of inventorship, then it may be necessary to clarify how the claimed invention could be determined to be based on or derived from the TK.

86. This suggests that – before addressing the application of disclosure requirements concerning GR/TK subject matter – a useful preliminary step would be to clarify the nature of the linkage relationship between the claimed invention and this subject matter. Put another way, it would be helpful to specify what linkage between input and invention is sufficient to trigger any particular disclosure requirement, in order to shed light on its implications for patent law and the international patent system. For instance, inasmuch as a disclosure requirement concerns GR, the question was put to the Committee whether it may be useful to consider "whether the proposed requirement would also apply when the invention, for which the application is filed, concerns synthesized substances that were isolated or derived from active compounds of an accessed genetic resource and, if so, what is an agreed definition of 'derived.'"[93]

87. The nature of the disclosure requirement may be very different depending on whether the GR/TK was incidental or fundamental to the development of the invention; whether the GR/TK contributed to one earlier step to a chain of innovations that over time culminated in

[93] WIPO/GRTKF/IC/1/3, paragraph 45.

the invention, or was a direct input to the claimed inventive step; whether particular qualities of a genetic resource were essential to the invention, or the genetic resource was in effect only a vehicle for a separate innovative concept; or whether a genetic resource was used in a particular embodiment or one example in the description of the invention, but was not indispensable to arriving at(or replicating) the invention as claimed.

Predictability and clarity of application of disclosure requirements

88. A number of proposals for disclosure requirements on GR and TK subject matter raise the possibility of significant implications,whether or not the requirement is considered as a 'substantive' requirement or as a 'formality.' For instance, some proposals call for the invalidation of the patent right as such if the requirement has not been met. Some commentators have suggested that it is necessary to link the disclosure requirement to patent validity, as this is the only significant sanction that might apply. In fact, as the above discussion clarifies, failure to meet certain formality requirements can have serious implications, whether or not the patent is invalidated on substantive patentability grounds. For example, there may in different jurisdictions be severe consequences of failure to declare the true inventor (or to include a co-inventor), failure to disclose known prior art, or failure to establish an entitlement derived from the inventor. Failure to comply with some requirements, such as payment of maintenance fees or good faith errors in naming inventors, can be remedied once the failure is identified. How to deal appropriately and fairly with unintentional errors and omissions needs to be considered in any disclosure requirement.

89. The prospect of invalidation, refusal or other serious implications (such as sanctions for a false declaration) for failure to meet a requirement creates a need for clarity and predictability: for users of the patent system, administrators and judicial authorities alike, a specific understanding would be needed of what circumstances create the obligation, what steps are considered sufficient to discharge the obligation, when a requirement has been met and when it has not. The complex pattern of inputs into a research program over time that may in turn yield a series of interrelated inventions may create a degree of uncertainty as to what is required for disclosure in any particular patent application, and on what basis. The questions that may arise can be illustrated by reference to two particular scenarios:

- where there are diffuse or diverse inputs leading to the invention (for instance, when an invention draws on an extensive plant breeding program based on successive generations of breeding lines from numerous sources): which inputs, and how many, should be identified and reported; and
- an extended chain of provenance (such as when an invention may draw on a novel use of an active compound that had been separately, earlier isolated from a biological sample): how far back along the chain of provenance from the precise inventive step should the disclosure requirement reach?

VI. THE NATURE OF DISCLOSURE REQUIREMENTS

Clarifying the nature of possible disclosure requirements

90. This section of the draft study seeks to create a structured approach to analyzing possible patent disclosure requirements concerning GR and TK subject matter. This approach could be applied to existing disclosure requirements, or to any potential approach which is

under discussion. The following issues could be considered in relation to any disclosure requirement:

(i) What would be the relationship between the claimed invention and the GR/TK; or what would be a sufficient link between the two to trigger a disclosure requirement?
(ii) What legal principle would form the basis of the requirement?
(iii) What would be the nature of the obligation placed on the applicant?
(iv) What would be the consequence of failure to comply with the requirement?
(v) How would the requirement be implemented, verified or monitored?

The consequence of failure to comply may clarify whether the requirement is linked to the substantive validity of the patent right, or sanctioned by other means such as prohibitions on false or deceptive declarations. While some commentators have suggested that refusal or invalidation of a patent is essential to give significant effect to a disclosure requirement, declarations may be subject to significant sanctions distinct from the validity of the patent itself (as indicated above in paragraph 70).

91. Behind these questions is the fundamental issue of whether a requirement would concern disclosure as such, or whether it would actually function as an effective prohibition on securing a patent if certain preconditions are not met. For instance, if there is a requirement to file evidence of prior informed consent of GR/TK holders, this may be:

- to provide information about the circumstances in which the GR/TK was obtained in the interests of transparency,
- a means of implementing an obligation to obtain prior informed consent before a patent application may be filed, or
- a requirement that may be met at any stage during the processing of a patent application (by analogy, for instance, with a translated priority document) or indeed made available at any time after patent grant as required.

By analogy with other areas of patent procedure, it may also be possible for a requirement involving the submission of detailed evidence to be imposed only in cases of reasonable doubt, rather than as an *a priori* requirement for all patent applications. By way of illustration, PLT Article 6(6) provides that a Contracting Party may require that evidence in respect of certain aspects of form and contents of the application, a translation or priority documentation "be filed with its Office in the course of the processing of the application only where that Office may reasonably doubt the veracity of that matter or the accuracy of that translation." Similarly, the PCT Regulations (Rule 51*bis*.2) provide that (subject to various conditions) a patent office "shall not, unless it may reasonably doubt the veracity of the indications or declaration concerned, require any document or evidence" concerning such matters as the identity of the inventor and the entitlement of the applicant to apply or to claim priority from another application.

V.1. What would trigger a disclosure obligations?

92. A fundamental legal and practical question is what linkage between the GR/TK in question and the claimed invention would be sufficient to establish an obligation to disclose. In discussion of disclosure requirements specifically for GR/TK, this connection has been characterized in various ways in documents considered by the Committee (with emphasis added in each case):

- Decision VI/24 of the CBD COP refers to disclosure requirements concerning material that is "*utilized in the development of the claimed inventions*" or that is simply "*utilized in the claimed inventions*."
- The Bonn Guidelines encourage disclosure where "the subject matter of the application concerns or makes use of genetic resources in its development" and "the subject matter of the application concerns or makes use of [traditional] knowledge in its development."
- The Bonn Guidelines (at paragraph 53(c)) mention, as a "national monitoring" mechanism, the possibility of using "applications for patents and other intellectual property rights *relating to the material supplied*."
- The CBD COP decision on the "Role of intellectual property rights in the implementation of access and benefit-sharing arrangements"[94] notes the existence of "provisions to ensure the recording of *contributions to inventions* such as disclosure of the country of origin or geographical origin of genetic resources"
- "an invention *developed on the basis of illegally acquired material or knowledge*"[95]

93. Reported or published national or regional measures apply several related concepts such as:

- "an invention *is based on* biological material of plant or animal origin or if it uses such material"[96]
- "*obtained or developed* through an access activity"[97]
- products or processes whose protection is being requested was *obtained or developed on the basis of the knowledge* originating in any one of the Member Countries'[98]
- "a process or product *obtained using samples or components* of the genetic heritage"[99]
- "innovations *involving elements of biodiversity*"[100]
- "biological material … when used in an invention" and "biological material *used for the invention*"[101]
- "an invention whose *subject matter* is plants or animals, known regular medicament, agricultural, industrial, handicraft, cultural heritage or environmental"[102]

94. A recent proposal[103] put forward in the WTO TRIPS Council proposes that the TRIPS Agreement be amended

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94 Role of intellectual property rights in the implementation of access and benefit-sharing arrangements, COP Decision VI/24.

95 WIPO/GRTKF/IC/1/5, "WIPO Committee on the Relationship between Intellectual Property, Genetic Resources and Traditional Knowledge," Annex II, pp. 7-8 (documents submitted by the Group of Countries of Latin America and the Caribbean (GRULAC)).

96 Recital 27 of Directive 98/44/EC of the European Parliament and the Council of July 6, 1998 on the legal protection of biotechnological inventions, document WIPO/GRTKF/IC/1/8.

97 Article 35 of Andean Community Decision 391 of July 2, 1996 – unofficial version annexed to document WIPO/GRTKF/IC/1/11.

98 Article 26(h) and (i), *ibid.*

99 Article 31 of Brazilian Provisional Measure No 2.186-16 of August 23, 2001 – see document WIPO/GRTKF/IC/5/INF/2.

100 Article 81 of Law No 7,788 of 1988, Biodiversity Law of Costa Rica.

101 Indian Patents (Amendment) Act of 2002, Sections 10(4) and 25(1).

102 Egypt, Law No. 82/2002.

103 IP/C/W/356, 24 June 2002.

to provide that Members shall require that an applicant for a patent relating to biological materials or to traditional knowledge shall provide, as a condition to acquiring patent rights:

(i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention;

(ii) evidence of prior informed consent through approval of authorities under the relevant national regimes;

(iii) evidence of fair and equitable benefit sharing under the relevant national regimes.

A recent "concept paper"[104] suggested that disclosure requirements "should be limited to information on the geographic origin of genetic resources or TK used in the invention which they know, or have reason to know."

95. Other, related concepts are present in the FAO International Treaty:

- "a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System" (13.2(d)(ii)); and
- "plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System" (12.3(d)).

96. Recent policy discussions have mentioned other possible kinds of linkage. For example, *Seeding Solutions* (Volume 2, Report of the Crucible Group II) suggests patent protection should be dependent on providing "a certificate of origin regarding the biological material he or she *relied upon in the course of developing* the invention."[105] The report of the Commission on Intellectual Property Rights contains a recommendation "for the obligatory disclosure of information in the patent application of the geographical source of *genetic resources from which the invention is derived*."[106]

97. One viewpoint mentioned in the Crucible Group II report highlights the practical questions raised when seeking to determine origin and prior informed consent in relation to a patented invention, by reference to an hypothetical example:

Invention: A (specified) anti-sense DNA-ripening gene driven by (any suitable) constitutive promoter, used to delay ripening in fruit and vegetables. The specification shows several specific examples, and suggests many alternatives and uses. The ripening gene was originally obtained from a UK apple variety, although it is found in one form or another in most fruit species. One of the suitable constitutive promoters (used in several examples) was obtained from cucumber mosaic virus, which is endemic in nearly all countries that grow cucumbers. No one can establish the original source of the particular promoter, which has been circulating widely in academic circles for some years. The specification gives detailed working examples of transformed apples (two varieties, one British and one Mexican), melons (one US and one Spanish variety) and

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104 WT/CTE/W/223, 14 February 2003, paragraph 54.

105 Seeding Solutions, Volume 2, Crucible II Group, 2001.

106 Integrating Intellectual Property Rights and Development Policy, Commission on Intellectual Property Rights, London, 2002.

bananas ("bought in a UK supermarket"), and proposes and claims (without giving any experimental detail) use of the constructs in peaches, guavas and durian.

98. These examples demonstrate a range of possible linkages between GR or TK and a patented invention – including whether the relationship was necessary or contingent, and whether the GR or TK was actually part of the process that led to the invention, or is necessary for understanding or carrying out the invention after the invention has been attained. For instance, the requirement may relate to:

- GR or TK that is used during the steps that led to the claimed invention (it may refer to material that was used in the course of creating the invention for the first time),

- GR or TK that is necessary to assess, understand, replicate or carry out the invention once the invention has already been achieved (in this case, it might refer to material that would be necessary to implement the invention, or TK that is relevant to judging the novelty of the claimed invention),

- GR or TK that was a necessary prerequisite for the invention, in that without access to this material, the inventor would not have been able to achieve the invention;

- GR or TK facilitated the invention in the sense that it did in fact make it easier to develop the invention and it did practically help the inventor(s) to conceive the invention, but it was not necessary for the inventors to have made the invention (for instance, the TK helped point the way to the invention, or the GR is used in the preferred embodiment of the invention);

- GR may be used in carrying out a particular example or preferred embodiment of the invention as set out in the description, but is not directly relevant to the invention as claimed (for instance, the invention relates to a genetic transformation, and the transformation is applied to a range of different genetic resource after the essential invention has been conceived, in order to demonstrate its widespread application, as the basis for a broadly-drafted claim for the invention); or

- the TK or GR was in the background to the invention, but did not play a direct role in the invention as claimed (for example, the TK was involved in the breeding of plant, which was in turn used as one of several vehicles for newly introducing a transgenic trait into a plant species).

99. A crucial issue is whether the GR was used in the process of developing the invention (inventing the invention), or is needed to carry out the invention once invented (implementing the invention), or both. Clearly if it is needed to carry out the invention, it is closer to the established forms of disclosure requirement in patent law. A further issue is whether the GR makes any particular contribution to the invention itself – this can be seen in the contrast between:

- an invention may entail the incorporation of inventive genetic material, in an inventive manner, into existing germplasm which serves as a medium to carry the invention, when other germplasm could equally be used; and

- an invention which makes use of specific genetic material derived from the germplasm, which expresses a trait (such as disease resistance or another desirable property) that is central to achieving the advantages of the inventive concept.

100. Similar considerations apply to traditional knowledge. TK may be relevant to the inventive concept in several ways:

- the TK may have pointed the way in a very general sense to the line of research that in turn led to the invention (e.g. traditional knowledge that a certain plant could be used to make a pleasant tasting beverage, which led researchers to investigate medicinal properties of the plant);
- the TK may have provided a more direct pointer to the invention (e.g. traditional knowledge that a plant has certain medicinal properties may lead researchers to explore other possible medicinal properties of active compounds in the plant);
- the TK may have directly contributed to the inventive concept (e.g. traditional knowledge that a certain plant extract was effective in treating skin infections may have led researchers to conclude that active compounds in the plant were effective antibiotics);
- the TK may be a component of the inventive concept itself (e.g. a traditional knowledge holder may have communicated to a researcher a new or undisclosed medicinal property of a plant extract, when this property is central to the invention as claimed).

In each case, the invention may be viewed as being based on or developed from the access to the TK, but the nature of the obligation to disclose the TK may differ considerably. In the first case, the TK may be used as part of the descriptive background to the invention; in the second case, it could arguably form part of prior art that may be caught by obligations to disclose material prior art; in the third case, it might either be relevant prior art or arguably form part of the invention itself; in the last case, it might form part of the invention as claimed, leading to an obligation to name the TK holder as an inventor or co-inventor.

