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INITIAL REPORT ON THE TECHNICAL STUDY ON DISCLOSURE REQUIREMENTS RELATED TO GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

Prepared by the Secretariat

I. OVERVIEW

1. This Initial Report is prepared pursuant to a decision taken at the third session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee'). It contains draft materials for a technical study on patent disclosure requirements relating to genetic resources and traditional knowledge (TK). The decision to prepare a draft study responds to an invitation made by the Conference of Parties (COP) of the Convention on Biological Diversity (CBD). It also flows from the general work program of the Committee which has included a range of intellectual property (IP) questions related to access to genetic resources and benefit sharing. Similar issues were considered, prior to the establishment of the Committee, by the Expert Group on Biotechnology and the WIPO Meeting on Intellectual Property and Genetic Resources.

2. As background to the technical study, this report gives an overview of salient aspects of the patent system and of legal mechanisms concerning access to genetic resources and associated TK, and summarizes the previous consideration given to this issue in WIPO forums. It reviews the responses to a questionnaire circulated to WIPO Member States, in order to set the issue in the context of legal requirements for disclosure in national patent laws. Issues that may need further consideration are identified at the conclusion of this report.

II. INTRODUCTION

3. 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.[1]

4. 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)[2] 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').[3]

5. 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

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1 See discussion in WIPO/GRTKF/IC/1/3

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

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

Secretariat of the CBD.[4] 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;
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> (b) The country of origin of genetic resources utilized in the claimed inventions;
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> (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."

6. 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.

"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.

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[4] 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").

"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."[5]

7. 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.

8. Following these consultations, the questionnaire was revised and circulated under cover of document WIPO/GRTFK/IC/Q.3, and is provided as an Annex to this document ('the Questionnaire'). Twenty-four responses to the Questionnaire have been received[6] up to November 15, 2002 and have been taken into account in the present draft. Any further responses will be taken into account in any future version of this document. As indicated in the Committee's decision (WIPO/GRTKF/IC/3/17 paragraph 81), the amended work program requested by Members had implications for the preparation of the present initial draft, which 'may not be complete, may not be translated into all working languages of the Committee and may be disseminated only a short time in advance of the fourth session.' The Committee also noted that the main discussion about this technical study would take place at its fifth session. It is suggested that comments on the current initial draft and any further responses to the Questionnaire could be passed to the Secretariat before March 14, 2003, so that a further version could be prepared and circulated in April, 2003. The Committee may wish to encourage the submission of further responses to ensure that a wide range of national perspectives is encompassed by the study.

III. BACKGROUND

9. 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. At the same time, there have been significant international developments in the legal framework that applies to

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

6 Up to November 15, 2002, responses were received from Argentina, Australia, Burundi, Canada, Czech Republic, France, Germany, Hungary, Italy, Malawi, Mexico, Niger, Portugal, Republic of Moldova, Romania, Russian Federation, Spain, Sweden, Switzerland, Uruguay, United States of America, Viet Nam, the European Commission and the European Patent Office.

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

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 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.

10. 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 used to generate benefits from the use of genetic resources, and 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

11. 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]

12. 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,

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[8] CBD, Article 1
[9] CBD, Article 3
[10] CBD, Article 15

organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.'[11]

13. 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 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.

14. The CDB 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.

15. 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

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11 CBD, Article 2

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.

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 '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]

National regulation of access to genetic resources

16. A full or authoritative discussion of national regulation of the principles and substantive provisions of the CBD is beyond the scope of this paper – the policy forums of the CBD itself have explored these issues in detail.[18] 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.

17. As part of the consideration of the implementation of the CBD, the most recent CBD COP adopted recommendations[19] 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 do give 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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> "27. In accordance with national legislation, prior informed consent may be required from different levels of Government. Requirements for obtaining prior informed

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

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

consent (national/provincial/local) in the provider country should therefore be specified."[20]

18. 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."

"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."[21]

19. 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;[22]
- Specific legislation on genetic resources as such, which may also concern associated TK;[23]
- Statutory and customary law regarding real estate and movables, and general property law;[24]
- Property and contract law, regulations concerning Federal National Parks, and state trade secret law applying to TK;[25]
- Use of contracts on access to genetic resources;[26]
- Deposits of biological material for patent purposes;[27]
- Specific rules on genetic resources of animal origin and of plant origin (selection achievements); [28] 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.[29]

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20 WIPO/GRTKF/IC/2/11, Annex, page 20
21 WIPO/GRTKF/IC/2/11, Annex, page 21
22 Canadian response
23 Response of Portugal
24 Response of Switzerland
25 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.
26 Response of Mexico
27 Response of the Republic of Moldova
28 Response of the Russian Federation
29 Response of Australia

20. 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.[30]

21. 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.' In view of the limited information currently at hand, more detailed analysis of the range of mechanisms notified will be provided in further drafts of this paper

Intellectual property and access to genetic resources and TK

22. 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.[31] 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 equitable sharing of benefits; much of the Committee's own work on TK is relevant in this regard.[32]

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30 Response of Australia

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

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

23. 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';[33] and that non-monetary benefits could include 'joint ownership of patents and other relevant forms of intellectual property rights.'[34]

24. 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);[35] the CBD;[36] the United Nations Conference on Trade and Development (UNCTAD);[37] and WIPO.[38] 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.'

