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THE ROLE OF INTELLECTUAL PROPERTY RIGHTS IN ACCESS AND BENEFIT-SHARING ARRANGEMENTS, INCLUDING NATIONAL AND REGIONAL EXPERIENCES

I. INTRODUCTION

1. At its sixth meeting, in decision VI/24 C, the Conference of the Parties addressed the issue of intellectual property rights as it relates to access to genetic resources and benefit-sharing. The Conference of the Parties identified specific measures to be undertaken by Parties on this issue.

2. In paragraph 1 of the decision, the Conference of the Parties invited "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".

3. In paragraph 2 of the same decision, the Conference of the Parties also "invited Parties and Governments to encourage the disclosure of the country 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".

4. The Conference of the Parties also recognized that further work was needed on issues related to the disclosure of origin of genetic resources and relevant traditional knowledge in applications for intellectual property rights. In paragraph 3 of the decision, it requested the Executive Secretary, with the help of other international and intergovernmental organizations such as the World Intellectual Property Organization and through the Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention, where appropriate, to undertake further information gathering and analysis with regard to issues listed under subparagraphs (a) to (g) of paragraph 3, namely:

(a) Impact of intellectual property regimes on access to and use of genetic resources and scientific research;

* UNEP/CBD/WG-ABS/2/1.

/...

(b) Role of customary laws and practices in relation to the protection of genetic resources and traditional knowledge, innovations and practices, and their relationship with intellectual property rights;

(c) Consistency and applicability of requirements for disclosure of country of origin and prior informed consent in the context of international legal obligations;

(d) Efficacy of country of origin and prior informed consent disclosures in assisting the examination of intellectual property rights applications and the re-examination of intellectual property rights granted;

(e) Efficacy of country of origin and prior informed consent disclosures in monitoring compliance with access provisions;

(f) Feasibility of an internationally recognized certificate of origin system as evidence of prior informed consent and mutually agreed terms; and

(g) Role of oral evidence of prior art in the examination, granting and maintenance of intellectual property rights.

5. In addition, in paragraph 4 of decision VI/24 C, the Conference of the Parties invited the World Intellectual Property Organization (WIPO) to prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, *inter alia*:

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

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

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

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

(e) Evidence of prior informed consent.

6. Pursuant to this invitation, WIPO prepared a technical study addressing the issues mentioned above. A questionnaire (WIPO/GRTKF/IC/Q.3) was circulated by WIPO to its member States regarding the issues identified in the invitation of the Conference of the Parties. Based on responses to the questionnaire, an interim report was prepared for consideration by the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore at its fourth session (EIPO/GRTKF/IC/4/11). A draft technical study on disclosure requirements related to genetic resources and traditional knowledge was then prepared for the consideration of the Intergovernmental Committee at its fifth session (WIPO/GRTKF/IC/5/10, annex 1). The Committee commented on the draft study and transmitted it to the WIPO General Assembly in September 2003. The WIPO General Assembly approved the transmission of the study as a technical reference document to the seventh meeting of the Conference of the Parties and for consideration by subsidiary bodies under the Convention on Biological Diversity, as required. This decision was subject to the following understanding:

> "The attached draft technical study has been prepared to contribute to international discussion and analysis of this general issue, and to help clarify some of the legal and policy matters it raises. It has not been prepared to advocate any particular approach nor to expound a definitive

interpretation of any treaty. It is to be regarded as technical input to facilitate policy discussion and analysis in the CBD and in other fora, and it should not be considered a formal paper expressing a policy position on the part of WIPO, its Secretariat or its Member States."

7. The study is available as an information document for the second meeting of the Working Group on Access and Benefit-sharing (UNEP/CBD/WG-ABS/2/INF/4) and will be transmitted to the seventh meeting of the Conference of the Parties.

8. Paragraph 7 of the above-mentioned decision VI/24 C of the Conference of the Parties also requested "the Executive Secretary to gather information and prepare a report on national and regional experiences".

9. In order to address paragraphs 3 (c)-(f) of decision VI/24 C, which relate directly to the issue of disclosure of genetic resources and traditional knowledge in applications for intellectual property rights, the Executive Secretary has made available, as information document (UNEP/CBD/WG-ABS/2/INF/2), a report prepared by an independent consultant entitled "Disclosure of origin and prior informed consent for applications of intellectual property rights based on genetic resources: a technical study of implementation issues".

10. Other issues raised in paragraph 3 of decision VI/24 C, namely: subparagraph (a) on the impact of intellectual property regimes on access to and use of genetic resources and scientific research; and subparagraph (g) on the role of oral evidence of prior art in the examination, granting and maintenance of intellectual property rights are examined under section II of this paper.

11. Based on the consultant's study and the WIPO technical study, section III of the present note highlights important issues to be taken into account when addressing the topic of disclosure of the country of origin of genetic resources and relevant traditional knowledge in applications for intellectual property rights.

12. Finally, in response to the request of the Conference of the Parties in paragraph 7 of decision VI/24 C, section IV includes an overview of requirements for disclosure included in national and regional legal frameworks.

13. It should, however, be emphasized that decision VI/24 C addresses a number of issues that are broad in scope and complex. The present note touches upon a number of these issues and highlights some salient features of the ongoing discussions on these matters. However, it does not purport to provide a comprehensive analysis of these highly technical issues.

II. SOME ISSUES RAISED IN PARAGRAPH 3 OF DECISION VI/24 C

A. The impact of intellectual property regimes on access to and use of genetic resources and scientific research

14. The impact of intellectual property regimes on access to and use of genetic resources and scientific research is an issue of much debate. The following highlights certain concerns raised with respect to patenting in the biotechnological sector and its potential impacts on scientific research.

15. The OECD reports that from 1990 to 2000, the number of patents granted in biotechnology rose 15% a year at the Unites States Patent and Trademark Office (USPTO) and 10.5% at the European Patent

Office (EPO), against a 5% a year increase in overall patents. A subset of these biotechnology patents covers "genetic inventions". 1/

16. In many OECD countries, patent protection for biotechnological inventions has been available and expanding for close to 20 years. 2/ The encouragement of patenting in State-funded research institutions or universities in the developed world contributed to this new situation. 3/ In addition, research and development expenditure in United States academic institutions increased by 150% in real terms between 1980 and 2000. 4/

17. Although there is little evidence on how patenting by universities affects research priorities, certain concerns have been raised. For example, in its report, the United Kingdom Commission on Intellectual Property Rights on Integrating Intellectual Property Rights and Development Policy 5/ considered "that there is considerable potential for tensions to arise between the need to secure intellectual property protection for the products of research institutions and the achievement of their wider social objectives, particularly those relating to the needs of poor producers". According to the report, "there is a danger that research priorities will adjust to focus on the largest potential markets which, in this case, will be the commercial agricultural sector, to the possible detriment of poorer farmers". 6/ It may also be argued however, that the distortion of research priorities may be due to sectoral policy settings, which drive research directions, rather than a consequence of patenting as such.

