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GENETIC RESOURCES: DRAFT INTELLECTUAL PROPERTY GUIDELINES FOR ACCESS AND EQUITABLE BENEFIT-SHARING: UPDATED VERSION

Document prepared by the Secretariat

I. 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") "invited the Secretariat to prepare and make available for the next session of the Committee […] as an information document, an updated version of document WIPO/GRTKF/IC/7/9 ("Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing")".[1]

2. The present information document is the updated version of document WIPO/GRTKF/IC/7/9. In preparing this updated version, the document has also been streamlined where possible to enhance its accessibility. In the interests of keeping the present document as concise and current as possible:

   – the cover document of the present document summarizes relevant background information, essentially reproducing the contents of the cover document of document WIPO/GRTKF/IC/7/9, with minimal editorial changes to reflect more recent developments and to update and streamline its content; and

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

- the Annex comprises the updated draft Guidelines, which incorporate various examples of actual and model contractual clauses contained in the WIPO database of sample contracts and received from Member States in response to questionnaires WIPO/GRTKF/IC/Q.2 and WIPO/GRTKF/IC/Q.6[2]; the sampling of intellectual property-related clauses is for illustration only and exemplifies how intellectual property aspects of access to genetic resources and benefit-sharing have been addressed in existing agreements; they are provided without any claim to be exhaustive, representative or complete; and
- the Appendixes to the Annex contain, in Appendix I, a list of monetary and non-monetary benefits as contained in the Bonn Guidelines and, in Appendix II, a list of actual and model contractual agreements for access to genetic resources and benefit-sharing referred to in the present document.

3. The remainder of this cover document describes the Substantive Context within which the draft Guidelines have been prepared (Part II), introduces the International Policy Context in which the Draft Guidelines should be framed including, in particular, the policy processes of the Convention on Biological Diversity (CBD) and the Food and Agriculture Organization of the United Nations (FAO) (Part III), briefly reviews the Previous Work of the Committee on this matter (Part IV), and outlines how this document was prepared and is structured (Part IV).

II. SUBSTANTIVE CONTEXT

4. Since its inception, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore has worked towards guidelines on the intellectual property (IP) aspects of mutually-acceptable terms in agreements that concern access to genetic resources and the equitable sharing of benefits from the use of accessed resources. This work has been aimed at producing a resource, to alert custodians of genetic resources to the practical issues that arise when they elect to enter into agreements on access and benefit-sharing. The Committee's work has been based on an empirical survey of experience in this field, and a database collecting actual terms of agreements. As a first step, the Committee agreed on a set of guiding principles to frame this work, then oversaw the collection and analysis of practical experience in this area, and considered a draft set of guidelines (WIPO/GRTKF/IC/7/9, submitted to the seventh session in November 2004).

5. Genetic resources can provide an important input for research and the development of new products, in an increasingly broad range of technological and industrial sectors. The terms and conditions of access to those genetic resources, the exercise of prior informed consent by the providers of genetic resources, and the resulting arrangements made for the sharing of benefits from their use and development are critical issues. Existing international law and a number of regional, national and sub-national laws and regulations set the framework for exercising prior informed consent and determining the terms and conditions of access, as well as benefit-sharing. Key elements of international law include the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) of the Food and Agricultural

[2] For further information on actual and model agreements referred to and contained in the Database of Biodiversity-related Access and Benefit-sharing Agreements, see WIPO/GRTKF/IC4/10, WIPO/GRTKF/IC/5/9 and WIPO/GRTKF/IC/17/INF/11 and http://www.wipo.int/tk/en/databases/contracts/index.html. Obvious type errors in these agreements were corrected and minor editorial changes made in order to increase the accessability

Organization (FAO). The CBD, adopted in 1992, provides an international framework for access and benefit-sharing for genetic resources. The ITPGR, adopted in 2001, covers plant genetic resources for food and agriculture (PGRFA) and established a multilateral system of access and benefit-sharing for certain PGRFA. In conformity with the access and benefit-sharing provisions of these international instruments, national regimes have been developed to regulate access to genetic resources. Within access and benefit-sharing agreements, the specific arrangements made for IP management can be crucial in ensuring that they operate to create benefits from access to genetic resources, and in particular to ensure that those benefits are shared equitably and the interests and concerns of the resource providers are fully respected.