101. Behind this discussion is the broader issue of whether the disclosure requirement under question stems from, elaborates or embodies existing patent law principles, or whether it is unrelated to patent law. In some cases, the relationship is such that conventional disclosure obligations already apply, and significant sanctions can be applied in line with established patent law when these requirements are not complied with. In other cases, the disclosure requirement may be proposed as an elaboration or a particular application of general patent law principles. Other forms of disclosure requirement may be unrelated to existing principles, and therefore less readily analyzed and applied within the existing patent framework. Further elaboration may be necessary to determine their range of operation and their relationship with patent law and the international patent system.

Alternative forms of patent description obligations for biological materials

102. A distinctive disclosure mechanism (introduced above from paragraph 45) is the system of deposit of microorganisms or biological materials with a recognized culture collection as part of the obligation to give a full description of the invention so as to make it feasible for a person skilled in the art to carry out or to repeat the invention. This illustrates one practical implication of the general patent disclosure requirement when applied to biological subject matter. The WIPO *Guide to the Deposit of Microorganisms under the Budapest Treaty* describes the development of this mechanism as follows:

> "A fundamental requirement of patent law is that the details of an invention must be fully disclosed to the public. For disclosure to be adequate, an invention must be described in sufficient detail to permit a person skilled in the art to repeat the effect of the invention: in other words, the disclosure should enable the average expert with access to the appropriate facilities to reproduce the invention for himself … inventions involving the use of new microorganisms (i.e., those not available to the public) present problems of disclosure in that repeatability often cannot be ensured by means of a written description alone. In the case of an organism isolated from soil, for instance, and perhaps 'improved' by mutation and further selection, it would be virtually impossible to describe the strain and its selection sufficiently to guarantee another person obtaining the same strain from soil himself. In such a case, the microorganism itself might be considered to be an essential part of the disclosure. Moreover, if the microorganism was not generally available to the public, the written disclosure of the invention might be held to be insufficient. This line of reasoning led to the industrial property offices in an increasing number of countries either requiring or recommending that the written disclosure of an invention involving the use of a new microorganism be supplemented by the deposit of the microorganism in a recognized culture collection. The culture collection would then make the microorganism available to the public at the appropriate point in the patenting procedure."

In this scenario, the biological material is related to the invention in that it is impossible to assess the utility of and to reproduce the invention without access to the actual biological material.

103. The deposit of a microorganism or other biological material does not relieve the patent applicant of the obligation to provide as full a written description as possible, and the disclosure through deposit of a sample supplements the regular written description so as to ensure that the invention as described in the patent specification can in practice be replicated by a third party. In addition, the patent specification generally has to disclose details of the deposit. For instance, the PCT Regulations (Rule 13*bis*.3) provide that "a reference to deposited biological material shall indicate the name and the address of the depositary institution, the date of deposit, the accession number given by the institution, and any additionalmatter of which the International Bureau has been notified."

104. The "additional matter" is determined and notified by individual PCT Member States. For example, China requires "(t)he scientific name (with its Latin name) of the microorganism, relevant information on the characteristics of the microorganism, a receipt of deposit and the viability proof from the depositary institution of a sample of the microorganism," and Finland requires "to the extent available to the applicant, all significant information on the characteristics of the biological material" (see also the responses of Russia and Moldova cited in paragraph 48 above). Depending on national law, the details of the deposit may have to be an integral part of the actual description of the invention, or may be provided on a separate form – the PCT provides for both possibilities, effectively using the same form for both purposes.[107] From the PCT perspective, there is no substantive check whether there should be a reference to deposited microorganisms or other biological material,

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[107] PCT International Preliminary Examination Guidelines, Chapter X, paragraph 229.

but the international phase does include checks for whether the references comply with formality standards, with the possibility of correcting any defects.[108]

105. This example illustrates how, in some cases, the applicant must ensure actual physical access to biological materials in order to meet general disclosure obligations. In this case, the linkage between the biological material (a potential genetic resource) and the invention is that such physical access to the material is necessary for third parties to carry out the invention or to replicate any aspect of the description of the invention.

Linkage based on access legislation

106. National and regional laws and regulations governing access to GR or TK may provide the basis for a linkage between this source material and a patented invention. Contracts such as material transfer agreements (MTAs) may be required as part of access regulations: for instance, the response of Kenya to the questionnaire advised that an MTA was the means of obtaining prior informed consent or determining the conditions of access, in accordance with laws regulating access to genetic resources.[109] Decision 391 of the Andean Community ("Common Regime on Access to Genetic Resources"), provides for an access contract between the State, represented by the Competent National Authority, and the applicant requesting access.[110] This is subject to the requirement that "when access is requested to genetic resources or their by-products with an intangible component, the access contract shall incorporate, as an integral part of that contract, an annex stipulating the fair and equitable distribution of profits from use of that contract."[111] This requirement for an access contract provides a linkage with a disclosure requirement that is set out in Decision 486 ("Common Intellectual Property Regime"). This provides that applications for patents shall contain:

> "a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or byproducts originating in one of the Member Countries;
>
> if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations;"[112]

Contract law: "derived products" under material transfer agreements

107. Another potential source of legal standards or precedents on this question concerns contractual law considered in itself, in contrast to contractual arrangements provided for within regulations governing access to genetic resources. This is because the relationship between resource provider and resource user has often been governed by MTAs, with which

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108 *op. cit.*paragraph 228.
109 Environment Management Coordination Act 1999, Section 124.
110 Andean Community Decision 391, Chapter III, Article 32 (unofficial translation).
111 Article 35 (unofficial translation).
112 Andean Community Decision 486, Article 26(h) and (i) (unofficial translation).

there is a great deal of practical experience. An MTA will commonly establish a contractual relationship between provider and user, and this will often govern subsequent use of material derived from the genetic resource as received (including ownership, licensing or other aspects of patent rights on products derived from the genetic resource). This leads to a wide range of approaches to characterizing the link between GR or TK and a patented invention, including in terms of a "derivative product." As was pointed out to the Committee in this regard:

> "Of particular importance is the scope of subject matter covered by an MTA, on which the genetic resource provider seeks to protect his rights. Normally, such protection extends to the derivatives of the genetic resource. An important problem in this respect is to determine what constitutes 'a derivative' and what does not. A common approach is to agree upon a definition of 'derived product' and make the MTA applicable to the provided genetic resources and its derived products."[113]

108. This approach is currently by far the most common way in current practice of determining the chain of obligations that are placed on a patent applicant resulting from access to genetic resources, and it is an area where extensive practical experience has been established. As noted, the approach is, in effect, for the two parties to the MTA to define what constitutes a derived product covered by the agreement, and accordingly to determine the extent of obligations flowing from the agreement, i.e. how far along the chain of provenance and process of development and modification of the original resource the agreement reaches. This applies both to the technical question of the development and modification of the resource as such (when is it so transformed that it ceases to be a covered derivative) and to the more purely legal question of whether the agreement permits the resource user to pass the resource to third parties, and whether and how those third parties should be bound by analogous contractual obligations. Any disclosure requirement that follows this approach, however, would likely be closely linked to compliance with contractual obligations as such (often in foreign jurisdictions), rather than distinct obligations established entirely under patent law. Whether a sufficient relationship existed between the genetic resource as provided (and, analogously, disclosed TK) and the invention would be a question of interpreting the terms of the contract (although the contract itself may be concluded as part of a broader access and benefit sharing regime, for instance, as a standard MTA stipulated in laws or regulations, the legislative basis of which may also influence the interpretation of contract provisions). As noted elsewhere (see paragraphs 118-119 below), this process of interpretation and application of contractual obligations between distinct jurisdictions may also raise private international law issues.

109. The database of IP contractual provisions established by the Committee (see documents WIPO/GRTKF/IC/5/9 and WIPO/GRTKF/IC/4/10) discloses a range of possible approaches to defining the contractual obligations that link IP rights with access to genetic resources. For instance:

> "[The provider] maintains ownership and all rights to the biological material and/or related information covered by this Agreement, understood so as to include ownership and rights to any derivatives thereof and information developed as a direct result of the provision of biological material and/or related information."[114]

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113 Document WIPO/GRTKF/IC/1/3, paragraph 38(v).

114 Agreement drafted by the International Centre of Insect Physiology and Ecology (ICIPE) for the transfer of Biological Material and/or Related Information, 2000.

"Should a patentable invention result from the Company's or the University's testing and analytical activity…"[115]

"In the event of the isolation of a promising agent from a plant, microbe or marine macro-organism collected in [Source Country], further development of the agent will be undertaken by DTP/NCI in collaboration with [SCI]. Once an active agent is approved by the DTP/NCI for preclinical development, [SCI] and the DTP/NCI will discuss participation by SCI scientists in the development of the specific agent."[116]

Disclosure concerning prior informed consent or legitimacy

110. Where disclosure requirements relate to consent of TK holders or GR access providers, or where requirements relate to legitimacy of access to TK or GI, another question of linkage arises. This concerns what action connected to the invention is relevant; in other words, what kind of behavior needs to be sanctioned by prior informed consent or which otherwise needs to be legitimate under the laws of the country of origin. Three broad categories may be discerned; a requirement for consent or legitimacy may turn on:

- whether the access itself to the TK or GR was legitimate (e.g. whether consent was given to permit the initial access to occur);
- whether the research process that led to the invention was consented to (e.g. a material transfer agreement may limit the initial scope of permitted use of a genetic resource to verification of certain properties, or an access contract may provide for medical research but not cosmetic research: for instance one contract in the WIPO GR Contracts database includes the proviso: "the (biological) materials will not be used for testing in or treatment of humans, and shall not be used, directly or indirectly, for commercial purposes"[117]); or
- whether the act of filing a patent application was consented to (e.g. an access contract for certain GR may specify that no IP rights may be taken out on products derived from the GR).

In other words, the access to the TK or GR may itself be entirely legitimate, but it may create contractual or other legal constraints that limit the directions and extent of research based on the TK or GR, or that limit the entitlement to apply for a patent in all or in particular jurisdictions. For instance, a research agreement contained in the WIPO GR contracts database provides for "patent rights on metabolites with Recipient except for joint patents in the territory of provider,"[118] which would oblige the recipient to apply jointly with the provider in one jurisdiction but not elsewhere.

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115 <http://www.wipo.int/globalissues/databases/contracts/texts/html/universitysl.html#patent1>.

116 Model Letter of Collaboration between the Developmental Therapeutics Program Division of Cancer Treatment/Diagnosis National Cancer Institute, United States of America (DTP/NCI) and a Source Country Government (SCG)/Source Country Organization(s) (SCO).

117 <http://www.wipo.int/globalissues/databases/contracts/summaries/sdsusimplemta.html>.

118 Research Agreement between Syngenta Crop Protection AG, Basel, Switzerland and HUBEL Academy of Agricultural Science, Wuhan, China, dated November 1997.

V.2 What legal principle would form the basis of the requirement?

111. The above discussion leads to the conclusion that the nature of the disclosure requirement may be clarified with reference to the legal or ethical principle that would form the basis of the requirement that TK or GR be disclosed. A number of the possible principles that apply have been discussed in the literature, or are implicit in the way the disclosure requirement is discussed. There are two general forms of disclosure requirement – those that directly use, or adapt and extend existing patent law mechanisms; and those that are intended to be distinct new requirements and are based on separate legal principles. By definition, the former category are more readily founded in general patent principles; the latter category may need more elaboration and examination to determine how they would cohere with the patent system.

Application or extension of existing disclosure requirements

112. The specific GR/TK disclosure requirement may be based on existing disclosure obligations. As discussed at length above, these obligations may relate to disclosure necessary to enable the invention to be carried out, disclosure of the best mode or preferred embodiment of the invention, disclosure of the actual inventor or inventors, and disclosure of known prior art. In particular, this may apply to:

- disclosure of the source of GR that are necessary to carry out the invention;
- disclosure of the source of GR required to carry out the best mode or preferred embodiment of the invention;
- disclosure of TK that is known prior art relevant to the assessment of the validity of the patent claims (Section C of COP Decision VI/24 recognizes that disclosure "may, *inter alia*, identification assist patent examiners in the of prior art;") or
- disclosure of the origin of TK provided by a TK holder where the TK itself forms a substantive contribution to the invention asclaimed.

113. Each of the above may be considered a direct application or extension of existing patent law practice, in that the disclosure obligation builds on an existing rationale or legal principle. Some discussions of disclosure requirements have indeed suggested that disclosure requirements for GR/TK may be a form of regularizing existing practice, for instance:

> "There is evidence suggesting that such a step would in large part involve simply regularizing a practice that is already common in filing patent applications. One recent study reviewed over five hundred patent applications in which the invention involved the use of biological materials, such as materials derived from plants or animals; most were in the pharmaceutical field, with some in other fields such as cosmetics and pesticides (Sukhwani 1996[119] and pers. comm). The applications reviewed came from a number of jurisdictions, including France, Germany, the UK, Spain, the USA, and the European Patent Office. Of the applications involving plants, the country of origin was

[119] Sukhwani, A. 1996. *Intellectual Property and Biological Diversity: Issues Related to Country of Origin.* Paper prepared for the Secretariat for the Convention on Biological Diversity (as cited in UNEP/CBD/COP/3/Inf.25).

invariably mentioned unless the plant was widely distributed or well known (such as the lemon or rosemary)."[120]

114. This also applies to disclosure of TK: "the 'background art' that typically must be disclosed in patent applications usually includes references to traditional uses of the biological material and its properties in its country or region of origin. Rule 27(1)(b) of the European Patent Convention, for instance, requires that the content of the description of the patent should indicate the background art which, as far as known to the applicant, can be regarded as useful for understanding the invention, for drawing up the European search report and for the examination, and, preferably, cite the documents reflecting such art. Thus, in the case of […] European patent, No. EP 0513671, reference is made to traditional uses of the biological material used: in the ancient Sanskrit, this gum resin is called *guggulu* and is a product which is still used in Indian popular medicine for the treatment of obesity and some arthritic forms."[121]

Legitimacy of use and exploitation of genetic resources and traditional knowledge

115. Other proposals for GR/TK disclosure requirements or analysis of needs for enhanced disclosure mechanisms appear to be directed more clearly towards the implementation of non-patent laws and obligations. In these scenarios, the patent process is viewed as a means of giving effect to obligations under distinct legal or ethical systems, including compliance with access regulations in other jurisdictions. Inasmuch as this concerns disclosure of information as such, it is viewed as a compliance monitoring mechanism, or as a means of sanctioning failure to comply with non-patent laws in other jurisdictions.