18. Another issue of concern that has been raised by some experts is the potential for recent trends in patenting to impede effective development of science. While intellectual property rights are to encourage innovation by providing adequate return on investments and encourage research by making inventions publicly available, there is concern that certain recent trends in patenting may impede the effective development of science by restricting the flow and exchange of information.

19. An example is the patenting of research tools and the so-called "tragedy of the anti-commons". The "tragedy of the anti-commons" refers to:

> "[A] situation where there are numerous property right claims over the building blocks necessary for research and development. If property rights are diffusely held by multiple owners, the negotiations necessary to bring these building blocks together can fail, thus stifling follow-on innovations. The proliferation of patents on biomedical research tools or on genetic inventions could, in theory, lead to a tragedy of the anti-commons, making it difficult for researchers to pool licences on all the technologies needed for R&D". 7/

1/ OECD, "Genetic Inventions, Intellectual Property Rights and Licensing Practices – Evidence and Policies", 2002.

2/ An important judicial development that certainly contributed to the increasing number of patents in this area is the 1980 United States Supreme Court Diamond v. Chakrabarty decision, following which inventions involving biological material and some life forms were deemed patentable in the United States.

3 The Bayh-Dole Act in the US permitted universities to patent inventions based on federally funded research on the premise that this would facilitate the commercialization of research, and hasten innovation – for further discussion see Commission on Intellectual Property Rights, "Integrating Intellectual Property Rights and Development Policy – Report of the Commission on Intellectual Property Rights", London, September 2002, p.123.

4/ Commission on Intellectual Property Rights, "Integrating Intellectual Property Rights and Development Policy – Report of the Commission on Intellectual Property Rights", London, September 2002, p. 124.

5/ The Secretary of State for International Development of the United Kingdom established the Commission on Intellectual Property Rights in May 2001.

6/ See footnote 4 above.

7/ In OECD, "Genetic Inventions, Intellectual Property Rights and Licensing Practices – Evidence and Policies", 2002, p. 49.

20. DNA sequences are valuable research tools for developing pharmaceuticals. Such tools are increasingly being patented and then marketed and licensed to industrial and academic researchers. There is concern that patents on such tools could inhibit research for a number of reasons including increased transaction costs, a reluctance to license due to exclusive arrangements and the need to license negotiations before research starts. 8/ Nevertheless, although there has been an increase in the patenting of research tools required for drug discovery, there is no evidence that drug discovery has been impeded, by virtue of a number of strategies which have been adopted to mitigate the potential problems. These strategies have included moving research offshore, inventing around patents, taking out licences on patents that may block research 9/ and simply using the technology without a license, often invoking a de facto broad "research exemption". It has thus been suggested that policy-makers should ensure an appropriate exemption for research intended for the public domain. 10/

21. In addition, "reach-through claims" that is research tool patents that claim downstream royalty payments on the product that was developed using these tools may also contribute to increased product development costs and negatively affect the development of science.

22. In the biotechnology sector, due to the fact that patents are relatively recent, other issues related to recent practice have become the subject of concern, 11/ including the scope of patents. The issuance of patents with excessively broad claims, seeking a scope of patent protection that is not justified by the contribution made by the invention has been a source of concern in recent years, particularly in pharmaceutical as well as agricultural biotechnology. 12/ Overly broad claims may create an impediment to research by creating obstacles to the work of scientists. It has been suggested that a strict application of the patentability criteria could assist in addressing this issue. 13/

23. In the United Kingdom Government's response to the report of the Commission on Intellectual Property Rights, it is stated with respect to the patenting of research tools that:

> "The Government agrees with the Commission that the patent system, while providing incentives for research may also create disincentives for those seeking to use protected products in research. (…) Striking the right balance between protecting current innovation and not hindering subsequent innovation is key to the IPR system for all countries."

B. The role of oral evidence of prior art in the examination, granting and maintenance of intellectual property rights

24. According to WIPO, " 'prior art' generally refers to the entire body of knowledge which is available to the public before the filing date or, if priority is claimed, before the priority date, of an application for certain industrial property titles, principally patents, utility models and industrial designs. The identification of prior art constitutes a cornerstone for the substantive examination of applications for these titles, since requirements such as novelty and inventive step are established by comparing the claimed subject matter with the relevant prior art". 14/

8/ The Royal Society, "Keeping science open: the effects of intellectual property policy on the conduct of science", April 2003, p. 10, paragraph 3.2.1.

9/ Commission on Intellectual Property Rights, "Integrating Intellectual Property Rights and Development Policy – Report of the Commission on Intellectual Property Rights", London, September 2002, p. 127.

10/ John P. Walsh, Ashish Arora, Wesley M. Cohen, "Science and the Law: Working Through the Patent Problem", Science, Volume 299, 14 February 2003.

11/ See footnote 8.

12/ For further discussion, see OECD, *op cit.*, p.64, and Royal Society, *op cit.*, p. 13, paragraph 3.34.

13/ Royal Society, *op cit.*, p. 13, par. 3.33.

14/ WIPO/GRTKF/IC/2/6, paragraph 2.

25. This section considers issues related to "the role of evidence of prior art in the examination, granting and maintenance of intellectual property rights" from two angles:

(a) The consideration of orally disclosed information as prior art in patent examinations, or how orally disclosed prior art can be considered during the patent examination process;

(b) The status of oral disclosure of information as prior art in the course of opposition or revocation proceedings.

26. The section first examines how oral disclosure of prior art is considered in the context of the international legal framework and in national and regional legislations. Against this background, the consideration of oral disclosure of prior art both at the stage of the patent examination process and in the course of opposition or revocation proceedings are then respectively examined.