6. The important role of IP practices and clauses within contractual arrangements for access to genetic resources and benefit-sharing has been widely recognized in most genetic resource policy processes. It is a specific requirement in a number of regional instruments and of several national laws which have already been considered by the Committee[3], as well as the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* ("Bonn Guidelines") adopted by the Conference of Parties of the CBD. The sixth CBD COP encouraged WIPO to "make rapid progress in the development of model intellectual property clauses which may be considered for inclusion in contractual agreements when mutually agreed terms are under negotiation".[4] This Draft Intellectual Property Guidelines in the Annex aim to heed and complement the international policy context of genetic resources policy making processes.

7. Within access and benefit-sharing agreements, the specific arrangements made for IP management can be crucial in ensuring that they operate to create benefits from access to genetic resources, and in particular to ensure that those benefits are shared equitably and the interests and concerns of the resource providers are fully respected. IP issues that can be determined in agreements include the entitlement to seek IP rights in inventions and other results of research using the resources, ownership and licensing of such derivative IP, responsibility for maintaining and exercising IP rights. Some commentators have pointed to the limitations of contracts as a means of defining and governing relationships in relation to the access and use of genetic resources. However, since this approach is already widely used in the field, and is required under many national genetic resource regulations, stakeholders have called for guidelines on the IP aspects of contracts concerning access and benefit-sharing.

III. INTERNATIONAL POLICY CONTEXT

8. The main intergovernmental processes and fora in which policy frameworks on access and benefit-sharing have been developed include the CBD and the FAO[5].

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[3] In particular, see the detailed discussion in document WIPO/GRTKF/IC/5/9, Section IV

[4] See decision VI/24

[5] For further information see document WIPO/GRTKF/IC/7/9

Convention on Biological Diversity (CBD)

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

9. In April 2002, the sixth meeting of the Conference of the Parties of the CBD adopted, as part of its Decision VI/24, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.[6] The Guidelines are meant to assist Parties to the CBD when developing and drafting legislative, administrative and policy measures on access and benefit-sharing, and also when developing contracts and other arrangements under mutually agreed terms for access and benefit-sharing[7].

International Regime on Access and Benefit-sharing

10. The World Summit on Sustainable Development (WSSD)[8] adopted a Plan of Implementation which 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".[9] The ninth meeting of the Conference of the Parties (COP 9) of the CBD in May 2008 set a comprehensive work program for the next two years, with the goals of adopting an international regime on access and benefit sharing (ABS) referring to genetic resources, and carrying out further work on traditional knowledge associated to genetic resources questions concerning Article 8(j) and related articles of the CBD. The international regime on ABS is currently being negotiated on the basis of a draft protocol for possible adoption at COP 10.

Food and Agriculture Organization of the United Nations (FAO)

International Treaty on Plant Genetic Resources for Food and Agriculture

11. In order to address the characteristics of plant genetic resources for food and agriculture (PGRFA), governments negotiated within the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA) the International Treaty on Plant Genetic Resources for Food and Agriculture. This Treaty has established a Multilateral System of Access and Benefit-Sharing (MLS) for PGRFA and entered into force on June 29, 2004. Article 12.4 on facilitated access to PGRFA within the MLS provides that facilitated access shall be provided pursuant to a standard material transfer agreement. In its Resolution 1/2006 of

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[6] See Decision VI/24A, Annex

[7] The Bonn Guidelines, when addressing mutually-agreed terms for access and benefit-sharing, make the following references to the possible role of IP in contractual arrangements for access to genetic resources and benefit-sharing: Contractual agreements can include the provision for the use of IP rights, including joint research, obligation to implement rights on inventions obtained and to provide licenses by common consent, and the possibility of joint ownership of IP rights, according to the degree of contribution; consideration should be given in any Material Transfer Agreement to whether IP rights may be sought, and if so under what conditions and whether any property rights, including IP rights, may be assigned or transferred; monetary benefits may include, but not be limited to: payment of royalties, license fees in case of commercialization; and joint ownership of relevant IP rights; non-monetary benefits may include joint ownership of relevant IP rights