Application of national regimes on access to genetic resources

116. The legal basis for a disclosure requirement may therefore have its roots in the laws and regulations of the source country that relevantly govern access and benefit-sharing. A number of such national and regional laws aim to give effect to the CBD, and in particular to apply at the national level principles concerning prior informed consent and equitable sharing of benefits in relation to access, as an expression of the sovereign right of parties to the CBD to exploit their own resources (recognized in Article 3 of the CBD). Thus national and regional laws fit in with the international framework established by the CBD, but the legitimacy or legality of access would be assessed according to the applicable national laws. The legal mechanisms that establish and enforce the conditions that apply to parties gaining access would equally operate under national laws. Where disclosure requirements within patent systems are intended to establish or disclose legitimacy of access, then their legal basis may not be in the patent law itself but in the operation of an access regime, potentially the national regime of a foreign jurisdiction. From a broader policy and international perspective, general principles may be derived from the CBD, but individual acts of access and arrangements for prior informed consent and benefit-sharing may be assessed and documented according to national laws.

117. One background issue is how compliance with one country's laws concerning legitimacy of use and exploitation may be assessed and sanctioned in another jurisdiction, and

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120 "The Convention on Biological Diversity and the Agreement on Trade-Related Intellectual Property Rights (TRIPS) (*sic*): Relationships And Synergies," UNEP/CBD/COP/3/23, at p. 19.

121 *ibid.*, p. 20.

what notion of legitimacy is therefore applied. One discussion document submitted to the Committee raised the question of legitimacy of the use of GR or TK as follows:

> "The Committee could study means of allowing the legitimacy of use and exploitation of biological and genetic resources and traditional knowledge to be checked when an invention purporting to be developed from them is claimed. In addition to other sanctions that laws might provide to discourage or restrain illegal use and exploitation of biological and genetic resources and traditional knowledge, the Committee could investigate the extent to which the unlawfulness of access might affect the acquisition of a patent for, or the validity of a patent granted in that way. It might also be necessary to define principles for the international harmonization of those criteria, in order that an unlawful act committed in one country may be recognized as being unlawful and sanctionable in other countries too. In the absence of central harmonization at the international level, biopiracy will be punished only in those countries that fall victim to the unlawful act, and not in those in which the products resulting from the act are commercially exploited."[122]

Contractual obligations as the legal basis

118. As this discussion suggests, further clarification may be necessary of how legitimacy of access and use would be assessed if this were to form the basis of a disclosure obligation. Depending on the nature of the requirement, this may become a complex question of private international law. The legitimacy of the access to and use of the GR/TK is based on a license or contract under the law of another country. Assuming there is a sufficiently close linkage between the GR/TK and a claimed invention (as noted above, this may be a question more of interpreting the contract provisions), a patent office may be required to interpret and assess the validity and the scope of the contractual obligations under the relevant foreign law to determine whether the nature of the invention, and the act of filing of a patent application for that invention in the patent office's own jurisdiction was consistent with the contractual obligations entered into under the law of the source country. This includes the question of whether the invention as claimed is sufficiently based on or derived closely enough from the GR/TK in question, and whether the contractual obligations covered the act of filing patents for such an invention in the relevant foreign jurisdiction.

119. The closest analogue to this requirement that can be found in established patent practice is the recording of ownership, licenses and security interests in a patent. For example, the claim to ownership or part ownership of a patent may be based on a contract in another jurisdiction – a research agreement may stipulate, for instance, that in consideration for financial or other (non-inventive) input to a research project, a party may be entitled to a share in the ownership of any patents based on the supported research, or a license to use patented technology based on the research. These interests may be enforced in a foreign jurisdiction concerning ownership of or licenses under patents filed there. The effect and legitimacy of the research agreement concluded under one jurisdiction may need to be weighed by judicial authorities in another jurisdiction to determine whether the ownership rights or a license interest may be recognized and recorded. Similarly, security interests may be enforceable (and there may be provision for these interests to be recorded) – such as when an agreement pledges patent rights as security against a loan (for instance, a loan to support development of the invention). Actual recordal of ownership, or license or security interests relating to

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[122] Document WIPO/GRTKF/IC/1/5, Annex II, pp 7-8.

patents is normally done routinely by patent offices (or other registration authorities), with no investigation into the veracity or legitimacy of documentation, beyond formality checks. These matters are generally only dealt with in the context of litigation, before the courts or administrative tribunals.

120. The recognition of ownership, license or security interests in a patent may involve extensive legal analysis and argumentation, especially when more the laws of more than one jurisdiction may apply – which law applies to determine the interest; how is it to be interpreted; and what are the implications for the ownership or validity of the patent? These complex issues of private international law[123] – in this context, concerning the recognition and enforcement of contractual obligations in several jurisdictions – would not normally be dealt with as patent law questions, although some specific elements of patent law may be relevant (such as those concerning employment relationships and patent ownership). As questions of private international law these issues have not been linked to the validity of patent claims as such, and have not been weighed in the patent examination process. To the contrary, they concern the determination of ownership and other interests in a patent that is itself considered valid according to patentability criteria (since those interests would be worthless in relation to an invalid patent or an ineligible patent application): this goes to the crucial distinction between the applicant's entitlement to apply for or to own the patent, and the eligibility of the invention itself for patent protection.

121. These considerations may apply in assessing the legitimacy of use or exploitation of GR/TK when there is an applicable contract, agreement or licence governing ownership or other interests in the patent, even where this contract is concluded under another jurisdiction (subject to resolution of the private international law and interpretative questions). In the absence of any such specific undertaking or contractual obligation, broader notions of legitimacy may need further clarification. The question may revolve around determining the implications for a patent right where a legitimate, patentable invention is based on non-inventive inputs (whether financial or otherwise) that are sourced illegitimately – for instance, where the research leading to an invention is financed by illegally gained funds, the research makes use of information which is fraudulently obtained (or which is in breach of a confidentiality agreement), or the research takes as its starting point stolen resources (genetic or otherwise). A related issue has arisen in the event that arguably unethical (rather than illegal) practices contributed to or made possible the invention. Inasmuch as these issues have arisen in practice (the present draft study has located little case law with bearing on the issue), the approach has tended to be one of distinguishing the entitlement to obtain a patent or to enforce the patent right from the patentability of the invention *per se*. Speculatively, if such a matter were brought before a court, the finding may conceivably be that a patent is technically valid, but cannot be enforced due to the inequitable behavior of its owner (see the discussion below from paragraph 124). However, this remains untested in practice, and may apply more to the duty of the applicant towards patent granting authorities, than the applicant's behavior in the process of developing the invention.

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123 "'Conflict of Laws' or 'Private International Law,' the terms are used interchangeably, is that part of the law which regulates the comity of states in giving effect, in one, to the laws of one another, relating to private persons or their contracts," CJS CONFLICTLW s 2.

Ordre public and morality

122. Another reported rationale that may be considered to form the basis for GR/TK disclosure obligations is the application of *ordre public* and morality requirements. This option appears to be linked to the option of excluding from patentability of inventions "the prevention … of the commercial exploitation of which is necessary to protect *ordre public* or morality."[124] This may require some specific finding under national law that it would be contrary to *ordre public* or morality for the subject invention to be commercially exploited, due to circumstances surrounding the development of the invention itself; this would appear to relate more to issues surrounding the patentability of the invention as such, rather than a specific disclosure requirement.

123. The experience of New Zealand in this regard was reported in its response to the Questionnaire (see paragraph 64 above). There is also a recent report of a draft proposal to link "compliance with the CBD to requirements that exploitation of an invention not be contrary to *ordre public* and morality."[125] This proposal reportedly stipulates "that the exploitation of an invention is contrary to *ordre public* and morality when the invention is developed on the basis of biological material that was collected or exported in breach of Articles 3 , 8(j), 15 and 16 of the CBD." On this basis, the patent application would be required to "contain, not only a formal request, a description, one or more claims, drawings and an abstract, but also the geographical origin of the plant or animal material on the basis of which the invention was developed."

'Clean hands,' fraudulent procurement, misappropriation and unfair competition

124. A range of proposals concerning disclosure requirements seek directly to create obligations to provide information about the circumstances in which relevant TK or GR were obtained, in particular to assess the legitimacy of actions taken prior to the process of invention in itself. This may lead to an obligation to declare that access was undertaken in conformity with relevant national laws (or, in the absence of applicable laws, in consistency with international treaties, notably the CBD and ITPGRFA), or to provide firm evidence to this effect. This shifts the focus from the act of invention to the background circumstances in which the invention was developed. Various legal principles have been put forward as the potential basis for such a requirement. This includes the question of compliance with national access regimes and with specific contracts, as discussed above. However, other legal doctrines have also been referred to in this discussion.

125. Some national systems have developed, through legislation or judge-made law, doctrines that seek to remedy cases where patents have been obtained through fraudulent behavior: this may arise when the applicant has misled the patent office, especially in making assertions as to the eligibility of the patent application or in failing to inform the office or judicial authorities of known material relevant to the patentability of the invention. Such cases have arisen, for instance, when a patent was enforced even though the patent owner was aware it had been based on false declarations concerning the circumstances and timing of the

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124 TRIPS Agreement, Article 27.2.

125 G. Van Overwalle, "Belgium goes its own way on biodiversity and patents", *European Intellectual Property Review* 5 (2002): 233-236, at 233.

invention,[126] or when the patent holder had suppressed evidence of prior use that would render the patent invalid.[127] The concepts of 'fraud on the office,' obtaining a patent "by fraud, false suggestion or misrepresentation," representation or fraudulent procurement generally apply to declarations or information made to a patent authority (or fraudulently withheld from it) relevant to patentability or eligibility to apply, including information known to be material to patentability[128] or known search results in general.[129]

126. The background law in relation to fraud and equity issues appears to have centered on information relevant to the validity of the patent. However, since these doctrines have in part arisen from the law of equity, the suggestion has been made that patents secured on the basis of illegitimately obtained source materials may be inequitable – or at least that courts may view enforcing such patents as inequitable. This kind of general proposal may hypothetically be applied in two distinct scenarios:

- material used to develop the invention has been obtained illicitly or inequitably: while not invalidating the patentability of the invention, it may be argued to undercut the eligibility of the patent holder to hold or to enforce the patent; or
- information about the source material used in the invention has been fraudulently withheld from the patent authorities, leading to the grant of the patent on the basis of a misrepresentation: this would require, in turn, that the applicant had a duty to inform the patent authorities about the materials used.

127. In this kind of analysis, there are two areas of behavior that may be considered relevant from the point of view of equity: the steps take to obtain source material; and the provision or withholding of information in dealing with the patent-granting or judicial authority. For instance, the recent CIPR report links equitable considerations with compliance with legislation concerning access to source material: "(t)he principle of equity dictates that a person should not be able to benefit from an IP right based on genetic resources or associated knowledge acquired in contravention of any legislation governing access to that material."[130] Alternatively, equitable considerations may apply in the case where the applicant is placed under an obligation to disclose information concerning the origin of TK/GR used in the invention. Hence the suggestion has been made that the "fraudulent procurement" doctrine could apply in the event of failure to comply with requirements reasonably to indicate "the source of genetic resources directly or indirectly used in obtaining the invention" or failure to obtain requisite prior informed consent.[131] This, it is argued, may create a situation of "unclean hands" in equity, which would have the effect of rendering an otherwise valid patent right unenforceable at least until the inequitable conduct had been corrected. This approach

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126 Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806, 65 S.Ct. 993.

127 Keystone Driller Co. v. General Excavator, 290 U.S. 240, 54 S.Ct. 146.

128 37 C.F.R. 1.56, see paragraph 43 above.

129 Australian Patents Act 1990, s.45(3).

130 "Integrating Intellectual Property Rights and Development Policy," Commission on Intellectual Property Rights, London, 2002, at page 87.

131 Nuno Pires de Carvalho, "Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution," 2 Wash. U. J.L. & Pol'y 371 (2000); see also the same author's forthcoming "From the Shaman's Hut to the Patent Office: In Search of Effective Protection for Traditional Knowledge," Wash. U. J.L. & Pol'y (forthcoming).

has been discussed by a number of commentators[132] but has not apparently formed part of a formal policy proposal nor any reported judicial decision. Generally speaking, this kind of approach would entail focussing on the legitimacy and equity of the circumstances, background and behavior that led to the inventive act, rather than the invention in itself, and then applying general equitable principles to deny the patent holder the entitlement to enforce patent rights on the invention (strictly, the inequitable conduct that contributed to the patent grant would be a defense against an infringement action). The technical legal validity of the patent itself is not, in this scenario, called into question. In this scenario, the issue would turn on the legal status of certain acts undertaken prior to and distinct from the inventive behavior itself, not on and relates less to disclosure as to the view a court would take of actual inequitable conduct. In relation to non-enforceability as a consequence of failure to disclose origin of source materials, the explanatory notes on the PLT, concerning Article 10(1), indicate that limitations on revocation and invalidation are "intended to also cover sanctions which are of equivalent effect to revocation or invalidation, such as non-enforceability of rights."

128. Other writers have proposed forms of protection of TK/GR based on unfair competition, liability or misappropriation rationales: if they are developed and applied, these legal concepts may in turn create a legal framework for the linkage between an invention, and the use of genetic resources or traditional knowledge.

Specific contractual obligation

129. An additional legal basis for disclosure of certain information by a patent applicant is as a specific requirement established by the terms of a contract. This may be applicable for a research agreement but also may appear in a material transfer agreement concerning the provision of biological materials. A requirement to disclose a benefit-sharing agreement or contract in a patent application, or to indicate the source of biological materials or knowledge may be based on an obligation in the contract itself. For instance:

> Reporting requirements [for a Cooperative Research and Development Agreement or other benefit-sharing agreement] might include notification of the development of any invention based upon research using research specimens collected in the parks and identification of the contract in any patent application claiming an invention developed as a result of the research on collected specimens or other materials.[133]
>
> The INSTITUTE shall apply for and obtain or cause to be granted and obtained the letters of patent on the products in the name of the INSTITUTE after the same has been developed and processed provided that the CONSULTANT HERBALIST'S name be included in the patent subject to the conditions hereinafter set forth.[134]

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132 See, for example, Graham Dutfield, "Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation," <http://www.ictsd.org/unctad-ictsd>, 2002, p. 25, and Charles R. McManis, "Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally," Washington University St. Louis, School of Law, Faculty Working Papers Series, Paper No. 02-10-03, 2003, p. 13.

