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GLOSSARY OF KEY TERMS RELATED TO INTELLECTUAL PROPERTY AND GENETIC RESOURCES

Document prepared by the Secretariat

INTRODUCTION

1. At its sixteenth session, held from May 3 to 7, 2010, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') decided that the Secretariat should prepare and make available for the next session of the Committee "as an information document, a glossary of key terms related to intellectual property and genetic resources".[1]

2. From the very first session of the Committee, the need for terminological clarity and for adopting internationally agreed uses of relevant terms, thereby capitalizing on decades of specialized work in other international fora, was emphasized.[2] In its second session, the Committee put forward terminological and conceptual issues in relation to intellectual property and genetic resources in Annex I "Glossary of Genetic resource terminology related to intellectual property and genetic resources" of document WIPO/GRTKF/IC/2/3 "Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to

[1] Draft Report of the Sixteenth Session of the Committee (WIPO/GRTKF/IC/16/8 Prov. 2)

[2] See document WIPO/GRTKF/IC/1/13 paras. 21, 22, 23, 27, 28, 32, 33 ,37, 39, 41, 43, 50, 51, 52, 57, 61, 82, 84, 91, 94, 104, 105, 106, 107, 112, 114, 119, 128, 155; WIPO/GRTKF/IC/1/3 para 16; See document WO/GA/26/10, paragraph 71 and WIPO/GRTKF/IC/2/3 Annex I

Genetic Resources and Benefit-Sharing".[3] At its sixteenth session, some Member States identified the need for a glossary to clarify the meanings of key terms related to genetic resources, arguing that a glossary would facilitate the negotiations of the Committee on this agenda item.[4]

3. This present document draws, as far as possible, from previous glossaries of the Committee and from existing United Nations and other international instruments. The document also takes into account definitions and glossaries which can be found in national and regional laws and draft laws, multilateral instruments, other organizations and processes and in dictionaries. Further, definitions are based on working documents of the Committee, other WIPO documents and documents of other work programs of WIPO. That said, the proposed definitions are not exhaustive. Other terms may also be relevant to intellectual property and genetic resources, and the terms selected may also be defined in other ways.

4. The selection of key terms has been based on the terms used most frequently in working documents WIPO/GRTKF/IC/17/6 and WIPO/GRTKF/IC/17/7. The selection and proposed definitions contained in the Annex are without prejudice to any other glossary or definitions of key terms contained in previous documents of this Committee or in any other international, regional or national instrument or fora. The selection and proposed definitions of key terms are not intended to suggest that the selection of terms or their proposed definitions are necessarily agreed upon by participants in the Committee. This is an information document and the Committee is not requested to endorse or adopt neither the selection of terms nor their proposed definitions.

5. The Committee is invited to take note of the glossary of key terms related to intellectual property and genetic resources contained in the Annex.

[Annex follows]

[3] See document WIPO/GRTKF/IC/1/3 paras. 64 and 71; and document WIPO/GRTKF/IC/2/3, Annex I. Annex I of document WIPO/GRTKF/IC/2/3 provided the definitions of the following terms: genetic resources, genetic material, biological resources, plant genetic resources, plant genetic resources for food and agriculture, cultivar, obsolete cultivar, primitive cultivar or landrace, weeds, special genetic stocks, line, elite line, current breeders' line, mutant

[4] Draft Report of the Sixteenth Session of the Committee (WIPO/GRTKF/IC/16/8 Prov. 2), para. 227

ANNEX

GLOSSARY OF KEY TERMS RELATED TO INTELLECTUAL PROPERTY AND GENETIC RESOURCES

Access and Benefit-sharing (ABS)

The Convention on Biological Diversity (CBD) has among its objectives "*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*". The CBD is currently negotiating an international regime on access and benefit-sharing for genetic resources.

For plant genetic resources for food and agriculture, the International Treaty on Plant Genetic Resources (ITPGRFA) for Food and Agriculture of the Food and Agriculture Organization (FAO) requires in Article 1 the "*fair and equitable sharing of the benefits arising out of' their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security*".

"Access" has been defined by Article 1 of the Andean Community Decision 391 as "*the obtaining and use of genetic resources conserved in situ and ex situ, of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things*".