[8] The WSSD took place in Johannesburg in September 2002

[9] See WSSD Plan of Implementation, para 44 (o)

16 June 2006, the Governing Body of the ITPGRFA adopted the Standard Material Transfer Agreement (SMTA). Several Research Centers are operating under the MLS.[10]

International Code of Conduct for Plant Germplasm Collecting and Transfer

12. A component of the Global System on PGRFA[11] which refers to access and benefit-sharing contracts is the FAO International Code of Conduct for Plant Germplasm Collecting and Transfer (1993).[12] The Code was adopted by the 1993 FAO Conference as a voluntary instrument providing a framework which governments may use in developing national regulations or formulating agreements for the collection of germplasm. In 2009 the Commission on Plant Genetic Resources for Food and Agriculture asked the FAO Conference to revise the Code[13].

IV. PREVIOUS WORK OF THE COMMITTEE

13. At its first session in April 2001, the Committee supported a Task which would lead to "the development of 'guide contractual practices' … 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".[14] When considering this Task, the Committee decided to take a two-step approach to the development of the Guide Contractual Practices.[15]

14. The first stage of this approach was "a systemic survey of actual contractual agreements" in the form of an online database[16]. Document WIPO/GRTKF/IC/2/3 identified possible operational principles for IP clauses of contractual agreements concerning access to genetic resources and benefit-sharing. Further, a study of IP and genetic resources licensing was based on a widely circulated survey (questionnaire WIPO/GRTKF/IC/Q.2) to secure information about relevant contracts and licenses. The responses received to the questionnaire were incorporated into a pilot, on-line database of contractual agreements relating to IP, access to genetic resources and benefit-sharing[17] and subsequent amendments were made to the electronic database available in three

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[10] The International Agricultural Research Centers of the Consultative Group on International Agricultural Research (CGIAR) have the mission "to reduce poverty and hunger, improve human health and nutrition, and enhance ecosystem resilience through high-quality international agricultural research, partnership and leadership". On October 16, 2006, eleven International Agricultural Research Centres (IARCs) of the CGIAR which *hold ex situ* germplasm collections signed agreements with the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture placing the collections they hold under the Treaty. See http://www.cgiar.org/impact/genebanksdatabases.html

[11] http://www.fao.org/nr/cgrfa/cgrfa-global/cgrfa-globplan/en

[12] http://www.fao.org/nr/cgrfa/cgrfa-global/cgrfa-codes/en

[13] See document CGRFA 12/09/Report paras 28 and 29

[14] Task A.1, WIPO/GRTKF/IC/1/3 paras 35 to 41; see also WIPO/GRTKF/IC/1/13

[15] The two-step approach was described as follows: first, "a complete and systematic survey of IP clauses could be undertaken ... [Second,] once existing access and benefit-sharing agreements have been compiled through the survey, the variables and principles identified [by the Committee members] may be applied for the development of guide practices and model IP clauses, based on the existing practices and clauses." (WIPO/GRTKF/IC/2/3, para 134)

[16] See WIPO/GRTKF/IC/2/3, para 133

[17] Based on a proposal set out in document WIPO/GRTKF/IC/3/4 and approved by the Committee at its third session

languages.[18] The WIPO Contracts Database demonstrated a broad divergence in the approaches taken to the identification and management of IP issues in this area[19]. In the fourth session, the Secretariat reported on this activity in document WIPO/GRTKF/IC/4/10 to illustrate current practices relating to contracts or licenses concerning IP and genetic resources.

15. At its fifth session, document WIPO/GRTKF/IC/5/9 reported on further updating of the contracts database to a fully operational and comprehensive version and analyzed the empirical data contained in the contracts database for further development of guidelines, best practice and other guidance on IP aspects of contracts.[20]

16. At its sixth session, the Committee considered draft guidelines provided in the Annex to document WIPO/GRTKF/IC/6/5 ("Draft Intellectual Property Guidelines for Access and Benefit-Sharing Contracts") and a number of delegations provided comments on them. The document built on information gathered and principles agreed or identified in the first five sessions of the Committee, in order to advance the task of developing guide contractual practices. It applied those principles in the form of draft Guide Contractual Practices.