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.[39] 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.'[40]

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33 Bonn Guidelines, Appendix I

34 Bonn Guidelines, Appendix II

35 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.

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

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

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

39 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.

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

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."[41]

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.[42] 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 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

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41 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.

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

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,[43] the Patent Cooperation Treaty (PCT),[44] and the Patent Law Treaty (PLT).[45] 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.[46] 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.

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[47] 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 only required to furnish information in three 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.[48] For inventions involving a new

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

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

45 Patent Law Treaty, adopted at Geneva on June 1, 2000

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

47 See PCT, Article 11(3)

48 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

[Footnote continued on next page]

microorganism, the disclosure obligation may also entail deposit of the microorganism itself;[49]

(b) 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;[50] and

(c) 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.

33. The obligation on an applicant to provide information can 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,[51] 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.

[Footnote continued from previous page]

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."

49 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.

50 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."

51 PCT Article 33(1) and TRIPS Article 27(1)

35. For instance, in relation to descriptions, the PLT (Article 5(i)(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, but 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 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.

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.'[52] 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 Two 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:

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[52] TRIPS Article 62.1

- 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;
- Indication of the scope of technology or field of the invention, or International Patent Classification data;
- Shares of ownership/entitlement to the patent right;[53]
- 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.[54] 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 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.[55]

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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53 See the response of Hungary

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

55 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."[56] There is reference in TRIPS to the option of requiring 'information concerning the applicant's corresponding foreign applications and grants.'[57]

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. Generally, there are obligations on the applicant to provide information on the prior art known by the applicant, 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…."[58]

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[59] and failure to translate material portions of documents in foreign languages.[60] 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.'[61] 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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56 Rule 5.1(a)(ii)

57 TRIPS, Article 29.2

58 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]

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

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

61 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.[62] 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 is not 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.'

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[62] For instance, the response from Sweden advised that it was broadening its requirement.

49. Several responses also noted that there were specific requirements for listings of nucleotide and amino acid sequences relevant to the invention[63] (including in computer readable form[64]).

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,'[65] 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.[66] 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 'The 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 part (or all) of the inventive step, and that person is not identified as an inventor, this could have substantial legal implications. If the knowledge has been disclosed to the public, then it could invalidate the claimed invention owing to lack of novelty; 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.[67]

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 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

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63 Response from the Russian Federation

64 Response from Canada

65 Article 4*ter*; cf PCT Article 4(1)(v)

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

67 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.'

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[68] 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.'[69] 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.' On the other hand, 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.

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.[70]

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."

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68 *Staeng's Patent* [1996] RPC 183

69 L. Bently & B. Sherman, 'Intellectual Property Law,' Oxford, 2001, p. 476.

70 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.'

> '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,[71] 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 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

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

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 German response 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 Vietnam 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 Australian response 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.'[72]

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.
>
> "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."

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.

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

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 description 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;[73]

- provision for revocation of the patent if the inventor named is not the true inventor;[74]

- more general sanctions, such as the application of criminal law for instance relating to forgery of documents,[75] and legal provisions on falsification of public documents;[76]

- 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;[77]

- 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;[78] 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,[79] provision of false or misleading information as grounds for opposition to grant or for revocation,[80] payment of damages in addition to invalidity or loss of right,[81] 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.'[82]

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 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

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

> 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.'

V. CONCLUDING COMMENTS

74. This initial report aims to set the object of the required study in context, and to provide a preliminary survey of the material made available to the Committee, and the responses to the Questionnaire in particular. To facilitate further discussion rather than to draw any specific conclusion, this section provides some concluding comments are provided, and issues mentioned for possible further consideration.

75. 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."[83]

76. 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 has emerged 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 (including through depositary authorities), 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.

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[83] WIPO/GRTKF/IC/1/13

(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.

77. 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).[84]

78. 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. The specific disclosure mechanisms (directly concerning genetic resources and TK) so far considered in this study 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.

79. While there has been no discussion in the current report of the kind of provisions that 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), further responses to the Questionnaire may raise this question. 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.

80. Some of the issues that may be further considered therefore include:

- the status of disclosure requirements for undocumented TK known to the applicant;

- the possible ways of characterizing in legal terms the relationship between a claimed invention and a genetic resource or element of TK that may have been used in the research and development leading to the invention;

- the distinction between international instruments and the national legal frameworks which give effect to them;

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

- 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;

- the degree to 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;

- the range and duration of obligations that may attach to such resources and knowledge, within the source country and in foreign jurisdictions;

- 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;

- the concept of 'country of origin' in relation to genetic resources covered by multilateral access and benefit-sharing systems, and implications for patent disclosure requirements; and

- implications of or the need to clarify the contrast between bilateral and multilateral frameworks for access and benefit sharing in the context of patent disclosure requirements.

81. The Intergovernmental Committee is invited to review the foregoing discussion, to comment on this initial report and to provide additional responses to the Questionnaire by March 14, 2003, with a view to shaping a further version of the report for distribution and further consideration in April 2003.

[Annex follows]

ANNEX

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 [85]

Contact Details

Name:

Title:

Office/Organization:

Member State:

Address:

Email:

Telephone:

Facsimile:

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[85] 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.

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 and of document