1. Provisions in international instruments dealing with prior art

Draft Substantive Patent Law Treaty

27. The draft Substantive Patent Law Treaty (SPLT) is presently under discussion within the framework of WIPO. It is aimed at establishing uniform standards on the criteria of substantive patentability, sufficient disclosure, grounds for refusal of an application, and revocation or invalidation of a patent. 15/

28. At its past sessions, the Standing Committee on the Law of Patents (SCP) considered draft provisions on the definition of prior art. These provisions on prior art provide in essence that any information made available to the public, anywhere in the world, in any form, including in written form, by oral communication, by display and through use, shall constitute prior art, if it has been made available to the public before the filing date, or where applicable, the priority date (for the full text of the provisions see document SCP/10/2 and SCP/10/3). These provisions would provide a broad definition of prior art covering oral evidence of prior art.

Patent Cooperation Treaty

29. The Patent Cooperation Treaty is an international instrument that allows for the processing of a single international patent application for patents in multiple countries members of the Patent Cooperation Treaty rather than having to process applications in the national office of each country. 16/

30. The international phase of patent processing includes the application, an international search, publication and a preliminary examination. Once the international phase is over, procedures will also need to be carried out at the national level in the countries where coverage is sought.

31. Article 15, paragraphs 1 and 2, of the Treaty provide that international applications will be subject to an international search with a view to discovering relevant prior art. Rule 33.1 of the regulations under the Treaty defines prior art for the purposes of article 15, paragraph 2 of the Treaty as:

> "[E]verything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) and which is capable of being of assistance in determining that the claimed invention is or is not new

15/ UNEP/CBD/WG-ABS/2/INF/2.

16/ Ibid.

and that it does not involve an inventive step (i.e. that it is or is not obvious), provided that the making available to the public occurred prior to the international filing date." 17/

32. In other words, oral evidence will not be considered in searches carried out under the Patent Cooperation Treaty. With respect to prior art, the Treaty is thus narrower in its scope than the proposed provisions of the draft Substantive Patent Law Treaty.

33. As outlined by WIPO, it should be noted however that rule 33.1 only directly concerns the non-binding international search and examination. Applicable rules for determining what prior art is relevant may vary according to national and regional laws. 18/

2. Examples of provisions at the regional and national levels dealing with prior art

34. As stated by WIPO:

"Patent laws and practices at the regional and national levels vary widely. Prior art in certain countries is defined to include everything that has been made available to the public anywhere in the world by any means, whereas in other countries, non-written disclosures, such as oral disclosures, or use outside their jurisdiction, do not form part of the prior art, and thus do not constitute a bar to patentability." 19/

35. It is also interesting to note, as mentioned by WIPO, that:

"Many patent offices do not conduct substantive examination of patent applications themselves, since this requires extensive human and financial resources. Many developing countries maintain cooperation agreements with large national or regional patent-granting authorities, and in many cases send their applications to the European Patent Office (EPO), Japanese Patent Office (JPO) or the United States Patents and Trademarks Office (USPTO). In 2000, 89.7% of international searches for international applications were carried out by these 3 offices as International Searching Authorities." 20/

European Patent Convention

36. Prior art is defined in article 54, paragraph 2, of the European Patent Convention, as follows:

"The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the filing of the European patent application." 21/

37. The Guidelines for Examination in the European Patent Office (EPO) state that:

"[T]he width of this definition should be noted. There are no restrictions whatsoever as to the geographical location, where, or the language or manner in which the relevant information was made available to the public (…) All traditional knowledge comprised in this wide definition of the state of the art is recognized as prior art by the EPO, for the purposes of Article 54(2), EPC."

17/ WIPO/GRTKF/IC/2/6, para. 40.

18/ WIPO/GRTKF/IC/5/6, para. 5.

19/ Ibid, para. 52.

20/ Ibid.

21/ The relevant text of article 54, paragraph 2 is provided in WIPO/GRTKF/IC/2/6.

38. The Guidelines also state that:

> "The PCT according to its Rule 33.1 (a) and (b) recognizes oral disclosure, use, exhibition, etc., as prior art only when this is substantiated by a written disclosure. In contrast, according to Article 54 of the European Patent Convention a public oral description, use etc is considered as prior art. However the search examiner, in carrying out a European search, should cite an oral description etc. as prior art only if he has available a written confirmation or is otherwise convinced that the facts can be proved."

39. According to jurisprudence under the European Patent Convention, the issue is not whether the general public is aware of the existence of the information but rather whether the information is available and accessible to anyone at any given time before the application is filed. Searches for prior art carried out by the European Patent Office are essentially documentary searches, based on documentation specified in Patent Cooperation Treaty regulations. An examiner will use his discretion to end his search when the probability of finding relevant prior art becomes low in proportion to the needed effort. 22/

United States Patent Act

40. The United States Patent Act does not provide a definition of "prior art", but section 102 sets the conditions under which a statutory bar against the grant of a patent is established. Title 35, section 102, paragraphs (a) and (b), of the United States Code (USC), on "Conditions of patentability; novelty and loss of right to patents", provides that:

> " A person shall be entitled to a patent unless-
>
> (a) The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 23/

41. Thus, the United States Patent Act does not recognize prior use in a foreign country unless it is described in a printed publication and makes no reference to oral disclosure of prior art.

42. Notwithstanding the existing legal frameworks described above, practical considerations are to be taken into account in the consideration of oral disclosure of information as prior art.

3. Consideration of oral disclosure of information as prior art in the patent examination process

43. As expressed by one commentator:

> "There has been considerable concern that patents have been granted for inventions which did not meet fundamental requirements for patentability, specifically in relation to the requirements of novelty and inventiveness, when compared to traditional knowledge from which these inventions might have been directly or indirectly derived. Had this traditional knowledge been known to patent authorities—examiners in particular—at the

22/ Royal Society, *op cit.*, p.9.

23/ See WIPO/GRTKF/IC/2/6, para. 61.

time of review of patent applications, it may have been considered as prior art and, subsequently, may have defeated the claims that the invention was new and involved an inventive step. This would have assisted in the prevention of biopiracy."24/

44. It is desirable for examiners to have access to any relevant information during the patent examination process, in order to ensure that when a decision is taken on granting a patent, it is based on a full consideration of prior art. However, in practice, it may not be possible to locate all potentially relevant information during the patent examination process.

45. The problem is likely to be more acute in situations where evidence of relevant prior art is not substantiated in written form. Therefore, in order to facilitate the consideration of traditional knowledge as prior art in patent examination procedures, evidence and substantiation of traditional knowledge in written form may be needed. As demonstrated above in the case of the European Patent Convention, although the Convention provides the opportunity to consider oral disclosure of information as prior art, it will be difficult for a patent examiner to take into account prior art which is non-written and which he is not aware of.