17. At its seventh session, document WIPO/GRTKF/IC/7/9 progressed to the second stage by furthering the "principles identified [by Committee members] applied for the development of guide practices", based on the four principles considered at its second session. The Committee was invited to note and comment upon the content of the document, the identified operational principles for the development of the Guide Contractual Practices, the possible distillation of model contractual provisions, and the annexed update to the draft Guide Contractual Practices, and to consider the options for future work including those identified in paragraphs 40 to 42, above.[21] A number of

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[18] See WIPO/GRTKF/IC/4/10, paras. 13 to 15

[19] The WIPO Contracts Database contained several contracts and licenses. The key IP-related issues that arise in these contractual arrangements can be broken down as follows: IP (general); Patents; Licensing; Plant Breeders' Rights; Copyright ; Trade Secrets; Distinctive Signs; Assignment; Confidentiality; Ownership; for a detailed analysis of the data contained in the WIPO Contracts Database, see document WIPO/GRTKF/IC/5/9

[20] See document WIPO/GRTK/IC/5/9 para 2 and Annex making reference to 16 model agreements and 13 actual agreements

[21] See WIPO/GRTKF/IC/7/9 paras 40 to 42: "IP aspects of contractual agreements for access to genetic resources and benefit-sharing have been a significant focus of the Committee's work on IP and genetic resources. The present document builds on information gathered and principles agreed or identified in the first five sessions of the Committee, in order to advance the task of developing guide contractual practices. It applies those principles in the form of draft Guide Contractual Practices which are contained in the Annex to the present document. The next steps in the Committee's work could be undertaken at three levels: developing the operational principles; developing model provisions such as those encouraged in the CBD COP decision; and, revising and further elaborating the draft Guide Contractual Practices. During its discussion at its seventh session, Committee members may wish to comment further upon the operational principles already identified, with a view to developing them, and could comment on the first draft of the Guide Contractual Practices contained in the Annex of this document. On the basis of this discussion, a revised set of operational principles may be considered for future elaboration or adoption by the Committee. A further revision of the draft guidelines could be developed on the basis of further input received at the seventh session, as well as further comments, input and examples provided to the Secretariat before February 28, 2005. Such guidelines may be consistent with a more general framework for the Committee's work, and could be produced without prejudice to the nature and legal status of the overall outcomes of the Committee. Some of the additional principles identified in earlier Committee discussions have not been addressed in the draft Guide Contractual Practices, because they may entail specific policy decisions or other developments. For example, the proposal that a 'special tribunal be established to

comments were made on the contents of document WIPO/GRTKF/IC/7/9 expressing support for the future work as proposed in paragraph 43 of the document. A number of delegations expressed strong opposition to the future work proposed in paragraph 43 of the document and to the contractual approach detailed in the document, and stated that this activity would inevitably detract from other work of the Committee, particularly considering the difficult financial situation of the organization. The Chair concluded at this session that there was no consensus on the future work of the Committee in this area and suggested that no decision should be taken at this session but that it should be kept on the agenda for the eighth session of the Committee.[22]

18. At the eighth session of the Committee, which took place in June 2005, work on the Draft Guidelines was reported on in document WIPO/GRTKF/IC/8/9. The Committee noted this and other documents on the genetic resources agenda item, and "further took note of the diverse views expressed on this issue." At the ninth session (April 2006) and the tenth session (November 2006) of the Committee, the Committee similarly considered reports on the Draft Guidelines but no substantive decisions were taken by the Committee.