133 Document WIPO/GRTKF/IC/4/13, paragraph 33.

134 Model Agreement between the National Institute for Pharmaceutical Research and Development, Nigeria and a Consultant Herbalist, 1997.

> Should a patentable invention result from the Company's or the University's testing and analytical activity, the Company is free to apply for patents with regard to such invention in its name and at its expense as it wishes. Any such patents will be filed by the Company indicating the name(s) of the University, its collaborator(s) and the representative(s) of the company, as the case may be, as inventor(s).[135]

In this scenario, the legal basis for the obligation to disclose information about the terms of access to GR/TK could be provided by the very contract or agreement establishing the terms of access, and this would be enforced as a contractual obligation.

Summary

130. Various possible legal bases for a GR/TK disclosure mechanism can thus be discerned:

- compliance with transparency requirements applied under national patent law in line with established patent principles (relevant prior art, enabling disclosure, identification of the true inventor(s));
- compliance with laws (including in foreign jurisdictions) governing access to genetic resources and associated traditional knowledge that may concern either use in general (such as commercial use or research involving the GR/TK) or may explicitly concern the entitlement to seek patent rights;
- compliance with contractual obligations (including contracts concluded under foreign jurisdictions) relating to access to and benefit sharing from genetic resources or traditional knowledge;
- compliance with morality and *ordre public* considerations relating to GR or TK applied within the jurisdiction of the patent filing, but considerations that may be based on concerns about GR or TK collected inconsistently with foreign laws or with international law;
- implementation of mechanisms for registering ownership or security interests when these may stem from the operation of contract law or access regulations, including when this is based on foreign jurisdictions;
- contractual obligations under an access agreement to disclose that agreement itself, or to disclose other required information, in any patent application ensuing from the access to GR/TK; and
- possible invocation of equitable principles to limit the enforceability of patent rights, when required information is withheld or when access to or use of GR/TK is considered to violate equity.

V.3 Nature of the obligation on the applicant

131. Disclosure requirements concerning GR and TK may impose various levels of obligations on a patent applicant. For instance, a stand-alone disclosure requirement (i.e. separate from general disclosure mechanisms) may be:

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135 Agreement for the Testing of Plant Extracts between the Company and the University (Sri Lanka), dated January 1st, 2000.

- an encouragement – in effect, a political exhortation to disclose details of GR or TK in patent specifications wherever relevant;[136]
- a measure that is a formal part of the patent application process, but is essentially voluntary in nature in that there is no immediate consequence of failure to comply;[137]
- a mandatory formality requirement, in that it must be complied with in order to obtain or preserve entitlement to a patent, akin to the obligation to providing details of priority documents (or copies and translations of priority documents) in order to sustain a priority date;
- mandatory in the sense that the assessment of the substantive validity of the patent application (by an examiner or by a court) requires a determination as to whether the requirement has been met before deciding whether a patent should be granted (or an existing patent should be upheld) for the invention.

A formality requirement and a substantive requirement may in practice overlap: to take the analogy of priority documentation, if an applicant fails to meet the formality requirements (such as timely submission of the necessary documents, with translations, certifications and any other formal requirement) to establish the documentary basis for a claim of priority, this could lead to loss of priority date for the claims concerned; in turn, this could lead to the examiner finding that the claimed invention is not novel due to intervening prior art.

Formality or substantive requirement?

132. This raises the key question of whether a requirement is a formality or a substantive requirement, an important distinction discussed variously above. For instance, the WIPO Working Group on Biotechnology characterised the distinction as "whether such a requirement should be dealt with by national laws as being substantive, thus leading to the rejection of the patent application in its absence, or rather a merely procedural one," a distinction that rests on the consequences of failure to comply (see section V.4 below). This distinction can be cast in various terms, and "the dividing line between formality requirements and substantive requirements [is] not always clear."[138] A procedural or formality requirement is generally a significant and important part of the patent procedure, and is not generally discretionary for the applicant. A simple example is the procedural requirement that fees be paid at various stages of patent processing or that an application should "comply with the prescribed physical requirements"[139]: this is not relevant to the substantive legal entitlement to the patent right but is nonetheless indispensable. Substantive legal provisions may relate to the applicant's *entitlement to apply*for or to be granted the patent, or may relate to the *eligibility of the invention* for the grant of a valid patent.

133. Regular examination of patent applications may be focussed on compliance with formalities only, or may also entail an assessment of the substantive eligibility of the claimed invention – typically, a determination whether the invention appears to meet the substantive criteria of patentable subject matter, novelty, inventive step and utility (or industrial applicability). Such a determination is not exhaustive, although it may increase the presumption of a patent's validity, and further objection may be raised as to the patent's

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136 For example, the encouragement in the Bonn Guidelines; see also the Questionnaire response of the European Commission, paragraph 54 above.

137 Refer for instance to paragraph 72 above.

138 Document SCP/5/6.

139 Patent Cooperation Treaty, Article 3(4)(ii).

validity at a later time – when a patent is enforced against an alleged infringer, for instance, there is often a counter-claim regarding the patent's substantive validity. It is very rare in the course of routine patent processing and examination for the applicant's entitlement to apply to be assessed. Many factors may apply in determining whether the applicant(s) was (or were) the true inventor(s), whether the application is based on a suitable chain of title from the single inventor or from all relevant co-inventors, and whether third party claims (based for instance on a research agreement or a material transfer agreement) may need to be taken into account. Typically, this issue would arise only in the event of challenge by an interested party, or when the patent holder seeks to enforce the patent in a court action, when questions over entitlement to the patent may form part of a counter-claim against the patent holder. Accordingly, it is necessary to distinguish between substantive requirements that are regularly checked during patent examination, and overall substantive validity of the patent (including patentability of the invention and the entitlement of the patent applicant or owner).

134. Existing general disclosure requirements in patent law have formality and substantive aspects. At the level of formalities, an applicant is generally required to meet the procedural requirement that a description of the invention be submitted with a patent application. The PLT provides that one element that is required for an applicant to establish a filing date to be "a part which on the face of it appears to be a description" (Article 5(1)(iii)) and the PCT contains a similar provision in Article 11(1)(iii)(d). This means that an application lacking a description of the invention would be subject to a formality objection, including during the international phase of the PCT procedure. Separately, the description must meet the substantive requirements for description (as discussed above), in particular whether it discloses "the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art" (Article 5, PCT; *cf.* Article 29 of TRIPS). This latter determination as to the sufficiency of description would occur later in the process of examination, or in the assessment of the granted patent by a court, and is in fact more likely to reflect on the validity of claims, particularly the breadth of their scope. Typically, in the course of substantive examination, a finding by the examiner that the description is insufficient is likely to lead to an obligation on the applicant to amend, and narrow, the claims, rather than by rectifying the description as such to provide descriptive material that was lacking (for example, an attempt to introduce new matter by amendment may not be allowed, meaning that a new application would have to be filed (see the answer of Finland, in paragraph 152 below); if an amendment introduces new matter extending beyond the content of the patent as filed, then it may open the patent up to revocation[140]). In other words, the substantive "disclosure requirement" becomes in practice a limitation on the claims that can be sustained (thus the PCT requires in Article 6 that "the claims shall be fully supported by the description").

135. To summarize, then, a disclosure requirement specifically relating to GR/TK may be characterised as a 'pure' formality (in that it is required as part of the patent procedure like payment of fees or compliance with physical format), it may be incorporated into the substantive legal criteria for patentability of the claimed invention, or it may be relevant to substantive legal determination of the applicant's entitlement to apply or of the patent owner's entitlement to ownership (in a variant form, it may be relevant to the owner's capacity to enforce the patent). If a formality only, then the obligation is likely only to apply during patent processing; if failure to comply with a formality is overlooked during patent examination and a patent is granted, it is not normally possible to overturn the granted patent

[140] For example, see United Kingdom Patents Act 1977 s.72(1)(d).

(unless the failure to comply was fraudulent[141]); by contrast, non-compliance with a substantive requirement (e.g. disclosure inadequate to support the claims) may be revisited after patent grant as a potential ground for revocation or a narrowing of the claims. Non-compliance with a substantive requirement relating to entitlement to apply may lead to cancellation or transfer of the patent.

Extent of the obligation

136. Associated with this question is what the applicant needs to do to exhaust the obligation; in other words, when an applicant can be reasonably confident that they have done all that is required of them. For instance, is it mandatory for the applicant actively to investigate and definitively determine the source of all relevant GR/TK and disclose it (and possibly also provide evidence of prior informed consent); is the applicant required to employ reasonable efforts or best endeavours to determine the source or the legal circumstances of access; or isthe applicant only required to disclose what is already known about the source or circumstances of access (or similarly to disclose what is known and considered to be relevant in good faith)? Alternatively, is the requirement considered unmet in the event that there is a demonstrated bad faith intention to conceal information that is known to be relevant to the requirement?[142]

Burden of proof

137. A related issue is the burden of proof, or the degree to which an application or granted patent is deemed *prima facie* to be compliant with a disclosure requirement. For instance, is the applicant required positively to discharge a burden of proof that the GR/TK was legitimately accessed (i.e., in compliance with the laws of the source country), or is the applicant's use of the relevant GR/TK considered to be legitimate unless there is proof to the contrary? Finally, a distinction may be made between the degree to which the burden of proof is to be discharged in practice in the course of routine patent examination, and the degree to which the issue could be pursued in principle (for instance, during litigation over a particularly controversial patent) – by analogy, certain practical bounds may be placed on routine prior art searching, but a far more intensive process may be undertaken when a patent's validity is challenged in litigation (to the point, for instance, of public advertising for prior art on a particular aspect of the invention).

Intent of applicant

138. A specific aspect of the nature of the obligation on the applicant is whether, and the degree to which, the intent of the applicant is to be weighed. For instance, the PLT makes a distinction in the consequences from failure to comply with a patent formality, and failure to comply with a formality with fraudulent intent (Article 10(1)). In patent systems where the applicant is obliged to disclose all known prior art relevant to the patent's validity, this may only have significant consequences when known, relevant prior art is intentionally withheld. There may be less serious consequences when failure to comply is unintentional or in good faith, and if the applicant takes timely action to rectify any failure. In some cases, the failure to comply with a disclosure obligation or other obligation to provide information may give rise to a distinct sanction (including criminal sanctions) when it amounts to a deliberate

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141 For example, see PLT, Article 10 (1).

142 *cf*. the obligation to disclose known prior art – see paragraphs 42 to 44 above.

attempt to mislead – variously defined in terms of fraud on the office, fraudulent procurement, or making false entries or false declarations on official documents; in the law of equity, this may also negate the right to enforce the patent (see discussion above, from paragraph 124). The responses to Question 13, summarized in paragraph 70 above, give some illustrations of these penalties. Where failure to comply with a substantive or formality requirement is due to a genuine error or omission, with no intent to falsify or mislead, the consequences are generally less severe, and the possibilities of remedying the problem are higher.

Conflicting obligations

139. An obligation to disclose the exact source of a genetic resource may create conflict with other obligations on the patent applicant, and this may need to be weighed in assessing and applying the disclosure requirement. For instance, in one access and benefit-sharing regime, the following stipulation is made:

> "The permittee agrees to keep the specific location of sensitive park resources confidential. Sensitive resources include threatened species, endangered species, and rare species, archeological sites, caves, fossil sites, minerals, commercially valuable resources, and sacred ceremonial sites."[143]

In such an instance, a disclosure obligation based on the requirement for enablement and reproducibility of the invention would presumably be met through the deposit of biological material with a recognized depositary authority, as this would provide sufficient disclosure while safeguarding the confidentiality of the origin. In cases where the obligation to disclose the origin of resources was a transparency or compliance monitoring mechanism, the obligation on the patent applicant may need to be less specific when the applicant is under an obligation to withhold specific information concerning the access, including when this withholding of information is itself a condition of prior informed consent and the agreed terms of access.

140. A similar conflict of obligations may concern an applicant who is aware of undocumented or sacred/secret traditional knowledge, but is under an obligation not to disclose it. For instance, it may be the subject of a non-disclosure agreement or subject to customary law restrictions. The very process of documenting the TK within the framework of a patent application may run contrary to the express wishes of TK holders.[144] This may arise for example when an invention is developed through innovation within the context of traditional technological knowledge, or in a research partnership involving TK holders. Existing patent law may provide solutions for dealing with the apparent dilemma between the obligation to make known prior art available to the patent office, and the obligation to protect undisclosed TK from unauthorized disclosure; for instance, it is likely to be relevant whether the TK had already been documented and made publicly available.

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143 Under "General Conditions for Scientific Research and Collecting Permit," United States Department of the Interior, National Park Service, document WIPO/GRTKF/IC/4/13.

144 See document WIPO/GRTKF/IC/5/5.

V.4 Consequence of failure to comply

141. One significant issue that was highlighted in earlier discussion was whether the disclosure of relevant genetic resources and TK (and related information such as prior informed consent arrangements) was to be simply encouraged (as in COP Decision VI/24), should be a formality with no sanctions, should become a formality with significant sanctions (e.g. a requirement to be finalized before a patent is accepted), or would be established as a substantive ground for patent validity (including possible revocation).[145]

142. In the case of existing, non-specific disclosure obligations, failure to meet these requirements can lead to significant sanctions, ranging from penalties for false, misleading or fraudulent statements, to refusal, invalidation or transfer of the patent right.

143. The specific disclosure mechanisms (directly concerning genetic resources and TK) covered in answers to the Questionnaire are either effectively direct applications or extensions of existing disclosure obligations (and thus subject to existing sanctions) or are not subject to direct sanctions through not being legally binding.

144. Other provisions may, however, go further and apply to the legal conditions of access of genetic resources and associated TK (e.g. whether prior informed consent requirements have been complied with at the point of access, and the provision of evidence to this effect). This would in turn raise further issues for consideration, in particular about the monitoring or enforcement of compliance with contracts, permits, licenses or other legal or regulatory systems by means of the patent system, especially when it concerns compliance in one jurisdiction and patent rights in another jurisdiction.