46. A number of activities have been undertaken by WIPO to address this issue, which contribute to integrating traditional knowledge documentation into searchable prior art. These activities include amendments to international patent systems that are administered by WIPO and the development of practical products and tools for stakeholders, such as inventories of periodicals and databases related to traditional knowledge, a WIPO portal on online databases and registries of traditional knowledge and biological/genetic resources, and a draft toolkit for intellectual property management when documenting traditional knowledge and genetic resources. 25/

4. Consideration of oral disclosure of prior art during opposition or revocation proceedings

47. The capacity to consider oral disclosure of information as prior art may have greater practical implications in the context of opposition or revocation proceedings.

48. The practical difficulties associated with securing evidence of prior art during patent examination processes would not arise in cases where a request for re-examination of a patent is submitted to the patent office. In such a situation, the person or entity making the request would naturally provide written or oral evidence of existing traditional knowledge as prior art.

49. However, in the absence of such practical difficulties, certain patent laws, as demonstrated above, do not allow consideration of prior art that is not in written form, either during examination or re-examination of patent applications.

50. The *ayahuasca* patent case provides an illustration of controversy over the United States Patent Act in relation to the consideration of prior art. As noted above, the Patent Act does not recognize an invention unless it is available in a printed publication.

51. In 1999, a reexamination request was filed by the Centre for International Environmental Law (CIEL) on a United States patent claimed on a purported variety (called by the patent holder "Da Vine") of the *ayahuasca* vine, *Banisteiropsis caapi,* a plant native to the Amazonian rainforest. A request for reexamination of the patent was filed with the United States Patent and Trademark Office on behalf of the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) and the Coalition for Amazonian Peoples and their Environment (Amazon Coalition). The objection to the patent was based on

24/ Manuel Ruiz, "The international debate on traditional knowledge as prior art in the patent system: issues and options for developing countries», in Occasional Papers, South Centre, October 2002, paras. 16-17.

25/ For further discussion see WIPO/GRTKF/IC/5/6.

the fact that the patent purported to appropriate for a United States citizen a plant that is sacred to many indigenous peoples of the Amazon and used by them in religious and healing ceremonies. 26/

52. In the request for reexamination, it was argued that prior art revealed that "Da Vine" was not distinct or new, thereby failing to meet the Patent's Act requirement of novelty. It was demonstrated that the patent application described *ayahuasca* as it was already illustrated in scientific literature and known by indigenous Amazonian peoples. Other arguments were also presented which are not relevant to the issue of prior art. The PTO ordered the rejection of the patent on the ground that the same plant had been described in herbarium sheets in Chicago's Field Museum over a year prior to the deposit of the application. The PTO did not however address the issue of whether prior use by indigenous peoples or the fact that the plant was a sacred religious symbol precluded issuance of the patent. 27/

53. The *ayahuasca* patent case raised considerable controversy over the recognition of prior art. It has been argued that the United States should recognize foreign use as prior art under the Patent Act's novelty requirement. In the words of one author:

> "[W]hile foreign patents and printed publications are considered prior art and preclude subsequent patent of the same invention in the U.S., the existence of foreign traditional knowledge, which is rarely printed, does not preclude issuance of a U.S. patent. As illustrated by the Ayahuasca patent, the exclusion of prior foreign use as a prior art makes it difficult for a foreign litigant to defeat a plant patent." 28/

54. Although the *ayahuasca* case does not provide a specific illustration of issues related to oral disclosure of prior art, issues surrounding the lack of recognition of prior use provide an illustration of the general concerns raised by the absence of recognition of unpublished prior art from foreign countries.

55. It has been argued that "the growing sense in developing countries that patent systems are not fairly acknowledging contributions from their jurisdictions has led some developing countries to adopt restrictions on access to knowledge and biological resources". 29/

III. IMPORTANT ISSUES FOR CONSIDERATION IN THE EXAMINATION OF REQUIREMENTS FOR DISCLOSURE IN APPLICATIONS FOR INTELLECTUAL PROPERTY RIGHTS, RELATED TO ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

56. As noted in paragraph 8 above, the following section is based on:

(a) The consultant's study commissioned by the Secretariat, referred to in paragraph 6 above (UNEP/CBD/WG-ABS/2/INF/2); and

(b) The technical study by WIPO prepared pursuant to the invitation in paragraph 4 of decision VI/24 C and referred to in paragraphs 3 and 4 above (UNEP/CBD/WG-ABS/2/INF/4).

57. In attempting to respond to issues raised in paragraphs 3 and 4 of decision VI/24 C, these two studies have identified elements that should be taken into account in further considering the issue of

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26/ Http://www.ciel.org/Biodiversity/ayahuascapatentcase.html

27/ Leanne M Fecteau "The Ayahuasca patent revocation: raising questions about current U.S. Patent Policy", 21 B.C. Third World L. J. 69, 70 (2001) - available at http:infoeagle.bc.edu/bc_org/avp/lwsch/journals/.

28/ Ibid.

29/ CIEL, "Comments on Improving Identification of Prior Art – Recommendations on Traditional Knowledge relating to Biological Diversity submitted to the United States Patent and Trademark Office", 2 August, 1999, p.6.

disclosure. The section highlights important issues raised by these studies to be taken into account when further examining the issue of disclosure in intellectual property rights as it relates to access and benefit-sharing.

58. In conformity with decision VI/24 C, the type of new disclosure requirements considered by the two studies are:

(a) Disclosure of the source or geographic origin of the genetic resource;

(b) Disclosure of evidence of prior informed consent;

(c) Disclosure of source and of evidence of prior informed consent.