19. At its eleventh session, document WIPO/GRTKF/IC/11/8(a), commissioned at the tenth session, proposed further options for continuing work on IP and genetic resources. In option IX of the cover document it proposed "considering options for stakeholder consultations on and further elaboration of the draft guidelines for contractual practices contained the Annex of document WIPO/GRTKF/IC/7/9" and in its Annex under "options for possible activities on IP and mutually agreed terms for fair and equitable benefit-sharing" in option C.2 that "based on the additional information available and included in the Database, the Committee might wish to consider to further develop the guide contractual practices contained the Annex of document WIPO/GRTKF/IC/7/9[23]".

20. The list of options on genetic resources including the option of further elaborating the Draft Intellectual Property Guidelines for Access and Equitable Benefit-sharing was reiterated in documents WIPO/GRTKF/IC/12/8(a) and WIPO/GRTKF/IC/13/8(a) in the twelfth (February 2008) and thirteenth (October 2008) sessions of the Committee, as well as in the revised version of document WIPO/GRTKF/IC/11/8(a) prepared and published in document WIPO/GRTKF/IC/16/6 Prov. The revised list of options prepared for the sixteenth session in document WIPO/GRTKF/IC/16/6 proposed in its Annex option C.2 [Draft guidelines for contractual practices] "considering options for stakeholder consultations on and further elaboration of the draft guidelines for contractual practices contained in the Annex of document WIPO/GRTKF/IC/7/9, based on the additional information available and included in the online database".

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adjudicate issues surrounding contracts for access to genetic resources and benefit-sharing' could be in part met by the development of tailor-made alternative dispute resolution procedures, taking account of the specific nature of disputes concerning IP aspects of genetic resources. This could be in line with the proposal, tabled by the Asian Group and China, that 'WIPO should study possibilities of offering alternative dispute resolution services, including but not limited to arbitration and mediation, which are particularly appropriate for the problems involving intellectual property issues related to traditional knowledge and folklore.'"

[21] Document WIPO/GRTKF/IC/6/6 (paras 62 to 64) discusses this issue more generally. The Committee may wish to consider this possibility in relation to genetic resources, including the possibility of a role for the WIPO Arbitration and Mediation Center

[22] See WIPO/GRTKF/IC/7/15 para 201

[23] See WIPO/GRTKF/IC/5/9; WIPO/GRTKF/IC/6/5; WIPO/GRTKF/IC/7/9

21. At its sixteenth session, in May 2010, the Committee requested the Secretariat to prepare this current update of the Draft Guidelines and update the WIPO Database of Biodiversity-related Access and Benefit-sharing Agreements currently online. Following this decision, the Secretariat circulated a questionnaire to Member States and observers (WIPO/GRTKF/IC/Q.6). Following this request, the Secretariat received several questionnaires, actual and model agreements, and seven model as well as further guidelines and other information resources on activities in this field. The material was received with the understanding that it could also contribute to the updated version of document WIPO/GRTKF/IC/7/9. Information on updating of the database and material received is contained in document WIPO/GRTKF/IC/17/INF/11 ("Note on Updating of WIPO's Online Database of Biodiversity-related Access and Benefit-sharing Agreements").

V. PRINCIPLES ESTABLISHED BY THE COMMITTEE FOR GUIDE CONTRACTUAL PRACTICES

22. At its second session, the Committee had identified and considered a set of draft principles for the development of Guide Contractual Practices which found broad support[24]. In addition to commenting on the four principles identified in document WIPO/GRTKF/IC/2/3, the Committee members also identified certain additional possible principles. The operational principles were identified in document WIPO/GRTKF/IC/2/3 as follows:

Principle 1: The IP-related rights and obligations set out in the Model IP clauses should recognize, promote and protect all forms of formal and informal human creativity and innovation, based on, or related to, the transferred genetic resources.

Principle 2: The IP-related rights and obligations set out in the Guide Contractual Practices should take into account sectorial characteristics of genetic resources and genetic resource policy objectives and frameworks.

Principle 3: *The IP-related rights and obligations set out in the Guide Contractual Practices should ensure the full and effective participation of all relevant stakeholders and address process issues related to contract negotiation and the development of IP clauses for access and benefit-sharing agreements, including in particular traditional knowledge holders where traditional knowledge is covered by the agreement*.