145. Such provisions may go beyond disclosure requirements as such (and thus go beyond the nominal scope of the present draft study), in that they require more than transparency and the provision of information to a certain standard: in some potential scenarios, these provisions may amount to substantive standards regarding the activities that led to the patented invention, such that non-compliant behavior (e.g. failure to secure applicable prior informed consent) would lead to rejection or invalidation of a patent. In other words, this goes beyond a formal requirement to disclose certain information, and becomes a substantive matter of judgement as to whether that information, when provided, meets certain specific standards This illustrates the uncertain relationship between a 'formality' requirement and a substantive ground for obtaining or maintaining a patent.

146. For example, to take a scenario in which a patent applicant is required to furnish either a declaration of whether prior informed consent was obtained, or to furnish direct evidence of prior informed consent, this may be treated during the prosecution of the application before the patent authorities as a formality requirement (in that an applicant should merely be seen to comply with this as a precondition for grant of a patent) or as a substantive obligation (in that a patent examiner may check whether the claim or evidence of prior informed consent is valid, either *prima facie* or to a stronger standard - e.g. is the prior informed consent that has been disclosed by the applicant actually sufficient consent for the filing of a certain patent application for a certain derivative invention in a particular jurisdiction?) However, within this scenario, whether or not this is checked during patent processing does not mean the

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[145] See, for instance, the discussion from the Working Group on Biotechnology cited in paragraph 26 above.

granted patent cannot be challenged and potentially invalidated. This could be the case even though the patent itself is valid from the point of view of substantive grounds of validity (novelty, inventive step and utility, as well as covering patentable subject matter).

147. Failure to comply with a documentary requirement during the application phase within a certain time limit can lead to a decision that the application has been effectively withdrawn. For instance, according to the response of China to the Questionnaire, if an application has already been filed in a foreign country, the State Intellectual Property Office (SIPO) "may ask the applicant to furnish, within a specified time limit, documents concerning any search made for the purpose of examining that application, or concerning the results of any examination made, in that country. If, at the expiration of the specified time limit, without any justified reason, the said documents are not furnished, the application shall be deemed to have been withdrawn." A number of patent-granting authorities have similar requirements concerning submission of search reports. Whether or not a search report is provided does not in itself render a claimed invention patentable or not (although it may help substantive examination). Hence what may be characterized as a formality or documentary requirement can nonetheless have significant consequences.

148. In general, the full potential consequences of failure to comply with a disclosure requirement should be distinguished from the substantive legal issues that are specifically checked during patent examination. As has been noted, patent examination does not normally focus on the fundamental question of whether the applicant is entitled to apply for the patent (for example, there may be a documentary requirement to furnish a deed of assignment demonstrating the title has passed to the applicant from the inventor, but the examiner would not normally separately investigate the facts surrounding the validity of the assignment, or the exact factual circumstances of the invention, the contribution of various), but this does not mean that these issues are not weighed fully when contested (e.g. when a third party claims a share in ownership or inventorship). In some cases, it may not be the responsibility of the patent office to check on questions of ownership.[146] For instance, the Questionnaire response by Finland states that:

> "disputes regarding the ownership of an invention are decided in courts… if a person claims before the Patent Authority that he has proper title to the invention and if the circumstances are held to be uncertain, the Patent Authority may invite such person to institute proceedings before a court of law within a period of time to be laid down. If proceedings for proper title to an invention are pending before a court, the patent application may be suspended until a final decision is given by the court."

Accordingly, not all items of required information are necessarily checked and assessed during the patent examination process, even in those patent systems that have mandatory substantive examination of patent applications. It may only be when a patent is the subject of litigation that such fundamental issues as inventorship and entitlement to apply are fully

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146 The Enlarged Board of Appeal described the situation concerning the EPO as follows: "[u]nder the European patent system, the EPO has no power to determine a dispute as to whether or not a particular applicant is legally entitled to apply for and be granted a European patent in respect of the subject-matter of a particular application… the "Protocol on Recognition"), which is an integral part of the EPC, … gives the courts of the Contracting States jurisdiction to decide claims to entitlement to the right to the grant of a European patent…," decision G 3/92 (Latchways Application), 13 June 1994.

assessed. Hence, even if failure to meet disclosure requirements does not have immediate consequences during examination, they may have major implications for the patent whenever it is enforced; and this can create a strong incentive to comply with such requirements.

149. There are diverse potential consequences of failure to meet requirements to disclose certain information. These include:

- narrowing or invalidation of patent claims that would need to be supported by the information that was not disclosed;
- penalties (including administrative and criminal penalties) for provision of false information on public documents, particularly when information is withheld with fraudulent intent;
- refusal to grant an application on the grounds that formality or documentation requirements had not been met within a specified time-frame;
- subsequent invalidation or transfer of the patent after its grant in the event of serious deficiencies (e.g. withholding the name of a joint inventor with fraudulent intent); and
- where doctrines such as fraudulent procurement, "fraud on the office" or obtaining by false representation apply, potential refusal or invalidation of the patent, or inability to enforce patent rights.

150. Which of these consequences applies in relation to a disclosure requirement may depend on the legal basis of that requirement. Clearly, if the legal basis of the disclosure requirement is the obligation to provide sufficient enabling disclosure, failure to comply will jeopardize claims relying on that disclosure. If the disclosure relates to entitlement to apply or inventorship, then the consequence may involve the full or partial transfer of rights, or their invalidation. Or if the legal basis of disclosure is a duty of candor and good faith (in particular, a duty to disclose known prior art material to a patent claim), the consequence may be refusal of a patent application, or unenforceability or invalidation of the granted patent. False suggestion or misrepresentation, including misleading the patent office, may be a ground for patent revocation. However, in the latter case, the consequence may not directly concern the patent's validity in itself, but may serve as a defense in an infringement case, effectively making the patent right unenforceable while not invalidating the patent itself. As noted in paragraph 138 above, the intent of the applicant in failing to comply can be a crucial consideration.

151. The consequences of failure to comply with disclosure requirements may also vary depending on the stage reached in the patent process. In general, the formal requirements to establish a filing date are considerably less than the requirements that must be met for a patent to be granted. For instance, no patent can be granted without a claim or claims, and the assessment of the claims is crucial in determining the scope of the patent right and the validity of the patent; yet under the standards of the PLT, no claims need be submitted in the first instance in order to secure a filing date. Other formalities, such as provision of priority documentation and translations, may normally be met during the prosecution of the patent application, and need not be complied with immediately on the point of initial application.

152. Hence it will often be the case that failure to comply with certain disclosure requirements will not lead to outright refusal of the patent application. Allowance would be given for the applicant to rectify any defect or to attend to any formality requirement within a certain period of time: for example, the failure to provide an incomplete address can be rectified. However, if the effect of an amendment would be to introduce new substantive

technical matter about the invention, not previously disclosed by the applicant, this would have implications for the patent right. For instance, the priority date of any claim even partially supported by this material may be tied to the date this new material was provided, and this may in turn adversely affect the validity of the claim. Alternatively, as for example the response by Finland to the Questionnaire sets out, "an application for a patent may not be amended in such a way that protection is claimed for matter not disclosed in the application at the time it was filed … The applicant has to file a new application in which the mistakes have been corrected."

153. After the grant of the patent, there is generally a restriction on the grounds for challenging the patent on formality grounds alone, and this may restrict the consequences of a disclosure requirement that is considered wholly a formality; typically, a granted patent may be challenged on substantive grounds concerning the patentability of the invention or the entitlement to hold or exercise the patent right. For instance, the effect of Article 10 of the PLT would mean that a patent that had already been granted could not be invalidated on the basis of failure to pay a fee, or to provide an abstract, if this was overlooked during the course of examination and processing, and was not the result of fraudulent intention on the part of the applicant.

154. Thus the consequences of failure to meet a particular disclosure requirement may depend on the legal basis of the requirement, the stage reached in the processing of the patent, and any steps taken to remedy the failure, as well as consideration of such issues as whether the failure was unintentional or done with fraudulent intent, and whether patent claims rely on the undisclosed material for support.

155. One key question is whether failure to disclose required information affects the validity of the patent, and in particular the patentability of the invention as claimed, or whether it has bearing on the applicant's entitlement to apply for a patent and the patent holder's entitlement to own or to enforce the patent. If a general trend can be discerned, there may be a tendency for the consequences of failure to comply to correspond to the nature of the information that is not supplied – for instance, failure to divulge information relevant to the circumstances of ownership and entitlement to apply would primarily have implications for the capacity to own the patent and to exercise the patent right; failure to provide information relevant to the assessment of the validity of the invention or necessary to support patent claims would primarily have implications for the validity of the patent as such. In practice, however, there are significant variations from this general tendency.

V.5 Implementing, verifying or monitoring the requirement

156. Depending on the nature of the obligation placed upon the applicant and the consequences of failure to comply with any particular disclosure requirement, the requirement may entail the development of significant tracking and verification mechanisms that may themselves raise questions of compatibility with established laws, principles and procedures. Some approaches to the development of specific GR/TK disclosure requirements would place new procedural and documentation obligations on the applicant – such as the obligation to submit to patent authorities a certificate of origin, access contract, certificate or license, or other documentation supporting the assertion that prior informed consent has been obtained and that access to GR or TK was legitimate. The practical operation of such a disclosure requirement may directly depend on the existence and effectiveness of separate regulatory, compliance or monitoring mechanisms, often in a foreign jurisdiction. The impact of such a

requirement would differ if it were a simple transparency obligation – a requirement to furnish copies of any documents considered in good faith to be relevant – from a requirement to meet a substantive standard, compliance with which may need at some stage to be checked and verified.

157. In the latter case, further consideration would be needed of how the relationship would be structured or articulated between the patent system in one jurisdiction and the laws concerning access to GR/TK and general contractual matters in another jurisdiction. For instance, a patent authority or a court may be required to make an assessment of whether a relevant act of access to GR/TK in another country was legitimate and forms a legitimate basis for a patent application or a granted patent (provided always that the necessary connection between GR/TK and the invention itself has been established). This sense of legitimacy may be expressed in terms of whether under either a general access law or a specific access contract (presumably interpreted according to the laws of the country of origin), the research leading to the claimed invention, the act of filing the patent and the claimed entitlement to apply (or designation of patent applicants of owners) are consistent with the obligations incurred in that separate jurisdiction. Where the matter has been litigated in the country of origin (or possibly a third country, such as the country in which the research was undertaken), this may create a need to determine whether and how the judgements of a foreign court would be recognized. In general, in determining legitimacy of access and any consequences for the entitlement of the applicant to apply for a patent, it may be necessary to address "choice of law" issues: that is, the question of which jurisdiction's law should be applied in determining the legitimacy of access and compliance with any relevant contractual obligations. This is a highly complex area of law, whether it concerns infringement of laws or compliance with contract obligations: some standard approaches are termed *lex fori* (a contract interpreted under the law of the jurisdiction where the action is brought), *lex loci contractus* (interpreted under *the* law of the jurisdiction where the contract was concluded), or *lex loci solutionis* (interpreted under the law of the jurisdiction where the contract was to be carried out); other considerations include the intention of the parties to the contract and the nature of any government interest.

158. One existing compliance monitoring and transparency mechanism that may be relevant in this case is the registration of relevant interests, whether these are ownership, license or security interests, each of which may arise in some form as a consequence of access and benefit-sharing regulations and agreements. For instance, if the parties to an agreement so chose, the benefit-sharing provisions of an access agreement may stipulate that the access provider is entitled to partly or fully own patents on inventions derived from the access, is entitled to a license under any such patent, or is entitled to assignment of patents in the event of default of payment or breach of contractual conditions. Varying mechanisms exist in national and regional patent systems for the recordal of such interests. Patent offices rarely monitor these records in an active way, or examine them for substantive legitimacy. Records of ownership, license or security interests are assessed in a substantive way as required when the legal status they record or establish becomes directly significant, for instance when it arises in litigation.

159. Another compliance reporting mechanism put before the Committee is the suggestion that access and benefit-sharing agreements could require, as a condition of access, that any patent applications on research ensuing from the access be reported and that the agreement itself be identified in any patent application on an invention resulting from this research; as

noted a, this uses a contractual requirement as the basis for disclosure concerning access conditions within patent applications.[147]

160. A requirement to submit documentary evidence of the terms of access may be facilitated by clearer, harmonized system of recording or certifying access. For instance, the Bonn Guidelines acknowledge the need for " further information gathering and analysis" on a range of issues including the "feasibility of an internationally recognized certificate of origin system as evidence of prior informed consent and mutually agreed terms." Standard or model material transfer agreements and similar coordinated or harmonized arrangements setting access conditions may also provide for recording or certifying conditions of access.

VII. TREATY PROVISIONS ON PATENT LAW

161. This section reviews some relevant aspects of WIPO treaties, in view of the request that this draft study address methods that are consistent with these treaties. Treaties administered by WIPO do not lay down exhaustive or comprehensive standards for national patent systems, but provide for a range of standards that may be applicable to disclosure requirements, both from the point of view of substantive law and formalities. For the sake of completeness, this section also cites some relevant provisions of the TRIPS Agreement, although it is not administered by WIPO nor can it be authoritatively interpreted by the WIPO Secretariat.

Paris Convention

162. The Paris Convention lays down certain core principles that apply to national patent laws. For instance, Article 2 has the effect of applying the principle of national treatment to patent law:

> "Nationals of any country of the [Paris] Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention. Consequently, they shall have the same protection as the latter, and the same legal remedy against any infringement of their rights, provided that the conditions and formalities imposed upon nationals are complied with."

This means that no disclosure requirement should be applied more advantageously to domestic nationals who are applying for or who hold patent rights, as compared to foreign nationals.

163. Article 4*bis* of the Paris Convention provides for the independence of patents obtained for the same invention in different countries "in an unrestricted sense," which includes independence "as regards the grounds for nullity and forfeiture." Article 4*ter* establishes the right of the inventor "to be mentioned as such in the patent," a disclosure mechanism that may be relevant to the present study as discussed at length above (see paragraph 50).

164. Article 4 *quater* requires that the basis for refusal or invalidation of a patent should not include "the ground that the sale of the patented product or of a product obtained by means of

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147 Document WIPO/GRTKF/IC/4/13, quoted above in paragraph 132.

a patented process is subject to restrictions or limitations resulting from the domestic law." For instance, whether or not a particular technology has been approved for use should not be the basis for refusal. This expresses a distinction between the authorization to market a product, and the determination of the validity of a patent relating to the product, a distinction that may be a background consideration for some disclosure requirements that effectively create new substantive grounds for patent validity.