A. Existing disclosure requirements

59. As clearly set out in the WIPO technical study:

> "Patent applications contain a combination of technical, legal and administrative information. Under national and regional patent law and related laws (and in line with established international standards), patent applicants are typically required to provide information in four general areas:
>
> "(a) Information that enables a person skilled in the art to carry out the claimed invention, and in some laws the disclosure of the best mode of carrying out the invention known by the inventor at the relevant date. 30/ For inventions involving a new microorganism, the disclosure obligation may also entail deposit of the microorganism itself;
>
> "(b) Information that defines the matter for which protection is sought (a claim or claims);
>
> "(c) Other information relevant to the determination of novelty, inventive step or non-obviousness, and capability or industrial application or utility of the claimed invention, including search reports, and other known prior art;
>
> "(d) Administrative or bibliographic information relevant to the claimed patent right, such as the name of the inventor, address for service, details of priority documents, etc." 31/

60. The WIPO study also underlines that "disclosure is at the core of the policy rationale and the practical operation of the patent system." 32/ In addition, as a matter of existing practice, patent applications already disclose significant information concerning genetic resources and traditional knowledge. 33/

61. Existing information and disclosure requirements in patent applications that are relevant to genetic resources and traditional knowledge, include: 34/ disclosure necessary to enable the invention to be carried out, disclosure of the best mode or preferred embodiment of the invention, disclosure of the

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30/ WTO/TRIPs Agreement, Article 29.1.

31/ UNEP/CBD/WG-ABS/2/INF/4, para. 32.

32/ Ibid, para. 199.

33/ Ibid, para.203.

34/ Ibid, para. 112.

actual inventor or inventors, and disclosure of known prior art. In addition, disclosure or documentation requirements may also apply to the entitlement of the applicant to apply for the patent. These disclosure requirements may relate to genetic resources or traditional knowledge in the following circumstances:

(a) "Access to genetic resources is necessary to carry out or replicate the invention as claimed". 35/ Disclosure of geographic origin of the genetic resource or of the source is necessary if the only way to carry out a specific invention is to use a biological resource that is only available in a specific country;

(b) `"Access to genetic resources is necessary to implement the preferred embodiment of the invention or other example given in the description of the patent". 36/ In this case, the disclosure of the source of genetic resources is required in order to carry out the best mode or preferred embodiment of the invention;

(c) "The traditional knowledge is prior art, known to the applicant, which is relevant to the assessment of whether the invention as claimed is novel and not obvious." 37/ Under these circumstances, in some jurisdictions traditional knowledge must be disclosed in order to assess the validity of the patent claim;

(d) "Traditional knowledge was provided by a traditional knowledge holder and is directly used in developing the invention, to the extent that the traditional knowledge holder is a potential co-inventor." 38/ When the traditional knowledge itself forms a substantive contribution to the claimed invention and the traditional knowledge holder is a potential co-inventor, the origin of the traditional knowledge is to be disclosed and the traditional knowledge holder may be recognized as a co-inventor.

62. As demonstrated above, a number of disclosure requirements based on the patent system already provide for the disclosure of the genetic resource and traditional knowledge in certain circumstances. However, these existing disclosure requirements do not require evidence of prior informed consent of competent authorities in order to obtain access to genetic resources or traditional knowledge. They are limited to disclosure of the actual traditional knowledge, or the identification of the source of the genetic resource or traditional knowledge.

B. Legal basis of disclosure requirements

63. One major distinction between existing information and disclosure requirements and possible new disclosure requirements is their legal basis.

64. As noted above, the patent system already provides for certain disclosure requirements that apply to genetic resources and traditional knowledge. The legal basis for these disclosure requirements is the patent law system.

65. The new disclosure requirements under discussion are directed rather towards the implementation of non-patent laws and obligations, such as those that may be adopted in implementation of the provisions of the Convention on Biological Diversity. With respect to these new proposals for disclosure examined below, the patent process is considered as "a means to giving effect to obligations under distinct legal or ethical systems, including compliance with access regulations in other jurisdictions". 39/ These new

35/ Ibid, para.183
36/ Ibid.
37/ Ibid.
38/ Ibid.
39/ Ibid, para. 115.

proposals for disclosure requirements are intended to provide additional compliance monitoring mechanisms and/or means of sanctioning failure to comply with non-patent laws in other jurisdiction, such as those regulating access and benefit-sharing.

C. Possible new disclosure requirements

1. Type of new disclosure requirements

Optional/voluntary disclosure requirement

66. In the case of optional disclosure, the applicant is encouraged to disclose but is not required to disclose in order to obtain a patent. "This is most similar to the present situation since present patent laws permit an applicant to note the origin of genetic resources upon which the patent application is based, but there is no explicit requirement." 40/ The European Community directive provides an example of an optional disclosure requirement.

Distinct or stand-alone disclosure requirement

67. This type of disclosure requirement is mandatory in the sense that it is required, but non-compliance would not bar patentability or enforceability of a patent. Non compliance would rather result in monetary fees, civil or administrative sanctions, or even criminal penalties. For example, as illustrated in the annex, in Denmark and Norway the absence of disclosure could be considered a breach to obligations under the penal code.

Enhanced disclosure requirement

68. The final possibility is that non-compliance with disclosure requirements would be directly linked to patent rights. In this case, failure to comply would either result in a bar to patentability or a subsequent loss of patent rights. The study commissioned by the Secretariat provides various alternatives in this regard:

- "First, the enhanced disclosure requirement could be an additional requirement for patentability, such that non compliance would bar patent issuance. The requirement could be independently verified by examiners, such as current substantive requirement that a patent application adequately disclose the invention. Alternatively, the requirement could be a pre-requisite to patent examination, with applications being returned where there is non compliance with the disclosure requirement." 41/

- "Second, the enhanced disclosure requirement could be an issue only when the patent is enforced. This would not impact current examination procedures." 42/

- Finally, "the enhanced disclosure requirement could be both a requirement for patentability, as well as an issue that could result in the loss of patent rights during subsequent proceedings if non compliance were later discovered. In this situation, the enhanced disclosure requirement would function like traditional elements of patentability (such as novelty or inventive step), which can bar a patent from issuing, or be utilized to cancel invalid patents." 43/ This option is reflected in India's most recent amendment to its patent law which provides "additional grounds for

40/ UNEP/CBD/WG-ABS/2/INF/2, para. 2.3.3.

41/ Ibid, para. 2.3.8

42/ Ibid, para. 2.3.9.