Biological Diversity

Article 2 of the CBD defines the term "biological diversity", often shortened to "biodiversity", as meaning the "*variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems*".

Biological Material

The term is defined in the European Union Directive on the legal protection of biotechnological inventions as "*material containing genetic information and capable of reproducing itself or being reproduced in a biological system*".[5]

According to the US Code of Federal Regulations, this term shall include "*material that is capable of self-replication either directly or indirectly*".[6]

The CBD uses the terms biological resources, genetic material and genetic resources.[7]

[5] Article 2.1(a) of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

[6] Section 1.801 of Chapter 37 of the Code of Federal Regulations (CFR) and USPTO Manual of Patent Examining Procedure (MPEP): 2403.01

[7] See below

Biological Resources

As defined in Article 2 of the CBD, this term "*includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity*". Genetic resources form, therefore, one category of biological resources.

Article 1 of the Andean Decision 391 defines the term as "*individuals, organisms or parts of them, populations or any biotic component of value or of real or potential use that contains a genetic resource or its by-products*".

Biotechnological Inventions

This term is defined in the European Union Directive on the legal protection of biotechnological inventions as "*inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used*".[8]

Biotechnological inventions fall into three categories: processes of the creation and modification of living organisms and biological material, the results of such processes, and the use of such results.[9]

Biotechnology

Article 2 of the CBD defines the term as "*any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use*".

According to the FAO's statement on biotechnology of 2000: "*Interpreted in this broad sense, the definition of biotechnology covers many of the tools and techniques that are commonplace in agriculture and food production. Interpreted in a narrow sense, which considers only the new DNA techniques, molecular biology and reproductive technological applications, the definition covers a range of different technologies such as gene manipulation and gene transfer, DNA typing and cloning of plants and animals*".[10]

The term "modern biotechnology" is also defined in Article 3 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which was adopted in 2000, as "*the application of: a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection*."

[8] Article 3.1 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July, 1998 on the legal protection of biotechnological inventions

[9] See document WIPO/GRTKF/IC/1/3, para. 16

[10] FAO Statement on Biotechnology, available at: http://www.fao.org/biotech/stat.asp

The Organization for Economic Cooperation and Development (OECD) uses a deliberately broad definition, covering all modern biotechnology but also many traditional or borderline activities. Biotechnology is "*the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services*" combined with a list of biotechnology techniques including *inter alia* the terms "*genetic engineering", "fermentation using bioreactor", "gene therapy", "bioinformatics" and "nanobiotechnology".*[11]

Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (Bonn Guidelines)

The Bonn Guidelines were adopted in 2002 by the Conference of Parties of the CBD in order to provide guidance in respect of implementation of relevant provisions under Articles 8(j), 10(c), 15 , 16 and 19 of the CBD related to access to genetic resources and benefit-sharing. The Guidelines are voluntary in nature and are addressed to a range of stakeholders[12]. They cover procedural and regulatory aspects, in particular, of prior informed consent, and identify monetary and non-monetary forms of benefit-sharing[13].

Clearing House Mechanism (CHM)

According to a glossary used by UNEP, the Clearing House Mechanism is a mechanism which facilitates and simplifies exchange of information or transactions among multiple Parties.[14]

The Clearing-House Mechanism of the CBD has been established further to Article 18.3 CBD. Its mission is to contribute significantly to the implementation of the Convention through the promotion and facilitation of technical and scientific cooperation, among Parties, other Governments and stakeholders.[15]

Convention on Biological Diversity (CBD)

An international convention adopted in June 1992 during the United Nations Conference on Environment and Development held in Rio de Janeiro, Brazil. According to Art. 1 of the CBD, the Convention aims at "*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*". It entered into force on December 29, 1993.

Country of Origin of Genetic Resources

According to article 2 of the CBD: "Country of origin of genetic resources" means "*the country which possesses those genetic resources in in-situ conditions*".

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[11] See definition and full list-based definition, available at: http://www.oecd.org/document/42/0,3343,fr_2649_34537_1933994_1_1_1_37437,00.html

[12] See Bonn Guidelines, Articles 1, 7(a) and 17 to 21

[13] See Bonn Guidelines, Articles 24 to 50 and Appendix II

[14] UNEP Glossary, available at: http://www.unep.org/dec/onlinemanual/Resources/Glossary/tabid/69/Default.aspx

[15] Further information available at: http://www.cbd.int/chm/

Other definitions include genetic resources in ex-situ conditions. For instance, country of origin is defined by article 1 of the Andean Community Decision 391 as a "*country that possesses genetic resources in in-situ conditions, including those which, having been in in-situ conditions, are now in ex-situ conditions*".