Principle 4: The IP-related rights and obligations set out in the Guide Contractual Practices should distinguish between different kinds of use of genetic resources, including commercial, non-commercial and customary uses.

23. These principles and comments received upon are reflected in the draft Intellectual Property Guidelines for Access and Equitable Benefit-sharing, contained in the Annex to this document. The following paragraphs summarize the comments provided on the four proposed principles by Committee members and reproduced additional principles identified by the Committee:

[24] See WIPO/GRTKF/IC/2/3, Section V.B, page 50ff. and see Chair's conclusions (WIPO/GRTKF/IC/2/16, para 96)

Principle 1: The IP-related rights and obligations set out in the Model IP clauses should recognize, promote and protect all forms of formal and informal human creativity and innovation, based on, or related to, the transferred genetic resources.

24. This principle reflects three parameters of the draft Guide Contractual Practices:

(a) the draft Guide Contractual Practices are limited to IP-specific elements of contractual agreements for access and benefit-sharing.[25] All other aspects lie outside WIPO's mandate and are left to the relevant fora and processes, while fully taking into account the legal frameworks and policy guidance which those fora and processes have produced;

(b) the draft Guide Contractual Practices reflect one of the basic objectives of IP, namely to promote human innovation and creativity, and the dissemination and application of its results, in particular the equitable sharing of benefits from access to and use of genetic resources;

(c) the forms of innovation and creativity based on genetic resources which are recognized by the draft Guide Contractual Practices include both formal and informal innovations, [26] and this accordingly entails respect for traditional knowledge (TK) associated with genetic resources.

25. A broad range of Committee members expressed support for this principle.[27] In deliberating on this principle, Committee members made the following comments on its appropriate application:

- the application of the principle should be without prejudice to the legal protection that had to be given to the providers of the genetic resource, the State and its communities;[28]
- if applied indiscriminately, the principle might be too wide;[29]
- the application should take into account that genetic resources in the form in which they existed in nature, and mere discoveries, did not qualify for the recognition of IP rights;[30]
- existing IP agreements should be used as guidance for defining the limits of IP systems;[31]
- the application should involve a clearer use of the terms "creativity" and "innovation", in particular the terms 'formal' and 'informal' innovation;[32] and
- the application should take into account possible *sui generis* protection of TK and genetic resources.[33]

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[25] See European Community and its Member States (WIPO/GRTKF/IC/2/16, para 75)

[26] For the definitions of the terms 'informal innovation' and 'formal innovation' in a genetic resource context, see WIPO/GRTKF/IC/1/3, para 9

[27] See in general document WIPO/GRTKF/IC/2/16

[28] See Ecuador (WIPO/GRTKF/IC/2/16, para 55)

[29] See Chair's conclusions (WIPO/GRTKF/IC/2/16, para 96)

[30] See Ecuador (WIPO/GRTKF/IC/2/16, para 55), United States of America (WIPO/GRTKF/IC/2/16)

[31] See United States of America (WIPO/GRTKF/IC/2/16, para 74)

[32] See Canada (WIPO/GRTKF/IC/2/16, para 77), China (WIPO/GRTKF/IC/2/16, para 82), Bolivia, Cuba, Dominican Republic, Ecuador, Panama, Nicaragua, Peru and Venezuela (WIPO/GRTKF/IC/2/3, para 56), Morocco (WIPO/GRTKF/IC/2/16, para79) and Switzerland (WIPO/GRTKF/IC/2/16, para 83)

[33] See South Africa (WIPO/GRTKF/IC/2/3, para 80)

All the comments which were provided by Committee members have been taken into account when applying Principle 1 in the development of the draft Guide Contractual Practices in the Annex.