Patent Law Treaty

165. The Patent Law Treaty (PLT) establishes standards for formalities and procedure with respect to national (regional) patent applications filed with national (regional) offices, and to international applications under the PCT once they enter the so-called "national phase." The PLT "does not establish a completely uniform procedure for all Contracting Parties, but provides assurance for applications and owners that, for example, an application that complies with the maximum requirements permitted under the Treaty and Regulations will comply with formal requirement applied by any Contracting Party."[148] Article 2(2), entitled "*No Regulation of Substantive Patent Law*," provides that "(n)othing in this Treaty or the Regulations is intended to be construed as prescribing anything that would limit the freedom of a Contracting Party to prescribe such requirements of the applicable substantive law relating to patents as it desires."

166. The PLT does nonetheless contain several provisions that may be relevant to the formality or procedural aspects of disclosure requirements. For instance, this may apply to the establishment of a filing date of an application. Article 5(1), entitled "*Elements of Application*" effectively requires that an applicant should be accorded a filing date if he or she has submitted to a patent office: "(i) an express or implicit indication to the effect that the elements are intended to be an application; (ii) indications allowing the identity of the applicant to be established or allowing the applicant to be contacted by the Office; (iii) a part which on the face of it appears to be a description." For instance, patent claims, which are fundamentally important both to the validity and to the legal effect of the patent right, need not be filed in the first instance for a patent application to be accorded a filing date. Similarly, the identity of the inventor, the disclosure of which may be required, need not be provided at the time of filing.

167. While this is essentially a question of filing formalities, it may have significant implications for some disclosure requirements. For example, discussion of disclosure requirements has suggested a strong form or requirement that would seem to entail failure to accord a filing date to an application unless it was submitted already with evidence of compliance with GR/TK access laws: "Applications unaccompanied by such documentation [official documentation from provider countries proving that genetic resources and associated TK] would automatically be *returned to the applicants for re-submission* with the relevant documentation."[149] This approach would suggest that the application would not be received and given a filing date without detailed documentation proving that GR/TK with some relationship with the patent application had been legitimately obtained. Such a requirement

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148 Paragraph 2.01, Explanatory Notes on the PLT and Regulations under the PLT, WIPO Publication No. 258, 2000: prepared "for explanatory purposes only."

149 Dutfield, Graham, "Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation," http://www.ictsd.org/unctad-ictsd, 2002, p. 25 (emphasis added).

would be at odds with provisions such as those in the PLT that set standards for securing a filing date. Practically, it is also difficult to see how a determination could be made as to whether a declaration of GR/TK might be relevant without a claim of the patented invention (assuming some form of relationship must be established between the GR/TK and the invention as claimed to trigger the disclosure requirement), and yet an application can initially be accepted without submission of claims altogether – the claims forming the crucial element of interpreting the effective scope of the invention.

168. As noted above (paragraph 32), the PLT also makes provision for the form and contents of patent applications and aligns these with the requirements of the PCT. WIPO document SCP/6/5 gives a detailed account of the interface between the PLT and PCT. The explanatory notes on the PLT[150] comment that Article 6(1) of the PLT applies the requirements relating to the form and contents of international applications under the PCT to national and regional applications. The wording of this provision is modeled after that of PCT Article 27(1). It is implicit that the expression form and contents of an application is to be construed in the same way as the expression in that Article. The Notes to that Article in the [relevant diplomatic records] contain the following explanation:

> "The words *form or contents* are used merely to emphasize something that could go without saying, namely that requirements of substantive patent law (criteria of patentability, etc.) are not meant."

169. The explanatory notes give illustrative examples as follows: "(t)he requirement, allowed under Article 29.2 of the TRIPS Agreement, that an applicant for a patent provide information concerning the applicant's foreign applications and grants, is not a requirement as to the "form or contents of an application" for the purposes of this provision. Similarly, requirements in respect of duty of disclosure, indications as to whether an application was prepared with the assistance of an invention marketing company and, if so, indications of the name and address of that company and requirements in relation to the disclosure of search results on related applications and patents, are also not requirements as to the "form or contents of an application" for the purposes of this provision. Further, requirements as to the "form or contents of an application" do not include any requirements relating to foreign investments, public concessions or public contracts under national laws and bilateral and multilateral agreements."[151]

170. Given that "in practice, different Contracting States have differing views"[152] on the issue of the distinction between substantive requirements and requirements as to form and contents, there is a degree of uncertainty and ambiguity as to how to draw this line. However, since the question has been avoided in the context of the PCT, it is deemed inappropriate for the PLT to strictly define a matter under the PCT which has intentionally been left ambiguous in the context of the PCT itself.[153] Equally, the nature of substantive standards is not prescribed within the PLT. There are two general areas of substantive law that are directly related to the grant of a patent: the eligibility of the disclosed invention itself for patent protection (its conformity with the definition of a patentable invention and with other

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150 Paragraphs 6.01 and 6.02, Explanatory Notes on the PLT and Regulations under the PLT, WIPO Publication No. 258(E), also provided as Annex I to WIPO document SCP/6/5.

151 *op. cit*. paragraph 6.03 and Annex I to WIPO document SCP/6/5.

152 Document SCP/6/5, paragraph 8.

153 *Ibid*.

patentability criteria), and the entitlement of the applicant to be granted the patent (inventorship, nature of the assignment of the right, etc.) Other areas of substantive law may not be directly relevant to the grant or validity of the patent as such – examples of such other areas are noted in the extract above, for instance foreign investment, public concessions or public contracts.

171. Article 10 of the PLT, entitled "Validity of Patent; Revocation" is also relevant to the present draft study, and has already been discussed above, particularly in relation to the nature of consequences of non-compliance with formal requirements. Article 10(1) provides that "non-compliance with one or more of the formal requirements referred to in Articles 6(1), (2), (4) and (5) and 8(1) to (4) with respect to an application may not be a ground for revocation or invalidation of a patent, either totally or in part, except where the non-compliance with the formal requirement occurred as a result of a fraudulent intention." Article 10(2) provides that "a patent may not be revoked or invalidated, either totally or in part, without the owner being given the opportunity to make observations on the intended revocation or invalidation, and to make amendments and corrections where permitted under the applicable law, within a reasonable time limit."

The Patent Cooperation Treaty

172. Because of the linkage between the two treaties that was consciously adopted during the PLT negotiations, the PCT itself is significant both in terms of determining the standards that apply to international applications (including the processing of international applications within national jurisdictions), and in terms of interpreting the PLT. The PCT Applicant's Guide introduces the PCT system in the following terms:

> "The PCT facilitates the obtaining of protection for inventions where such protection is sought in any or all of the PCT Contracting States. It provides for the filing of one patent application ("the international application"), with effect in several States, instead of filing several separate national and/or regional patent applications. The PCT does not eliminate the necessity of prosecuting the international application in the national phase of processing before the national or regional Offices, but it does facilitate such prosecution in several important respects by virtue of the procedures carried out first on all international applications during the international phase of processing under the PCT. The formalities check, the international search and (optionally) the international preliminary examination carried out during the international phase, as well as the automatic deferral of national processing which is entailed, give the applicant more time and a better basis for deciding whether and in what countries to further pursue the application."[154]

173. The PCT system is a patent filing system, not a patent granting system. It provides for an *international phase*, comprising filing of the international application, international search, international publication and international preliminary examination; and a subsequent *national phase* before designated national or regional patent offices, which process international applications as national or regional patent applications. The decision on granting or refusing patents is taken exclusively by national or regional offices in the national phase. Nonetheless, the PCT has the effect of harmonizing procedural and administrative matters, including the form and contents of patent applications.

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[154] PCT Applicant's Guide, Volume I, Chapter II, paragraph 11.

174. PCT provisions may therefore be relevant to disclosure issues both in the international phase and in relation to national requirements concerning the form or contents of international applications. The requirements for the form or contents for the international application are set out in the Treaty itself, and the Regulations established under the PCT – these were discussed above in the review of disclosure obligations generally. In brief, the PCT specifies that an "international application shall contain … a request, a description, one or more claims, one or more drawings (where required), and an abstract." The nature of each of these elements is specified in some detail in the Treaty and Regulations.

175. Concerning the national phase, Article 27 of the PCT provides that "(n)o national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations" but that this does not "preclude any national law from requiring, once the processing of the international application has started in the designated Office, the furnishing … of documents not part of the international application but which constitute proof of allegations or statements made in that application…" The same Article provides that nothing in the PCT or its Regulations "is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires" and that "national law may require that the applicant furnish evidence in respect of any substantive condition of patentability prescribed by such law."

176. PCT Rule 51 *bis* elaborates on Article 27 and specifies (at 51 *bis*(i)(a)) that "the national law applicable by the designated Office may … require the applicant to furnish, in particular: (i) any document relating to the identity of the inventor, (ii) any document relating to the applicant's entitlement to apply for or be granted a patent," as well as information in certain circumstances concerning priority documentation, oath or declaration of inventorship, and evidence concerning non-prejudicial disclosures or exceptions to lack of novelty.

177. Potentially, and depending on the applicable national law, "any document relating to the applicant's entitlement to apply for be granted a patent" could concern issues such as whether the applicant is party to a legal agreement (such as a materials transfer agreement) concerning inputs to the inventive process that affected the applicant's legal entitlement to apply or to hold a granted patent. A PCT applicant may be required under national law to provide a declaration concerning their entitlement to apply for and be granted a patent (in the case of the majority of designated States): this can be complied with already upon filing or at a later stage during the international phase (by providing the appropriate declaration), or upon or after entry into the national phase before the designated Offices concerned. Where the designated Office "may reasonably doubt the veracity of the indications or declaration concerned" it can require documents or evidence concerning the applicant's entitlement and concerning the identity of the inventor.

178. The PCT system has specific provisions relevant to disclosure requirements in the form of deposit of biological materials and nucleotide or amino acid sequence listings. Rule 13*bis*.1 defines "reference to deposited biological material" as "particulars given in an international application with respect to the deposit of biological material with a depositary institution or to the biological material so deposited." Rule 13*bis*.2 stipulates how such references should be made (as discussed above, paragraph 103) and provides that "if so made, [a reference] shall be considered as satisfying the requirements of the national law of each designated State." Rule 13*ter*, concerning nucleotide and/or amino acid sequence listings, effectively requires that such listings be provided according to the standards set out in the

PCT Administrative Instructions, including submission in machine readable form. The consequence of failing to submit the listing within a certain time limit is that the international search would not be required to cover that application to the extent that failure to submit the information in the prescribed form prevents a meaningful search from being carried out. During the national/regional phase, a designated Office cannot require a sequence listing other than a listing in accordance with the standards provided in the Administrative Instructions.

179. The PCT does not have a mechanism for a distinct declaration concerning source of GR/TK as a separate element of the form or content of an international application, or as an additional national requirement relating to the form or content of an international application. The PCT stipulates that it is not "intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires." This clearly applies to patentability of the invention as such. However, as has been noted several times above, the entitlement of the applicant to apply for and be granted a patent is also a matter of substantive law, distinct from the technical patentability of the invention as such, but potentially at least as important in terms of the ultimate ownership and exercise of the patent.

TRIPS Agreement

180. A number of provisions of the TRIPS Agreement may also be relevant to disclosure requirements. These are outside the scope of the present draft study, and the interpretation of TRIPS provisions is undertaken under the procedures of the World Trade Organization.[155] Nonetheless, a number of these provisions are noted here as they may form relevant background to the issues under consideration. As document WIPO/GRTKF/IC/1/3 pointed out when this issue was first considered by the Committee:

> "From the intellectual property point of view, existing standards on the availability, scope and use of patents, such as those set out in Articles 27, 29, 32 and 62 of the TRIPS Agreement, may afford some guidance as to how those WIPO Member States which are also WTO Members may address this concept."[156]

TRIPS Article 27.1 provides that "subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." This refers to the patentability of the invention as such, and does not make specific provision for the entitlement of the applicant, which is separately determined; clearly, the technical patentability of the disclosed invention does not mean any applicant is entitled to a patent on that invention. TRIPS Article 29 provides a firm requirement for disclosure as a specific obligation on the patent systems of WTO Members, who "shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application." Paragraph 2 of this Article adds that "[WTO] Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and

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155 See in particular Article IX.2 of the *Agreement Establishing the World Trade Organization.*

156 Document WIPO/GRTKF/IC/1/3, paragraph 45.

grants." Thus Article 29 codifies various disclosure requirements that have been discussed above.

181. TRIPS Article 32 provides that "an opportunity for judicial review of any decision to revoke or forfeit a patent shall be available," which may be relevant to the consequence of certain disclosure obligations (*cf.* also Article 10(2) of the PLT). Article 62 lays down a range of standards for the acquisition or maintenance of intellectual property rights and related *inter partes* procedures. For instance, it specifies that "[WTO] Members may require, as a condition of the acquisition or maintenance of [specified] intellectual property rights … compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of [TRIPS]." It also specifies that "procedures concerning the acquisition or maintenance of intellectual property rights and, where a Member's law provides for such procedures, administrative revocation and *inter partes* procedures such as opposition, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of Article 41." These principles include, for instance, a requirement that procedures be "fair and equitable." (Article 41.2)

VIII. REVIEW OF METHODS FOR REQUIRING DISCLOSURE

182. This part of the draft study builds on the foregoing discussions by reviewing methods consistent with obligations in WIPO-administered treaties for requiring patent applicants to disclose various forms of information concerning genetic resources and traditional knowledge. This review considers each of the general aspects of the issue distinguished in the above discussion. It covers relevant disclosure requirements that are inherent in existing patent law and thus operate within the existing framework, requirements that may involve the clarification or elaboration of existing disclosure mechanisms, and requirements that may be entirely distinct new forms.

(i) Trigger for the disclosure requirement

183. This section considers the possible linkages that may be necessary to trigger disclosure requirements, or what relationship may need to exist between the patent subject matter and the GR/TK before the obligation is incurred by the patent applicant. Generally, it assumes that some form of relationship must need to be established between the GR/TK concerned on the one hand, and the invention as claimed on the other hand. However, it may be appropriate to consider disclosure requirements that draw a link between GR/TK and other characteristics of the invention, such as preferred embodiments or specific examples given in the description of the invention. The possibilities include:

- access to the genetic resources is necessary to carry out or replicate the invention as claimed;

- access to the genetic resources is necessary to implement the preferred embodiment of the invention or other example given in the description of the patent;

- the traditional knowledge is prior art, known to the applicant, which is relevant to the assessment of whether the invention as claimed is novel and not obvious;

- traditional knowledge was provided by a TK holder and is directly used in developing the invention, to the extent that the TK holder is a potential co-inventor.