Country providing Genetic Resources

According to article 2 of the CBD: "Country providing genetic resources" means "*the country supplying resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country*".

Database of Biodiversity-related Access and Benefit-sharing Agreements

The WIPO Database of Biodiversity-related Access and Benefit-sharing Agreements is an electronic online collection of "*guide contractual practices, guidelines, and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing, taking into account the specific nature and needs of different stakeholders, different genetic resources, and different transfers within different sectors of genetic resource policy*".[16] As a capacity building tool, it aims to provide information resources for those seeking assistance on current practices relating to IP, access and benefit-sharing and genetic resources and, as an empirical basis, it aims to contribute to the development by WIPO of IP guidelines on access to genetic resources and benefit-sharing[17].

Defensive Protection

The term "defensive protection" refers to a set of strategies to ensure that third parties do not gain illegitimate or unfounded IP rights over traditional knowledge/traditional cultural expression subject matter and related genetic resources.[18]

Disclosure Requirements

Disclosure is part of the core rationale of patent law[19]. Patent law imposes a general obligation on patent applicants, as referred to in Article 5 of the Patent Cooperation Treaty (PCT), "*to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art*". However, "disclosure requirements" are recently used as a general term for reforms made to patent law at the regional or national level, and proposals to reform international patent law, which would specifically oblige patent applicants to disclose several categories of information concerning traditional knowledge and/or genetic resources when these are used in developing the invention claimed in a patent or patent application.[20]

Three broad functions have been considered for disclosure methods relating to genetic

[16] See document WIPO/GRTKF/IC/2/3 page 4 para. 2; the online database is available at: http://www.wipo.int/tk/en/databases/contracts/index.html

[17] See document WIPO/GRTKF/IC/17/INF/11

[18] See for example document WIPO/GRTKF/IC/5/12 para. 28, but also Committee documents on TK and TCEs

[19] See document WIPO/GA/32/8, Annex, page 32

[20] For further information see document WIPO/GRTKF/IC/16/6, Annex I, pages 7 to 11 and WIPO, TK Division, database on national and regional legislative measures in patent law, available at: http://www.wipo.int/tk/en/laws/genetic.html

resources and traditional knowledge:

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

- to disclose the actual source of the genetic resources/traditional knowledge (a disclosure function, relating to where the genetic resources/traditional knowledge was obtained) – this may concern the country of origin (to clarify under which jurisdiction the source material was obtained), or a more specific location (for instance, to ensure that genetic resources can be accessed, so as to ensure the invention can be duplicated or reproduced); and

- to provide an undertaking or evidence of prior informed consent (a compliance function, relating to the legitimacy of the acts of access to genetic resources/traditional knowledge source material) - this may entail showing that genetic resources/traditional knowledge used in the invention was obtained and used in compliance with applicable laws in the country of origin or in compliance with the terms of any specific agreement recording prior informed consent; or showing that the act of applying for a patent was in itself undertaken in accordance with prior informed consent.[21]

At the invitation of the CBD Conference of Parties (COP), the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has prepared a technical study on this issue, as well as an examination of issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, which have been made available to the CBD.[22]

Several proposals on an international level have been made at the WIPO IGC.

The Swiss proposal to introduce a disclosure requirement in the PCT applying to both international and national applications and requiring the patent applicants to disclose the source of genetic resources and/or traditional knowledge.[23]

The proposal made by the European Union and its Member States includes an obligation to implement a mandatory requirement to disclose the country of origin or source of genetic resources for all international, regional and national patent applications.[24]

Alternative mechanisms to disclosure requirements have been proposed.[25]

Another current international initiative for a disclosure requirement is the proposed Article 29*bis* of the WTO TRIPS Agreement propounded by a number of countries.[26]

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[21] See WIPO Technical Study on Patent Disclosure Requirements related to Genetic Resources and Traditional Knowledge, WIPO Publication No. 786(E), page 65