Principle 2: *The IP-related rights and obligations set out in the Guide Contractual Practices should take into account sectorial characteristics of genetic resources and genetic resource policy objectives and frameworks.*

26. This principle foresees that the Guide Contractual Practices would take into consideration the sectorial genetic resource policy objectives and frameworks which have been, or are being, developed in the relevant international fora. These objectives and frameworks are taken into account while ensuring that patent rights shall be available without discrimination as to the place of invention or the field of technology and whether products are imported or locally produced. The principle rests, *inter alia*, on the fact that Committee members have decided that the work of the Committee should be consistent with the work of the CBD and the FAO.[34] It takes account of general principles, guidelines and concepts which have been developed by the relevant fora for access and benefit-sharing. For example, in the case of contracts concluded in the context of the Multilateral System of Access and Benefit-sharing, which will be established under the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGR), the parties would be acting not only in their private interests, but in that of the international community. Furthermore, the Member States suggested since the first session of the Committee that "it would … be important to include prior informed consent in contractual arrangements".[35] Moreover, the guide contractual practices would be consistent with and reflective of current contractual and commercial practices within those genetic resource sectors.

27. At the second session, the Chair concluded that this Principle had found "broad support".[36] In deliberating on this principle, the Committee members made the following comments regarding its appropriate application:

- the application of this principle should be consistent with the interests of the international community as reflected in the major international treaties on genetic resources, such as the CBD and ITPGR;[37]
- the application should provide adequate guidance for the fulfillment of requirements to disclose the source of genetic material used in patented inventions;[38]
- the definitions provided for the application of this principle should also include the term "derivatives";[39]
- the application should cover prior informed consent (PIC) for access to the concerned genetic material;[40] and,

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[34] 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 and 155

[35] See document WIPO/ GRTKF/IC/1/13, paragraph 106.

[36] See WIPO/GRTKF/IC/2/16, para 96

[37] See Ecuador (WIPO/GRTKF/IC/2/16, para 55)

[38] See Bolivia (WIPO/GRTKF/IC/3/17, para 37), Brazil (WIPO/GRTKF/IC/2/16, para 59), Peru (WIPO/GRTKF/IC/3/17, para 37), Venezuela (WIPO/GRTKF/IC/3/17, para 33)

[39] See Brazil (WIPO/GRTKF/IC/3/17, para 40).

- the application of this principle should be without prejudice to, but should take account of, discussion regarding implementation of the ITPGR.[41]

Principle 3: *The IP-related rights and obligations set out in the Guide Contractual Practices should ensure the full and effective participation of all relevant stakeholders and address process issues related to contract negotiation and the development of IP clauses for access and benefit-sharing agreements, including in particular traditional knowledge holders where traditional knowledge is covered by the agreement.*

28. This principle would provide for the full and effective participation of all relevant stakeholders in the development of IP clauses of the access and benefit-sharing agreement. Through this principle, the guide contractual practices would address "process" dimensions of the development of IP clauses for access and benefit-sharing contracts. This would imply, in particular, that indigenous peoples, local communities and other TK holders should be fully involved in contractual agreements for bioprospecting activities, if their TK is being utilized. Associated TK will often be intrinsically linked to the genetic resources themselves, and access to the genetic resources may be linked with access to the associated TK. As pointed out by Committee members, this principle could be attained through the simplicity of the Guide Contractual Practices and the provision of detailed commentary in clear and practical language. Committee members expressed general support for draft principle 3.[42] In deliberating on this principle, Committee members made the following comments on its appropriate application:

- the Guide Contractual Practices should include a detailed commentary;[43]
- the Guide Contractual Practices should be written in simple everyday language;[44]
- the Guide Contractual Practices should further specify the terms "relevant stakeholders" and "TK holders";[45]
- the Guide Contractual Practices should aim to promote the effective participation of indigenous and local communities;[46]
- the Guide Contractual Practices should take into account prior informed consent requirements that may apply to genetic resources;[47]
- the Guide Contractual Practices should cover all stakeholders;[48] and
- the Guide Contractual Practices should recognize the intrinsic limitations of contracts, as parties involved might not be in the same negotiating position.[49]

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[40] See Brazil (WIPO/GRTKF/IC/2/16, para 59), Peru (WIPO/GRTKF/IC/3/17, para 37), Bolivia (WIPO/GRTKF/IC/3/17, para 37)

[41] See Norway (WIPO/GRTKF/IC/2/16, para 72)