The above four possibilities draw on existing patent law principles, so that well-established rules may be used to determine case by case whether a particular invention is subject to relevant disclosure requirements, potentially providing a degree of clarity and consistency in operation.

- the genetic resources were used in the course of research that led to the invention, and were essential to deriving the invention;

- the genetic resources were used in the course of research leading to the invention, but were only incidental to the attainment of the invention;

  These possibilities may require further clarification on how the linkage is to be determined in practice, and what kind of contribution from the GR or TK is to be considered sufficiently substantive, direct or immediate to trigger the obligation. One possibility of clarifying this link is to draw on existing patent principles: for instance, if access to a genetic resource is essential to carry out or reproduce the invention, this may be deemed to be a sufficiently important contribution to the attainment of the invention in the first place.

- the research leading to the invention, the attainment of the invention itself, or the act of filing the patent application, falls within the scope of an obligation incurred under an access agreement or access legislation.

  This may require clarification of how a patent authority or judicial authority is to interpret and apply contractual or other legal obligations arising under another jurisdiction.

(ii) The legal principle forming the basis of the requirement

The possible legal principles that would provide the basis of a relevant disclosure requirement can be categorized as those derived from existing patent law, and those based in other legal systems. In the first category, the possibilities include:

- The obligation to disclose the invention sufficiently for it to be carried out by a person skilled in the art, and where appropriate to disclose the best mode for carrying out the invention known to the inventor;
- The requirement that patent claims be supported sufficiently by the technical disclosure in the patent;
- The requirement to provide information concerning known prior art relevant to the assessment of the patent claims;
- The requirement to establish entitlement to apply for or be granted a patent;
- Requirements concerning the registration of licenses and security interests; and
- A requirement derived from the interaction between patent law and principles of *ordre public* and morality.

Among these possibilities within the general sweep of patent law, the distinction can be drawn between patent law concerning the patentability of the invention *per se*, and the entitlement of the applicant to apply for and be granted a patent. These are both areas of substantive law, which have been developed and applied distinctly. Substantive patent examination has generally focussed on the analysis of whether the invention itself is eligible

for a patent (its novelty, inventive step and utility or industrial applicability). Questions as to whether the applicant is entitled to apply have not, as a rule, been considered substantively in the course of patent examination, but addressed only when specific issues arise.

184. In the second category, non-patent law principles underpinning a disclosure obligation may be drawn from laws concerning access to GR/TK, and related benefit-sharing. These legal principles may be drawn from international standards, notably the CBD and the FAO ITPGR, or potentially from applicable national laws in the country of origin, the country of research/invention, or the country where the patent application is lodged. Contract law may provide the legal basis, whether it is considered as the legal basis in its own right, or when contracts or licenses are used as a legal mechanism for implementing access and benefit-sharing regulations. Where the disclosure obligation is founded entirely on a distinct separate legal basis, such as the application of foreign access regimes and contract provisions, then it may be necessary to clarify their operation and interpretation under the law of the patent granting country.

(iii) The nature of the obligation placed on the applicant

185. Various proposals for disclosure requirements have defined the obligation in different ways, ranging from an exhortation or encouragement to a potential ground of refusal or revocation of a patent. The nature of disclosure obligations has generally been construed in terms of whether they are formality or substantive requirements. Yet this does not mean that formality requirements are necessarily less important from the point of view of obtaining a patent. Failure to pay a necessary fee within the required time, and without taking timely remedial action, would normally lead to the absolute refusal of the application. One important distinction is that, once a patent has been granted, it can rarely be revoked or cancelled on grounds of formal non-compliance alone, unless the failure to comply was with fraudulent intent (this principle was codified in the PLT, Article 10(1)). The PLT and the PCT deal respectively with formal requirements, or the "form or contents."

186. A disclosure requirement may be defined in formal terms (for instance, the information about a deposit of biological material that may be required within a patent application), or in substantive terms (the requirement that a deposit of biological material be made when this is necessary to achieve the substantive purpose of disclosure of the invention as required to sustain the validity of the patent claims). Disclosure requirements concerning GR/TK have formal or procedural aspects (such as format and documentation requirements, and deadlines for compliance), as well as meeting substantive tests (for instance, in disclosing enough about genetic resources used in the invention to ensure a skilled person can replicate the invention). Therefore, rather than being classified as purely formal or purely substantive, a disclosure requirement may be analysed as having both aspects, and both may be significant. For instance, a requirement that an application, when first submitted, must include documentary evidence relating to access to genetic resources or TK is likely to conflict with general standards concerning the material that must be filed under the PLT or within the PCT system to be accorded a filing date. Other material may be required after the initial application is filed but before the application is accepted by the patent office. In other cases, failure to meet a requirement may only arise when the patent is challenged in court, or when the patent holder wishes to enforce patent rights. The simple fact that a patent office does not check such matters does not mean that the applicant has no incentive to ensure substantive requirements: for instance, a patent based on a false or inadequately documented assignment of the right to receive a patent may prove to be impossible to enforce in practice, and thus lack practical value.

187. The fundamental nature of a disclosure obligation may best be determined with reference to the consequences of failure to comply. But it may also be important to clarify what compliance entails: for instance, in terms of the extent to which the applicant must go beyond information that is readily available, and the diligence with which the applicant should trace the origins of GR/TK and investigate the circumstances of its acquisition. The intent of the applicant may also be a significant question: whether a failure to provide relevant information was nonetheless in good faith, or fraudulent in intent. And it may be important to clarify where the burden of proof lies: whether the applicant is obliged positively to prove that access to GR/TK met a certain standard, or whether legitimacy of access is assumed in absence of evidence to the contrary.

(iv) The consequences of failure to comply

188. Since disclosure requirements generally have both formal and substantive aspects, the consequences of failure to comply with either aspect may differ. Failure to comply in formal terms may not necessarily have serious consequences, provided it is not fraudulent and is remedied in a timely manner. Failure to comply in substantive terms (such as requirement to disclose sufficient material to sustain patent claims) may have major consequences for the fate of a patent application or granted patent.

189. The consequences of failure to comply with a particular disclosure obligation may, in principle, flow from the reason for the imposition of the requirement. A failure to disclose genetic resources necessary to carry out the invention may lead to the refusal, narrowing or invalidation of claims that would depend for their legitimacy on that disclosure. A failure to provide adequate information to substantiate entitlement to apply for or be granted a patent may lead to the loss of the patent right.

190. There is an uncertain area where disclosure requirements are not derived from substantive requirements relating to patentability of the invention or the entitlement of the applicant to receive a patent. Some disclosure requirements may be linked to distinct legal mechanisms, including in foreign jurisdictions, and may be aimed at monitoring or enforcement of regulations or specific contracts. One way of characterizing the relationship may be to draw a link between inequitable behavior in one context or jurisdiction, and entitlement to exercise patent rights in another, where the patented invention is in some way a consequence of the inequitable behavior. Another way of defining the link would be to view the denial or invalidation of a patent right in one jurisdiction as a form of sanction for non-compliance with other laws. Some uncertainty surrounds this kind of mechanism in international policy debate, and further study may be necessary of approaches to enforcing non-patent legal requirements through the patent system.

Possible disclosure scenarios

191. This section provides several possible disclosure scenarios that may be consistent with general patent law and with the international framework established by WIPO treaties. This deals with the three general aspects of GR/TK that are covered by the decision to undertake the present draft study[157] – disclosure of the GR/TK itself; disclosure of the origin; and disclosure of the legal circumstances surrounding its access. These scenarios are intended

[157] See document WIPO/GRTKF/IC/3/17, paragraph 79.

purely to promote discussion and further analysis, and not to propose any particular model or approach, nor to take the place of specific interpretation of any applicable treaty obligations.

192. *TK as relevant prior art*: An obligation to disclose any TK that is known to the applicant and that the applicant reasonably considers in good faith to be relevant to the determination of novelty or non-obviousness of the invention (or TK that is useful for the understanding, searching and examination of the invention), including any TK that is cited in search and examination at the international level or in other corresponding national applications. Documents reflecting this TK prior art should be cited where possible. Provision to amend the patent application to include additional information concerning TK prior art as it becomes known to the applicant. Failure to disclose such information with fraudulent intent may entail sanctions equivalent to entry of false declarations, incapacity to enforce the patent right, or potential invalidation of the patent.

193. *TK holder as inventor*: An obligation to disclose as an inventor or co-inventor any holder of TK who contributed TK which was in itself a substantive inventive contribution to the claimed or patented invention, to the extent that this contribution would be considered under the applicable patent law to amount to inventorship or co-inventorship. The consequences of failure to comply would be those that apply in general cases of failure to indicate all the true inventors (e.g. if the inventor is not designated, the application is treated as having been withdrawn – see Article 91 of the European Patent Convention)

194. *Disclosure of origin of genetic resources*: An obligation to disclose the origin of genetic resources when access to the genetic resources is reasonably required to carry out the invention as claimed, or to carry out the best mode or preferred embodiment as set out in the specification, and when the genetic resources concerned are not generally available and the source would not readily be known to the person skilled in the art. Consequences of failure to disclose this information would be the same as for failure in general to provide sufficient disclosure, with the prospect of claims being narrowed or invalidated. This could also be expressed as an obligation to disclose the origin of genetic resources that were used in the course of developing the invention, where access to these resources is also essential to carrying out the invention or reproducing an example or best mode described in the patent application, and the resources are not generally available; in other words, the test of whether the resources are sufficiently closely linked to the invention as such would be determined by whether a skilled person seeking to implement the invention would also need access to the same genetic resources.

195. *Disclosure of the actual genetic resources*: In contrast to an obligation to disclose origins, this would be an obligation to disclose actual genetic resources that are necessary for the person skilled in the art to carry out the invention as claimed, or to carry out the best mode or preferred embodiment asset out in the specification, and the genetic resources concerned are not generally available to the person skilled in the art. Consequences of failure to disclose this information would be the same as for failure in general to provide sufficient disclosure, with the prospect of claims being narrowed or invalidated. The deposit of microorganisms and other biological material (such as under the Budapest Treaty) is an example of disclosing the genetic resource as such (as opposed to disclosure of its origin).

196. *Evidence of entitlement to apply:* An applicant may be required to furnish documents or evidence when the patent office reasonably doubts the veracity of statements or indications that the applicant is entitled to apply for or be granted the patent, for instance where it appears likely that the development of the invention could be covered by a contractual or other

obligation relating to access to genetic resources *in situ* or from an *ex situ* collection. A declaration relating to entitlement to apply may have the effect of confirming that the application is in conformity with any access and benefit sharing agreement that affects the applicant's entitlement to apply for or be granted a patent on the subject invention. If the applicant is aware that the circumstances of access to certain materials affect this entitlement, then it could jeopardize their ownership of the patent and the viability of investment based on the patent: should there be an attempt to enforce the patent, the circumstances surrounding the entitlement to apply for and to own the patent. In any event, at the time the patent application is being processed, the consequences of failure to conform with a patent office request to furnish evidence on request would be the same as for any failure to demonstrate entitlement to apply.

197. *Disclosure of information in compliance with other legal obligations:* An applicant may be required to disclose certain information (including information concerning the conditions of access to GR/TK) on the basis of obligations entered into under contracts or other forms of access regulation in the country of origin of GR/TK – especially where such contracts are used to implement access regulations. Several examples of this nature have been cited above. This information may be disclosed within the description as such, in the identification of the owner, as the basis of a claim to entitlement to apply or be granted an application, or in the recordal of ownership, license or security interests.

198. *Specific GR/TK disclosure mechanisms:* Under this scenario, a distinct obligation is established to mandate disclosure of certain information relating specifically to the nature and origin of GR/TK used in the invention. This may be extended to include information about the circumstances of the access to the GR/TK, and positive evidence that relevant prior informed consent was obtained at the point of access. The requirement would be distinct and independent from other patent disclosure requirements such as those set out above. Analyzing and interpreting such methods of requiring disclosure leads to some of the legal and procedural issues that have been explored in detail in the foregoing discussion. The relationship of a disclosure method to existing patent law and procedures will depend on the approach taken to these issues. Factors that may be considered include the following:

(a) One starting point is what would trigger the requirement to disclose, and how the necessary link between the GR/TK and the patent application is defined in practice: is this based on a defined relationship between the invention as claimed and certain specific resources or knowledge, or is it based on defined aspects of the research activities that led to the invention?

(b) What is the legal basis of the disclosure requirement: is it based on an expanded conception of the patentability of the invention as such, is it based on the entitlement of the applicant to apply for or to be granted the patent, or is it based on non-patent legal obligations, distinct from patent law as such, but which the patent system is used as to monitor or enforce?

(c) Is disclosure of information required as an end in itself (i.e. a transparency or disclosure mechanism), or is the disclosure mechanism linked to a requirement for substantive compliance with specified standards (e.g. compliance with access regime in the country of origin as the basis of entitlement to apply)? Similarly, is it strictly a formality requirement (in the sense that any disclosure that apparently meets the requirement will be sufficient); or is it a substantive requirement, in that what is disclosed may influence decisions on the acceptance, validity or enforceability of the patent, and if so, does this relate to the

patentability of the invention as such, or the entitlement of the applicant or patent owner to hold or enforce the patent?

(d) What are the implications of failure to comply from a formal and from a substantive point of view?

199. There has been extensive international debate about patent disclosure requirements in relation to GR/TK. The above disclosure scenarios illustrate that the provision of technical and legal information, often to exacting standards, is central to the operation of the patent system. Disclosure is at the core of the policy rationale and the practical operation of the patent system. General international standards and more detailed national jurisprudence provide for disclosure in ways that are relevant to GR/TK used in patented inventions. Where additional disclosure requirements have been developed or proposed that are specifically focussed on GR/TK, the legal analysis of these requirements will in part be shaped by how they interact first with the patent system as such, and second with the broader legal environment.

IX. CONCLUSION

200. The present draft technical study is intended to respond to the invitation to report on "methods consistent with obligations in treaties administered by [WIPO] for requiring the disclosure within patent applications of, *inter alia*:

(a) Genetic resources utilized in the development of the claimed inventions;

(b) The country of origin of genetic resources utilized in the claimed inventions;

(c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;

(d) The source of associated traditional knowledge, innovations and practices; and,

(e) Evidence of prior informed consent."