43/ Ibid/

revocation, including the fact that an applicant did not disclose or wrongly disclosed the geographical origin of biological material used in the invention". 44/

2. Relationship between the genetic resource/traditional knowledge and the claimed invention—trigger of the obligation

69. The WIPO study raises a core question that needs to be addressed in order to move forward on the issue of disclosure requirements, namely, the relationship or linkage between the claimed invention and the genetic resource or traditional knowledge. 45/ In this regard, the WIPO study notes that:

> "The nature of the disclosure requirement may be very different depending on whether the genetic resource/traditional knowledge was incidental or fundamental to the development of the invention; whether the GR/TK contributed to one earlier step to a chain of innovations that over time culminated in the invention, or was a direct input to the claimed invention step; whether particular qualities of a genetic resource were essential to the invention, or the genetic resource was in effect only a vehicle for a separate innovative concept; or whether a genetic resource was used in a particular embodiment or one example in the description of the invention, but was not indispensable to arriving at (or replicating) the invention as claimed." 46/

70. On this basis, "a fundamental legal and practical question is what linkage between the GR/TK in question and the claimed invention would be sufficient to establish an obligation to disclose".47/

3. Consistency with international legal obligations

71. Both the WIPO technical study and the consultant's study examine WIPO international treaties and the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) in order to determine the compatibility of new disclosure requirements with the international patent system. Participants in the Working Group are invited to consult these studies for a detailed examination of these issues.

72. There does not seem to be a simple answer to these questions. Consistency with international legal obligations will likely depend on the type of disclosure requirement established. It is likely that a voluntary disclosure requirement or a distinct or stand-alone disclosure requirement may be less likely to be inconsistent with existing international legal obligations than an enhanced disclosure requirement.

73. As set out in the consultant's study:

> "TRIPs is of importance because it establishes minimum standards of intellectual property protection, such that any modification to intellectual property rights that arguably deviates from TRIPs could subject a WTO country to potential sanctions. A mandatory disclosure requirement, established as a condition to patentability, would be most problematic because of its likely inconsistency with the minimum requirements for patentability under TRIPs. In addition, even an optional requirement might be problematic if it altered the examination of patents or resulted in discrimination as to field of technology."

44/ Indian Patent Act, section 25 (Second Amendment 2002).

45/ WIPO technical study, UNEP/CBD/WG-ABS/2/INF/4, para. 86.

46/ Ibid, para. 87.

47/ Ibid, para. 92

74. The study also considers possible amendments to TRIPs, as well as a possible declaration/interpretation that might address the inconsistency issue.

75. Several amendments to the TRIPs Agreement have been suggested in order to ensure compatibility between it and the Convention on Biological Diversity. The consultant's study also suggests that a disclosure declaration could be considered as an alternative to an amendment. 48/

76. According to the same study, the Substantive Patent Law Treaty, presently under negotiation under the auspices of WIPO, could, if certain proposals were agreed, be consistent with an enhanced disclosure requirement. 49/ With respect to the Patent Cooperation Treaty, Switzerland has made specific suggestions to amend the regulations under the Treaty to allow for an enhanced disclosure requirement.

77. According to the WIPO study, existing disclosure mechanisms are consistent with WIPO treaties. However, when considering a stand-alone or distinct disclosure requirement, the issue of consistency with international treaties and the relationship with the patent system may need to be clarified. 50/ First, the actual nature of the disclosure requirement needs to be clarified—in particular, what the legal basis is of the disclosure requirement (Does it stem from breach of the access law or a contractual obligation under the law of the country of origin, does it go to the applicant's entitlement to apply for and to be granted a patent, or does it link the applicant's behaviour in realizing the invention with the true patentability of the invention itself?).

D. Practical considerations related to enhanced disclosure requirements

78. Some practical considerations linked to the functioning of the patent system may be relevant in assessing the value of new disclosure requirements in contributing to meet the objectives of the Convention on Biological Diversity related to access and benefit-sharing. These include:

(a) *Time allocated to patent examination*. 51/ An important consideration is the actual time that examiners have to consider information. The current and future workload of patent examiners may not realistically allow them to handle additional information; and

(b) *Capacity of patent examiners*. 52/ Imposing obligations on the patent office that are not linked directly to the technical elements of patentability should be approached with caution since history suggests that patent offices have difficulty doing so.

E. Alternative solutions

79. Finally, it has been suggested that alternative solutions may also be worth considering, such as broadening the scope of prior art. The expansion of both national and international definitions of prior art could enable patent offices to consider information that might preclude the issuance of patents when the subject matter of the application is based on existing traditional knowledge. Section II B above further addresses this issue.

IV. NATIONAL AND REGIONAL EXPERIENCES WITH RESPECT TO THE DISCLOSURE REQUIREMENTS RELATED TO THE

48/ UNEP/CBD/WG-ABS/INF/2, par. 3.1.32.

49/ Ibid, para. 3.1.35.

50/ WIPO technical study (UNEP/CBD/WG-ABS/2/INF/4), para.204.

51/ UNEP/CBD/WG-ABS/2/INF/2, paragraph 4.2.

52/ UNEP/CBD/WG-ABS/2/INF/2, subsection on "policy considerations for non-traditional patent examination" under section 4.3.

SOURCE OF GENETIC RESOURCES AND RELEVANT TRADITIONAL KNOWLEDGE IN INTELLECTUAL PROPERTY RIGHTS APPLICATIONS

80. A number of initiatives have been taken to address the issue of disclosure of origin of genetic resources in intellectual property applications both through regional frameworks and national legislation.

A. Regional frameworks

81. Initiatives at the regional level to address the issue of disclosure have been taken by the Andean Community, the European Community and the Organization of African Unity (OAU) (now called the African Union). The Andean Community addressed the issue in decision 391 on the common regime on access to genetic resources and decision 486 on the common intellectual property regime, the European Community in the preamble of directive EC-98/44 on biotechnological inventions and OAU in the African Model Law on the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources.

82. It is interesting to note that the approaches adopted by each of these regional frameworks is substantially different.

83. The Andean Community have addressed the issue of disclosure in both regional instruments dealing with access and benefit-sharing and intellectual property rights, demonstrating a certain degree of policy integration. The disclosure requirement involves disclosure of the access contract, prior informed consent of indigenous and local communities and acquisition of material in accordance with national, Andean Community and international law. A patent may be declared null or void if copy of the access contract was not submitted or if the prior informed consent of relevant indigenous and local communities was not obtained, in the case of a patent granted for a product or a process based on a genetic resources or traditional knowledge.

84. The European Community directive encourages the inclusion of geographical origin of biological material in patent applications. It does not however affect the processing of patent applications or the validity of rights arising from granted patents.

85. With respect to the African Model Law, patents over life forms and biological processes are not recognized and are, therefore, not applicable.

86. The detail of the specific provisions dealing with the issue of disclosure in each of these agreements are included in the annex to the present note.