[22] WIPO Technical Study on Patent Disclosure Requirements related to Genetic Resources and Traditional Knowledge, WIPO Publication No. 786(E); WIPO/GA/32/8 ("Examination of Issues regarding the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications"), 2005

[23] See document WIPO/GRTKF/IC/11/10 (Swiss Proposal) and document WIPO/GRTKF/IC/16/6 Annex, page 13

[24] See document WIPO/GRTKF/IC/8/11 (EU Proposal) and document WIPO/GRTKF/IC/16/6 Annex, page 14

[25] See document WIPO/GRTKF/IC/9/13 (Alternative Proposal)

[26] See document TN/C/W/52

Ex-situ

Referring to the definition of "ex situ conservation" in Article 2 of the CBD, "ex situ" may be understood as "*components of biological diversity outside their natural habitats*".

Food and Agriculture Organization (FAO)

A United Nations specialized agency committed to defeating hunger and poverty at the international level. The Organization's mandate includes "*raising levels of nutrition, improving agricultural productivity, bettering the lives of rural populations and contributing to the growth of the world economy*" [27].

Genetic Material

Article 2 of the CBD defines the term "genetic material" as meaning "*any material of plant, animal, microbial or other origin containing functional units of heredity*".

Genetic Resources

Article 2 of the CBD defines the term "genetic resources" as "*genetic material of actual or potential value*." Further, it defines the term "genetic material" as meaning "*any material of plant, animal, microbial or other origin containing functional units of heredity*".

It has also been suggested that genetic material can be understood "*as material from any biological source where units of heredity are operating or having a function*".[28]

Article 1 of the Andean Decision 391 defines "genetic resources" broadly as "*all biological material that contains genetic information of value or of real or potential value*".

The FAO Glossary for Fisheries defines the term as "*germplasm of plants, animals or other organisms containing useful characters of actual or potential value. In a domesticated species it is the sum of all the genetic combinations produced in the process of evolution*".

Other legal instruments make reference to genetic resources using different terms:

Article 2 of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture defines "plant genetic resources" as "*any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity*".

Article 2 of the FAO International Code of Conduct for Plant Germplasm Collecting and Transfer defines plant genetic resources as "*the reproductive or vegetative propagating materials of plants*".

Article 2.1 (a) of the FAO International Undertaking on Plant Genetic Resources (1983) defines the term as "*the reproductive or vegetative propagating material of the following categories of plants: i) cultivated varieties (cultivars) in current use and newly developed*

[27] http://www.fao.org/about/mission-gov/en/

[28] See document UNEP/CBD/WG-ABS/9/INF/1 (The Concept of "Genetic Resources" in the Convention on Biological Diversity and how it relates to a functional international regime on access and benefit-sharing")

varieties; ii) obsolete cultivars; iii) primitive cultivars (land races); iv) wild and weed species, near relatives of cultivated varieties; and v) special genetic stocks (including elite and current breeders' line and mutants)". The International Undertaking did not refer to "functional units of heredity".

Other legal instruments on IP do not use the term and refer to "biological material". The European Union Directive on the legal protection of biotechnological inventions defines it as "*material containing genetic information and capable of reproducing itself or being reproduced in a biological system*".[29]

According to the US Code of Federal Regulations, biological material shall include "*material that is capable of self-replication either directly or indirectly*".

According to article 2 of the CBD, biological resources "*includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity*".[30]

In-situ

According to article 2 of the CBD: "In-situ conditions" means "*conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties*".

Intellectual Property Guidelines for Access and Benefit-sharing

From its first session, the IGC supported a task which would lead to the development by WIPO of Intellectual Property Guidelines for Access and Benefit-sharing. It was proposed that the Guidelines be based on a systemic survey of actual and model contractual agreements in the form of the WIPO Database of Biodiversity-related Access and Benefit-sharing Agreements[31].

A first draft[32] was prepared taking into account the operational principles identified by the IGC for the development of such Guidelines[33]. This draft was later updated for purposes of the seventeenth session of the IGC[34].