201. The discussion in this draft technical study has highlighted that there is a range of methods that are consistent with the essential elements of patent law and key aspects of WIPO treaties. The draft study draws both on the specific information provided by WIPO Member States about disclosure requirements in national and regional patent laws, and general background information about the operation and the fundamental principles of patent law. It is not intended to be exhaustive nor comprehensive, but seeks to set the development and application of disclosure requirements in a practical and operational context, building on established mechanisms and principles that have direct bearing on the disclosure of information concerning genetic resources or traditional knowledge relevant to the invention claimed in a patent document.

202. Three broad functions have been considered for disclosure methods relating to GR/TK:

- to disclose any GR/TK actually used in the course of developing the invention (a descriptive or transparency function, pertaining to the GR/TK itself and its relationship with the invention);

- to disclose the actual source of the GR/TK (a disclosure of origin function, relating to where the GR/TK was obtained) – this may concern the country of origin (to clarify under which jurisdiction the source material was obtained), or a more specific location (for instance, to ensure that genetic resources can be accessed, so as to ensure the invention can be duplicated or reproduced); and,
- to provide an undertaking or evidence of prior informed consent (a compliance function, relating to the legitimacy of the acts of access to GR/TK source material) – this may entail showing that GR/TK used in the invention was obtained and used in compliance with applicable laws in the country of origin or in compliance with the terms of any specific agreement recording prior informed consent; or showing that the act of applying for a patent was in itself undertaken in accordance with prior informed consent.

The patent system and disclosure

203. The essence of the patent system is transparency and disclosure (the concept of laying open for public inspection is the source of the English word 'patent'). Patent law has developed a set of exacting standards for information disclosure which have deep policy and legal foundations within the patent system. The grant of a patent, and the effective exercise of patent rights, are founded on the principle of sufficient disclosure. The very operation of the patent system involves making publicly available a great detail of legal, administrative and technological information, in a harmonized and accessible format. Several treaties administered by WIPO provide a framework for applying and implementing a range of disclosure mechanisms, and in particular, through the PCT system, provide an actual disclosure system for international patent applications. Patent applications do, as a matter of existing practice, disclose significant information concerning genetic resources and traditional knowledge. The disclosures in patent applications have already been used as a resource for those monitoring the use of genetic resources and traditional knowledge in inventions, including where the traditional knowledge background and the nature of genetic resources used in the invention.[158] This monitoring function of the international patent system has been enhanced by the increasing searchability and availability on-line of patent information. Further enhancements are likely in the future, including the proposed increased coverage of traditional knowledge subject matter in the principal tool for indexing patent subject matter for search purposes, the International Patent Classification (IPC).[159]

204. This draft study highlights the manner in which disclosure systems function and how they may serve to enhance disclosure relevant to genetic resources and traditional knowledge. The draft study accordingly aims to contribute to international discussion and analysis in this area drawing on the international treaty system. It does not pass judgement on the consistency of specific provisions in national laws with international treaties. Rather, it focuses on the ways patent law systems can support and give effect to policy interests connected with the interaction between genetic resources and traditional knowledge and claimed inventions. It has therefore considered a range of disclosure mechanisms relevant to genetic resources and traditional knowledge. Such mechanisms may be positively consistent with WIPO treaties, in that they are positive obligations (for instance, Article 4 *ter* of the Paris Convention provides that the "inventor shall have the right to be mentioned as such in the

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158 For recent examples see documents WIPO/GRTKF/IC/5/6 and WIPO/GRTKF/IC/5/13.

159 See document IPC/CE/32/8 ("Development of Classification Tools for Traditional Knowledge").

patent," PCT Article 5 requires that the description in an international patent application "shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art"), or they may be implicitly consistent, in the sense that they do not conflict with treaty requirements. Where there is a stand-alone or distinct disclosure requirement, its legal and practical relationship with the patent approval and grant process may need to be clarified: the possible structures range from a separate reporting obligation placed on the applicant in relation to distinct regulatory (subject to distinct sanctions), comparable to reporting requirements relating to foreign investment or public contracts, to a new element of the substantive assessment as to patentability of the invention that is undertaken by the patent or judicial authorities.

Some key issues

205. A key issue is the relationship between the genetic resource and traditional knowledge on the one hand, and the claimed invention on the other. This includes clarification of the range and duration of obligations that may attach to such resources and knowledge, within the source country and in foreign jurisdictions, and how far these obligations 'reach through' subsequent inventive activities and ensuing patent applications. Clarity in this area is required so that patent or judicial authorities and the patent applicant or owner know when the obligation takes effect, and when on the other hand the relationship between background genetic resources or traditional knowledge is sufficiently remote or non-essential not to trigger the obligation. This is particularly so if the obligation is mandatory, bears a burden of proof or due diligence responsibility, or may lead to invalidation of patent rights. In the discussion of possible disclosure requirements, a diverse range of ways of expressing a linkage between genetic resources and traditional knowledge is canvassed. General patent law principles provide certain more specific ways of expressing this relationship, even if the objective of the requirement is not conceived in traditional patent terms. Patent law may also be drawn on to clarify or implement more generally stated disclosure requirements: for example, a general requirement to disclose genetic resources used in the invention may be difficult to define in practice, and may implemented through a more precise test that requires disclosure only when access to the resources would be necessary to reproduce the invention. The degree of clarity and predictability of impact of any disclosure requirement, and thus its practical impact, is likely to depend on whether the requirement can be analysed or expressed in terms of patent law.

206. Another key issue is the legal basis of the disclosure requirement in question, and its relationship with the processing of patent applications, the grant of patents and the exercise of patent rights. This raises also the legal and practical interaction of the disclosure requirement with other areas of law beyond the patent system, including the law of other jurisdictions. Some of the legal and policy questions that arise are:

- the potential role of the patent system in one country in monitoring and giving effect to contracts, licenses, and regulations in other areas of law and in other jurisdictions, and the resolution of private international law or 'choice of law' issues that arise in interpreting and applying across jurisdictions contract obligations and laws determining legitimacy of access and downstream use of GR/TK;

- the nature of the disclosure obligation, in particular whether it is essentially a transparency mechanism to assist with the monitoring of compliance with non-patent laws and regulations, or whether it incorporates compliance

- the ways in which patent law and procedure can take account of the circumstances and context of inventive activity that are unrelated to the assessment of the invention itself and the eligibility of the applicant to be granted a patent;

- the situations in which national authorities can impose additional administrative, procedural or substantive legal requirements on patent applicants, within existing international legal standards applying to patent procedures, and the role of non-IP international law and legal principles in this regard;

- the legal and operational distinction (to the extent one can be drawn) between patent formalities or procedural requirements, and substantive criteria for patentability, and ways of characterizing the legal implications of such distinctions;

- clarification of the implications of issues such as the concept of 'country of origin' in relation to genetic resources covered by multilateral access and benefit-sharing systems, differing approaches to setting and enforcing conditions for access and benefit sharing in the context of patent disclosure requirements, and coherence between mechanisms for recording or certifying conditions of access and the patent system.

207. A further question to be clarified is what actions of the inventor or patent applicant are intended to be monitored or regulated through the disclosure requirement – the actual use of the GR/TK, or the act of filing a patent application. Does the policy concern relate to the legitimacy (including prior informed consent given) of the research or commercial behavior that makes use of the GR/TK, in which case the patent application has a secondary role in providing evidence of such behavior, or does it concern the act in itself of filing a patent application or holding a patent (for instance, where prior informed consent is given to research but not to seeking IP, or prior informed consent includes agreement on assignment, co-ownership or similar disposition of ensuing IP)? In the former case, the patent system is unlikely to provide a comprehensive monitoring and compliance tool for all relevant use of GR/TK, and additional requirements may increase the relative appeal of other non-patent strategies (including reliance on non-disclosure mechanisms such as trade secret protection). In the latter case, where access conditions and regulations, including prior informed consent, govern the very act of applying for a patent, the issue may be interpreted in terms of entitlement to apply, and the recordal of ownership, license or security interests, are not as a rule the subject of substantive examination of patent applications, but are dealt with in distinct processes.

208. The foregoing discussion is intended to highlight and clarify the legal and policy issues that arise from disclosure requirements with bearing on GR/TK, and to set them in the context of WIPO treaties relating to the international patent system. Some of the core issues raised are the subject of ongoing international policy debate. These may involve specific policy choices, such as the distinction between formal requirements or 'form or contents' and substantive patent law and how to certify the basis of prior informed consent or legitimacy of access to GR/TK. The above discussion may contribute background considerations and material for the ongoing policy debate. The current international discussion of disclosure issues relating to genetic resources and traditional knowledge is dynamic and relatively complex. A number of the key legal concepts and approaches raised in this debate are untested, the subject of policy development, or in the initial stages of implementation, and thus cannot be definitively analyzed. The information provided in this study is therefore intended as a resource to facilitate the continuing debate rather than to prescribe any particular

approach. The Secretariat of WIPO is available to provide further information and analyze further legal and policy issues that may arise in international discussion, including in the context of the CBD COP deliberations that led to the invitation to undertake this study.

[Annex II follows]

ANNEX II

QUESTIONNAIRE ON VARIOUS REQUIREMENTS FOR DISCLOSURE RELATING TO GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN PATENT APPLICATIONS

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

JULY 2002

QUESTIONNAIRE [1]

Contact Details

Name:	Address:
Title:	Email:
Office/Organization:	Telephone:
Member State:	Facsimile:

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[1] Responses to this questionnaire may be sent, preferably by email, to the Global Intellectual Property Issues Division at grtkf@wipo.int or at WIPO, 34, chemin des Colombettes, 1211, Geneva 20 (Switzerland), Fax 41 22 338 8120. It would be appreciated if all responses could be received by the Secretariat of WIPO before Monday, September 30, 2002.

[*Subsequent note for document WIPO/GRTKF/IC/5/10:* at the fourth meeting of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, it was agreed that further responses be submitted by March 14, 2003 (see document WIPO/GRTKF/IC/4/15, paragraphs 174 and 175(x)). Up to April 30, 2003, responses had been received from Argentina, Australia, Burundi, Canada, China, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Kenya, Malawi, Mexico, New Zealand, Niger, Philippines, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Spain, Sweden, Switzerland, Uruguay, United States of America, Viet Nam, the European Commission and the European Patent Office.]

Question 1: Please identify any national and/or regional laws and/or regulations which regulate access to genetic resources and/or traditional knowledge (TK) in your national territory. Concerning these laws or regulations, please indicate:

(a) What genetic resources or TK the law and/or regulation applies to;
(b) What requirements are stipulated for obtaining prior informed consent or determining the conditions of access, such as benefit-sharing arrangements;
(c) Whether a distinction has been made between access for non-profit research and access for commercial purposes;
(d) Any requirements for disclosure, reporting or otherwise monitoring of access to genetic resources and associated TK; and
(e) How these laws or regulations have been implemented in your national territory.

Question 2: Please itemize the information that a patent applicant is required to provide in the course of gaining a patent with effect in your country, and indicate the requirements for disclosure of the invention in a patent application. Please indicate the consequence of failure to meet such requirements.

Question 3: Is there a *specific* requirement, in any law and/or regulation that already applies to your country, or in any pending legislation, for a patent applicant to disclose:

(a) Information about any genetic resources used in the development of the claimed invention;
(b) The geographical origin (including country of origin) of genetic resources used in the claimed invention;
(c) An indication or evidence of prior informed consent given by those granting access to genetic resources used in the development of the claimed invention;
(d) The nature or source of associated TK used in isolating or distinguishing the genetic resources used in the claimed invention;
(e) The nature or source of associated TK used in the development of the claimed invention; and
(f) An indication or evidence of prior informed consent given by holders of TK that was used in the development of the claimed invention?

If your answer to all of questions 3(a) to (f) is 'no,' there is no need to answer questions 4 to 10; please go on to answer questions 11 to 14.

Question 4: Do the disclosure or information requirements covered by your answers to question 3 apply only to patent applications for inventions in a particular field or category of technology, or do they apply to patent applications for any inventions, regardless of the nature of the technology involved? Do the requirements apply equally to patent applications by domestic and foreign nationals?

Question 5: Are there particular guidelines defining the relationship that must exist between the genetic resources or TK and the claimed invention in order to trigger the obligation for disclosure; for example, in the case that access to the genetic resources is necessary for

carrying out the invention, or the TK was integral to the invention or was known prior art relevant to the invention?

Question 6: If there is a requirement to disclose the geographical origin of genetic resources, as specified in question 3(b), does it apply only if the genetic resources have been obtained within the legal jurisdiction or territory of your country?

Question 7: If there is a requirement to give evidence of prior informed consent, as specified in questions 3(c) and 3(f), does it apply only if the granters of access to genetic resources or holders of TK are nationals of your country?

Question 8: If there is a requirement to give evidence of prior informed consent, as specified in questions 3(c) and (f), does it specify the required form of such evidence?

Question 9: What are the consequences for the patent applicant or patent holder of any failure to meet any of the requirements covered in your answers to question 3? What means are available for the applicant or patent holder to remedy any failure to meet the requirement(s)? If the initial patent application, as lodged by an applicant, fails to meet these requirements, until what time can this information be subsequently provided?

Question 10: Is all information provided in accordance with these requirements published or available for public inspection, or are there mechanisms for preserving confidentiality of such material; for example, in relation to a confidential contract by which prior informed consent is given?

Question 11: Are there any analogous requirements (similar to questions 3(a)-(f)) in the law that applies in your country for other registered industrial property rights, such as utility models, petty patents, trade marks, or industrial designs?

Question 12: This question concerns the conventional patent disclosure requirements that apply in your country, such as a requirement for the invention to be disclosed in a manner sufficiently clear and complete to enable a person skilled in the art to carry it out, or a requirement to disclose the best mode known to the inventor of carrying out the invention.

(a) Are there circumstances in which these requirements have actually obliged, or may potentially oblige, a patent applicant to disclose any of the categories of information set out in questions 3(a) to (f)?
(b) Do you have information about any particular cases in which patent applicants have disclosed any of the categories of information set out in questions 3(a) to (f) in the normal course of meeting conventional patent disclosure requirements?

Question 13: What provisions apply in the event that information provided in a patent application in your country is false or misleading?

Question 14: If possible, please provide excerpts from or summary details of any legislative provisions, or judicial or administrative findings, that relate to your answers to any of the above questions. (Brief excerpts or quotations would be preferred over full texts of laws or regulations).

[End of Annex II and of document]