B. National initiatives

87. At the national level, countries have also taken different approaches to address the requirement for disclosure of the country of origin of genetic resources and relevant traditional knowledge in relevant intellectual property rights applications. Certain countries have chosen to amend their patent law, others have chosen to include the disclosure requirement in their biodiversity or access and benefit-sharing laws, and others still have included reference to the requirement in both laws on patents and laws on biodiversity or access and benefit-sharing.

88. Disclosure requirements have already been included in a number of legislations while others are still at the stage of proposals. The details of the proposals put forward and also the text of existing laws that have addressed the issue of disclosure are available in the annex to the present note. As illustrated in

the text of the legislation either enacted or proposed, the extent of the disclosure requirement largely varies depending on the countries.

89. However, certain similarities are notable among the various approaches/initiatives adopted by countries. They include the following:

90. The disclosure requirement is a condition of patentability for the following countries: Member States of the Andean Community, Brazil, Costa Rica, Egypt and India.

91. In other countries, such as Sweden, Norway and Denmark, lack of disclosure does not affect processing of patent applications or the validity of rights arising from such patents. However, in Denmark and Norway, the absence of disclosure could be considered a breach to obligations punishable under the Penal Code.

C. Proposal to amend an international instrument

92. Finally, it is interesting to note that Switzerland has proposed to amend the regulations under the WIPO Patent Cooperation Treaty (PCT) of to allow PCT Contracting Parties to require patent applicants to declare the source of genetic resources and/or traditional knowledge, if an invention is directly based on such knowledge:

> "Switzerland proposes to afford applicants the possibility of satisfying this requirement at the time of filing an international patent application or later during the international phase. By reference, the proposed amendment to the PCT would also apply to the Patent Law Treaty (PLT) of WIPO. Accordingly, the Contracting Parties of the PLT would be able to require in their national patent laws that patent applicants declare the source of genetic resources and/or traditional knowledge in national patent applications." 53/

53/ Submission by Switzerland to the Secretariat.

Annex

NATIONAL AND REGIONAL INITIATIVES WITH RESPECT TO DISCLOSURE REQUIREMENTS RELATED TO THE SOURCE OF GENETIC RESOURCES AND RELEVANT TRADITIONAL KNOWLEDGE IN APPLICATIONS FOR INTELLECTUAL PROPERTY RIGHTS

A. Regional frameworks

Andean Community 54/

1. Decision 391 of the Andean Community, on the common regime on access to genetic resources, 1996 include the following provisions related to intellectual property over genetic resources:

2. Article 16 provides that:

> "All access procedures shall require the presentation, admittance, publication and approval of an application, the signing of a contract, the issuing and publication of the corresponding resolution and the declarative registration of the acts connected with the access."

3. Article 26 dealing with applications for access provides that:

> "The procedure starts with the presentation to the Competent National Authority of an application for access which should contain:
>
> "(…)
>
> "(b) Identification of the supplier of the genetic and biological resources and their by-products or of the associated intangible component."

4. Article 35 states that:

> "When access is requested to genetic resources or they by-products with an intangible component, the access contract shall incorporate, as an integral part of that contract, an annex stipulating the fair and equitable distribution of the profits from use of that component."

5. Finally, with respect to intellectual property rights more specifically, the second "Complementary provision" provides that:

> "The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this decision. Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents."

6. Decision 486 of the Andean Community, 2000, on the common intellectual property regime, first provides in Article 3 that:

54/ The member States of the Andean Community include: Bolivia, Colombia, Ecuador, Peru and Venezuela.

"The Member Countries shall ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities. As a result, the granting of patents on inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law.

7. It then provides in Article 26 that:

"Applications for patents shall be filed with the competent national office and shall contain:

"(…)

"(h) 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 by products originating in one of the Member Countries;

"(i) 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 were 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;"

8. Finally, under Chapter IX, on the "Invalidation of the Patent", article 75 provides that:

"The competent national authority may, either ex officio or at the request of a party, and at any time, declare a patent null and void, where:

"(…)

"(g) when pertinent, the products or processes in respect of which the patent is being filed have been obtained and developed on the basis of genetic resources or their by-products originating in one of the Member Countries, if the applicant failed to submit a copy of the contract for access to that genetic material;

"(h) when pertinent, the products or processes whose protection is being requested have been obtained or developed on the basis of traditional knowledge belonging to Indigenous, African American, or local communities in the Member Countries, if the applicant has failed to submit a copy of the document certifying the existence of a license or authorization for use of that knowledge originating in any one of the member Countries"

EC directive 98/44

9. The recital of directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions provides that the patent application should where appropriate, include information on the geographical origin of biological material if known. This is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

10. In relation to the recital, the European Commission provided the following comments to WIPO:

> "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/

OAU Model Law

11. The preamble provides the following:

> "Whereas, all forms of life are the basis for human survival, and, therefore, the patenting of life, or the exclusive appropriation of any life form or part or derivative thereof violates the fundamental human right to life."

12. Article 9 then states that:

> "(1) Patent over life forms and biological processes are not recognized and cannot be applied for.
>
> (2) The collector shall, therefore, not apply for patents over life forms and biological processes under this legislation or under any other legislation relevant to the regulation of access and use of a biological resource, community innovation, practice, knowledge and technology, and the protection of rights therein."

13. The African Model Law both in its preamble (last paragraph) and in part III on access (article 9), states that patents over life forms and biological processes are not recognized and are, therefore, not applicable. The Model Law considers the patenting of life a violation of the fundamental right to life, as well as of the principle of respect for all forms of life.

14. As mentioned in the explanatory booklet of the Model Law, parts of organisms (e.g. cells, genes) are considered to be biological resources and, as such, are subject to both the provisions of the Convention on Biological Diversity and the African Model Law. This is related to the use made of "derivatives" of plants, animals, or micro-organisms. According to the Model Law, derivatives are products developed or extracted from a biological resource and may include products such as plant varieties, oils, resins, etc.

15. On the basis of the Model Law, patents cannot be taken out on the accessed material, biological processes or any of their derivatives.

B. National initiatives

1. Legislative proposals

Norway 56/

16. The Norwegian Government submitted on 9 May 2003 a legislative proposal to amend the current Patent Law to Parliament. The legislative proposal (Ot. Prp. Nr. 86 (2002-03) reads as follows (free translation from Norwegian, new paragraph 8 (b)):

55/ WIPO/GRTKF/IC/5/10, para. 72.

56/ Submission from the Norwegian Government.