The purpose of the Intellectual Property Guidelines for Access and Benefit-sharing is to serve both providers and recipients of genetic resources when they negotiate, develop and draft the IP elements of mutually agreed terms for access to genetic resources and benefit-sharing. They illustrate the practical IP issues that providers and recipients are likely to face when negotiating an agreement, contract or licence. The diversity of national law and of the practical interests of providers and recipients are likely to lead to a wide range of choices when actual provisions are negotiated and drafted. Guidelines may

[29] See above on biological material

[30] See above

[31] See document WIPO/GRTKF/IC/2/3, para. 133; see above

[32] See document WIPO/GRTKF/IC/7/9 (Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-sharing)

[33] See operational principles in document WIPO/GRTKF/IC/2/3, Section V.B, page 50

[34] See document WIPO/GRTKF/IC/17/INF/12 (Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-sharing: Updated version)

therefore support providers and recipients in ensuring that access and benefit-sharing is on equitable, mutually agreed terms, but does not prescribe one template or set of choices.

Further, nothing in such Guidelines should be interpreted to affect the sovereign rights of States over their natural resources, including their entitlement to set terms and conditions on access and benefit-sharing. Guidelines would be voluntary and illustrative only. They would be no substitute for relevant international, regional or national legislation[35].

International Regime (IR) on Access and Benefit-sharing

The CBD is currently negotiating an International Regime on Access and Benefit-sharing. Paragraph 44 (o) of the Plan of Implementation adopted by the World Summit on Sustainable Development 2002 called for action to ·"*negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources*".

The seventh session of the Conference of the Parties (COP) decided "*to mandate the Ad Hoc Open-ended Working Group on Access and benefit-sharing with the collaboration of the Ad Hoc Open ended Inter-sessional Working Group on Article 8(j) and related provisions, ensuring the participation of indigenous and local communities, non-governmental organizations, industry and scientific and academic institutions, as well as intergovernmental organizations, to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions of Article 15 and Article 8(j) of the Convention and the three objectives of the Convention*".[36]

Since the ninth session of the Working Group on Access and Benefit-sharing in March 2010, the negotiations are based on a Draft Protocol of the IR scheduled to be adopted by COP 10 in October 2010.

Inventive Step

Inventive step (also referred to as "non-obviousness") is one of the criteria of patentability and relates to the question of whether the invention would have been obvious to a person having ordinary skill in the art[37].

According to article 33 of the PCT, a claimed invention shall be considered to involve an inventive step "*if, having regard to the prior art as defined in the Regulations, it is not, at the prescribed relevant date, obvious to a person skilled in the art*".

Article 56 of the European Patent Convention and Section 35 U.S.C. 103 provide for similar definitions. Section 35 U.S.C. 103 uses the equivalent term "non-obvious subject matter".

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[35] See document WIPO/GRTKF/IC/17/INF/12

[36] COP Decision VII/19

[37] WIPO Intellectual Property Handbook, WIPO Publication No. 489 (E), 2008, page 20

Licensing Agreements

Licensing agreements are described as agreements setting out certain permitted use of materials or rights that the provider is entitled to grant, such as agreements to license the use of genetic resources as research tools, or to license the use of associated traditional knowledge or other IP rights.[38]

Material Transfer Agreements (MTAs)

Material Transfer Agreements are agreements in commercial and academic research partnerships involving the transfer of biological materials, such as germplasm, microorganisms and cell cultures to exchange of materials from a provider to a recipient and setting conditions for access to public germplasm collections, seed banks or *in situ* genetic resources[39].

WIPO has developed the Database of Biodiversity-related Access and Benefit-sharing Agreements containing contractual clauses related to the transfer and use of genetic resources.[40]

The FAO has developed and adopted in 2006 a Standard Material Transfer Agreement (SMTA) as required for the implementation of the ITPGRFA.[41] Appendix I of the Bonn Guidelines suggests elements for material transfer agreements.

Minimum Documentation PCT

According to the WIPO PCT Glossary, the Minimum documentation could be described as "*The documents in which the International Searching Authority must search for relevant prior art. It also applies to International Preliminary Examining Authorities for examination purposes. The documentation comprises certain published patent documents and non-patent literature contained in a list published by the International Bureau. The Minimum Documentation is set out by the PCT Regulations Rule 34*".[42]

In the PCT International Search Guidelines, the international search minimum documentation is defined as "*a document collection that is systematically arranged (or otherwise systematically accessible) for search purposes according to the subject matter content of the documents, which are primarily patent documents supplemented by a number of articles from periodicals and other items of non-patent literature*".[43]

[38] See document WIPO/GRTKF/IC/17/INF/12

[39] See document WIPO/GRTKF/IC/17/INF/12

[40] Available at: http://www.wipo.int/tk/en/databases/contracts/index.html

[41] Available at: ftp://ftp.fao.org/ag/cgrfa/gb1/SMTAe.pdf

[42] Available at: http://www.wipo.int/pct/en/texts/glossary.html#M

[43] Para IX-2.1, PCT International Search Guidelines (as in force from 18 September 1998)

Mutually Agreed Terms (MAT)

Besides recognizing the authority of national governments to determine access to genetic resources, Article 15 of the CBD provides that "*access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article*".[44] The Executive Secretary of the CBD has noted that "*contracts are the most common way of recording "mutually agreed terms"*".[45] The Bonn Guidelines indicate some basic requirements for mutually agreed terms in Articles 41 to 44.

Novelty

Novelty is one of the criteria of patentability in any examination as to substance. An invention is new if it is not anticipated by prior art[46].

According to Article 33 of the PCT, novelty is defined as follows: "*For the purposes of the international preliminary examination, a claimed invention shall be considered novel if it is not anticipated by the prior art as defined in the Regulations*". Rule 64.1(a) of the Regulations under the PCT defines "prior art" as "*everything made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) shall be considered prior art provided that such making available occurred prior to the relevant date*".

Article 54 of the EPC defines "Novelty" as follows: "*An invention shall be considered to be new if it does not form part of the state of the art. 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 date of filing of the European patent application*".

Section 35 of the U.S.C.102 [Conditions for patentability; novelty and loss of right to patent] defines the concept of novelty as follows: "*A person shall be entitled to a patent unless — 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,* …".

Prior Art

Prior art is, in general, all the knowledge that existed prior to the relevant filing or priority date of a patent application, whether it existed by way of written and oral disclosure. In some legal instruments there is a differentiation between printed publications, oral disclosures and prior use and where the publications or disclosure occurred.[47]

For the purposes of the PCT, prior art is defined by Rule 33.1 of the PCT Regulations as "*everything 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 and that it does or 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*".

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[44] Article 15.4, CBD

[45] See document UNEP/CBD/COP/4/22, para. 32

[46] WIPO Intellectual Property Handbook, WIPO Publication No. 489 (E), 2008, page 19

[47] WIPO Intellectual Property Handbook, WIPO Publication No. 489 (E), 2008, page 19

In the case of Europe, Article 54(2) of the EPC defines the equivalent term "the state of the art" as comprising "*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*". With reference to this provision of the EPC, the *Guidelines for Examination in the European Patent Office* (EPO) emphasize that *"[t]he width of this definition should be noted. There are no restrictions whatever as to the geographical location where, or the language or manner in which the relevant information was made available to the public; also no age limit is stipulated for the documents or other sources of the information. However certain specific exclusions exist (see IV, 8)*".[48]

Section 35 of the U.S.C. 102 defines prior art indirectly through the concept of novelty as anything "*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, …*".

Section 29 of Japanese Patent Law indirectly defines "prior art" as "*(i)inventions that were publicly known in Japan or a foreign country, prior to the filing of the patent application; (ii) inventions that were publicly worked in Japan or a foreign country, prior to the filing of the patent application; or (iii) inventions that were described in a distributed publication, or inventions that were made publicly available through an electric telecommunication line in Japan or a foreign country, prior to the filing of the patent application*".

Prior and Informed Consent (PIC)

A right or principle of "*prior and informed consent*" (PIC) or sometimes "*free, prior informed consent*" (FPIC) is referred to or implied in several international instruments, particularly in the environmental field, such as Article 6(4) of the Basel Convention on the transboundary movement of hazardous wastes, 1989, and the CBD.

In respect to access to genetic resources, the CBD states in Article 15(5) CBD that it "*shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party*".

The WIPO draft provisions for the protection of traditional knowledge and traditional cultural expressions incorporate the principle of PIC for the beneficiaries of the protection, at Articles 7 and 3, respectively.