> "If an invention concerns or uses biological material, the inventor shall disclose in the patent application the country providing such material. If national legislation in the providing country requires prior informed consent before providing such material, the application shall include information on whether such consent has been sought.
>
> "In cases where the providing country is different from the country of origin of the biological material, the country of origin shall also be disclosed. Country of origin is defined as the country from where the material is accessed in *in situ* conditions. In cases where national legislation in the country of origin requires prior informed consent before providing such material, the application shall include information on whether such consent has been sought. If the applicant does not know the country of origin or whether prior informed consent is required, the applicant shall state this fact in the application."
>
> "These obligations are applicable even if the inventor has changed the structure of the material. They do not concern human material.
>
> "Violations of the requirement to disclose information is punishable under paragraph 166 of the Penal Code. The requirement to disclose information does not affect that handling of a patent application or the validity of a patent."

17. The information requirements are not applicable to international patent applications submitted through the Patent Cooperation Treaty system, as this would be contrary to the obligations pursuant to the Patent Cooperation Treaty.

Belgium 57/

18. The proposed article 4(4) of the Belgium Patent Act provides that exploitation of an invention is contrary to ordre public and morality when the invention is developed on the basis of biological material that was collected or exported in breach of articles 3, 8(j), 15 and 16 of the Convention on Biological Diversity. In addition, proposed article 15 (1) of the Belgium Patent Act specifically adds a new paragraph which requires patent applications to contain not only the typical description, claims, drawings and abstract, but also the geographic origin of the plant or animal material that formed the basis for the development of the invention.

Sweden

19. According to the WIPO draft technical study, 58/ a Swedish government memorandum on the implementation of the European Community directive 98/44/EC proposes a new draft rule 5(a) of the Patents Decree. The draft rule mainly reiterates paragraph 27 of the preamble of the European Community 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 of 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."

57/ See UNEP/CBD/WG-ABS/2/INF/2.

58/ WIPO/GRTKF/IC/5/10, para. 55.

20. In its submission to WIPO, Sweden advised 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". 59/

Romania

21. The WIPO draft technical study 60/ also refers to a pending amendment to the patent law of Romania 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".

22. Romania has advised WIPO that "there are no consequences in case of non-compliance" in relation to its draft measure on traditional knowledge disclosure. 61/

2. Legislation

Denmark

23. In 2000, Denmark has enacted a "disclosure of origin clause" in its intellectual property rights legislation, as follows: 62/

> "Act 412, 31/5 2000 amended the Danish Patent Act (consolidated Patent Act 926/22/9 200) in order inter alia to implement the EU Directive on biotechnological inventions. Based on the Act, the existing ministerial regulation on patents (Reg. 374 19/6 1998) was amended (reg. 1086 11/12 2000) by supplementing its paragraph 3 with the following provision (unofficially translated):
>
> > "If an invention concerns or makes use of biological material of vegetable or animal origin, the patent application shall include information on the geographical origin of the material, if known. If the applicant does not know the geographical origin of the material, this shall be indicated in the application. Lack of information on the geographical origin of the material or on the ignorance hereon does not affect the assessment of the patent application or the validity of the rights resulting from the granted patent.
>
> "Breach of this provision could imply a violation of the obligation in the Danish Penal Code (par. 163) to provide correct information to a public authority."

India

24. The Biological Diversity Bill, passed by the Indian Parliament in December 2002 provides under chapter V, article 19:

> "(2) Any person who intends to apply for a patent or any other form of intellectual property protection whether in India or outside India may make an application in such form an in such manner as may be prescribed to the National Biodiversity Authority.

59/ Ibid., para. 72.

60/ Ibid., para. 56.

61/ Ibid., para. 72.

62/ Submission by Denmark.

> (3) On receipt of an application under sub-section (1) or sub-section (2), the National Biodiversity Authority may, after making such enquiries as it may deem fit and if necessary after consulting an expert committee constituted for this purpose, by order, grant approval subject to any regulation made in this behalf and subject to such terms and conditions as it may deem fit, including the imposing of charges by way of royalty of for reasons to be recorded in writing reject the application:
>
> "Provided that no such order for rejection shall be made without giving an opportunity of being heard to the person affected.
>
> "(4) The National Biodiversity Authority shall give public notice of every approval granted by it under this section."

25. In addition, the Patents Act 1970 was amended by the Patents Second Amendment Act (2002) and contains a number of requirements related to the disclosure of the source and geographical origin of any biological material.

26. More specifically, section 10 on "Contents of specification" of the Patents Act 1970, as amended by the Patents Second Amendment Act (2002), provides that the applicant must disclose the source and geographical origin of any biological material deposited in lieu of a description. Section 25 related to "Opposition to grant of patent" as amended allows for opposition to be filed on the ground that "the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention". Finally, in accordance with the amendment to section 64, if "the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention" a patent may be revoked by the High Court, subject to the provisions contained in this Act, whether granted before or after the commencement of this Act, on the petition of any person interested or of the Central Government or on a counter-claim in a suit for infringement of the patent.

Costa Rica

27. The Biodiversity Law No. 7788 of Costa Rica, 1998, under article 79 on "Congruence of the intellectual property system" states that "decisions taken in the realm of intellectual property protection related to biodiversity must be congruous wit the objectives of this law, in application of the principal of integration".

28. Article 80 on "Obliged prior consultation" also provides that:

> "Both the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission before granting protection of intellectual or industrial property to innovations involving components of biodiversity. They must always provide the certificate of origin issued by the Technical Office of the Commission and the prior informed consent. Justified opposition from the Technical Office will prohibit registration of a patent or protection of the innovation."

29. It should be noted that the Commission as referred to in article 80 is the body responsible for the management of biodiversity.

Brazil

30. In Brazil, article 31 of Provisional Measure No. 2.186-16, of 23 August 2001 dealing with access and benefit-sharing provides that:

> "The grant of industrial property rights by the competent bodies for a process or product obtained using samples of components of the genetic heritage is contingent on the observance of this Provisional Measure, the applicant being obliged to specify the origin of the genetic material and the associated traditional knowledge, as the case may be."

31. The provisional measure does not apply to human genetic resources, as specified in article 3.

Egypt

32. The Egyptian Law on the protection of intellectual property rights, 2002, provides in article 13:

> "Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should have acquired the sources in a legitimate manner."

New Zealand

33. In submission to WIPO, New Zealand stated that:

> "Under Section 17 of the Patents 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 traditional knowledge, 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." 63/

63/ WIPO/GRTKF/IC/5/10, para. 64.