The notion was originally derived from medical ethics in which a patient has the right to decide whether or not to undergo a medical treatment after being fully informed about the risks and benefits of that particular treatment. For instance, the Universal Declaration on the Human Genome and Human Rights of 1997 states in Article 5 that in all cases of research, treatment or diagnosis affecting an individual's genome the potential risks and benefits should be assessed and "the prior, free and informed consent of the person concerned shall be obtained". Article 6 of the UNESCO Declaration on Bioethics and Human Rights of 2005 requires the "*prior, free and informed consent of the person concerned*" when it comes to "*preventive, diagnostic and therapeutic medical intervention*" or "*scientific research*".

[48] See *Guidelines for Examination in the European Patent Office*, Part C, Chapter IV, para 5.1

Providers and Recipients

Providers and recipients may include the government sector (e.g., government ministries, government agencies (national, regional or local), including those responsible for administration of national parks and government land); commerce or industry (e.g., pharmaceutical, food and agriculture, horticulture, and cosmetics enterprises); research institutions (e.g., universities, gene banks, botanic gardens, microbial collections); custodians of genetic resources and traditional knowledge holders (e.g. associations of healers, indigenous peoples or local communities, peoples' organizations, traditional farming communities); and others (e.g., private land owner(s), conservation group(s) *etc.*).[49]

Public Domain

In general, a work is considered to be in the public domain if there is no legal restriction for its use by the public.[50]

Black's Law Dictionary defines the public domain as "*[t]he universe of inventions and creative works that are not protected by intellectual-property rights and are therefore available for anyone to use without charge. When copyright, trademark, patent, or trade-secret rights are lost or expire, the intellectual property they had protected becomes part of the public domain and can be appropriated by anyone without liability for infringement*".[51]

The public domain has been defined in the field of copyright and related rights as "*the scope of those works and objects of related rights that can be used and exploited by everyone without authorization, and without the obligation to pay remuneration to the owners of copyright and related rights concerned – as a rule because of the expiry of their term of protection, or due to the absence of an international treaty ensuring protection for them in the given country*".[52]

In general, the public domain in relation to patent law consists of knowledge, ideas and innovations over which no person or organization has any proprietary rights. Knowledge, ideas and innovations are in the public domain if there are no legal restrictions of use (varying in different legislations and forming, therefore, different public domains), after expiration of patents (regularly 20 years), in consequence of non renewal, after revocation and after invalidation of patents.[53]

The role, contours and boundaries of the "public domain" are under active discussion in several forums, including in WIPO and this Committee. Document WIPO/GRTKF/IC/7/INF/8 discusses the meanings of the "public domain" in relation to TK and TCEs further.[54]

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[49] See document WIPO/GRTKF/17/INF/12

[50] See document SCP/13/5

[51] Black's Law Dictionary 1027 (8th ed. 2005)

[52] WIPO publication "Guide to the Copyright and Related Rights Treaties by WIPO and Glossary of Copyright and Related Rights Terms"

[53] See document SCP/13/5

Source of genetic resources

In its proposal "Declaration of source of genetic resources and traditional knowledge in patent applications" Switzerland proposed to require patent applicants to declare the "source" of genetic resources and traditional knowledge. It stated that "*the term 'source' should be understood in its broadest sense possible*", since "*a multitude of entities may be involved in access and benefit-sharing. In the foreground to be declared as the source is the entity competent (1) to grant access to genetic resources and/or traditional knowledge or (2) to participate in the sharing of the benefits arising out of their utilization. Depending on the genetic resource or traditional knowledge in question, one can distinguish: primary sources, including in particular Contracting Parties providing genetic resources*[55]*, the Multilateral System of FAO's International Treaty*[56]*, indigenous and local communities*[57]*; and secondary sources, including in particular ex situ collections and scientific literature*". [58]

[End of Annex and of document]

[54] See document WIPO/GRTK/IC/17/INF/8 "Note on Meanings of the Term 'Public Domain' in the Intellectual Property System, with Special Reference to the Protection of Traditional Knowledge and Traditional Cultural Expressions/Expressions of Folklore"

[55] See Articles 15, 16 and 19 of the CBD

[56] See Articles 10-13 of the ITPGRFA

[57] See Article 8(j) of the CBD

[58] See document WIPO/GRTKF/IC/11/10