[42] E.g. Brazil (WIPO/GRTKF/IC/2/16, para 59), Canada (WIPO/GRTKF/IC/2/16, para 77), China (WIPO/GRTKF/IC/2/16, para 82), Ecuador (WIPO/GRTKF/IC/2/16, para 55), Morocco (WIPO/GRTKF/IC/2/16, para 79), United States of America (WIPO/GRTKF/IC/2/16,
para 74), the Saami Council (WIPO/GRTKF/IC/2/16, para 91)

[43] See Ecuador (WIPO/GRTKF/IC/2/3, para 55)

[44] See Ecuador (WIPO/GRTKF/IC/2/3, para 55)

[45] See China (WIPO/GRTKF/IC/2/16, para 82)

[46] See Ecuador (WIPO/GRTKF/IC/2/3, para 55)

[47] See Ecuador (WIPO/GRTKF/IC/2/3, para 55)

[48] See Asian Group (WIPO/GRTKF/IC/2/16); United States of America (WIPO/GRTKF/IC/2/16, para 74)

[49] See Brazil (WIPO/GRTKF/IC/2/16, para 59), INADEV (WIPO/GRTKF/IC/2/16, para 88)

Principle 4: The IP-related rights and obligations set out in the Guide Contractual Practices should distinguish between different kinds of use of genetic resources, including commercial, non-commercial and customary uses.

29. According to this principle, the Guide Contractual Practices would distinguish between different uses of genetic resources and would provide specific IP considerations for different categories of uses of the transferred resource. One of the aspects integrated under this principle would be to enable and ensure continued customary use of genetic resources by the customary users of the resources in the local context. While the Chairman concluded at the second session that this Principle had received "broad support", it was also "questioned if Principle 4 on the distinction between various kinds of use had any independent importance".[50] While the Chair summarized that "both the bioprospecting scenario and the public sector conservation and breeding scenario should be included",[51] some Committee members commented that the Guide Contractual Practices should focus on basic research, rather than commercial research.[52] Thus the precise modalities of applying this principle may require some further qualification and elaboration by the Committee Members. Even so, the distinction between commercial and non-commercial usage has been made in many laws and agreements (some definitions of bioprospecting refer, for example, to the commercial potential of genetic resources and associated TK), and a number of laws refer specifically to the need to protect and respect continuing customary uses of genetic resources. Accordingly, these distinctions have been found important in practice.

Additional Possible Principles Identified by Committee Members:

30. Besides the above-mentioned principles, the Chair concluded from the deliberations of the Committee at its second session that "[a]dditional principles, such as those included in the CBD and flexibility and simplicity, should be taken into account."[53] In particular, the Committee members identified the following possible additional principles:

- the Guide Contractual Practices should be non-binding,[54] flexible[55] and simple;[56]
- the Committee's work on the Guide Contractual Practices should be without any prejudice to, and closely coordinated with, the work of the CBD and FAO;[57]

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[50] See Chair (WIPO/GRTKF/IC/2/16, para 96)

[51] See Chair (WIPO/GRTKF/IC/2/16, para 96)

[52] See United States of America (WIPO/GRTKF/IC/2/16, para 74)

[53] See Chair (WIPO/GRTKF/IC/2/16, para 96)

[54] See Canada (WIPO/GRTKF/IC/2/16, para77), China (WIPO/GRTKF/IC/2/16, para82), Colombia (WIPO/GRTKF/IC/2/16, para 58), European Community and its Member States (WIPO/GRTKF/IC/2/16, para 75), Indonesia (WIPO/GRTKF/IC/2/16, para 63), Japan (WIPO/GRTKF/IC/2/16, para 76), New Zealand (WIPO/GRTKF/IC/2/16, para 73), Peru (WIPO/GRTKF/IC/2/16, para 69), Switzerland (WIPO/GRTKF/IC/2/16, para 83), United States of America (WIPO/GRTKF/IC/2/16, para 74), BIO (WIPO/GRTKF/IC/2/16, para 92), ICC (WIPO/GRTKF/IC/2/16, para 95), Chair (WIPO/GRTKF/IC/2/16, para 54 and 96)

[55] See Canada (WIPO/GRTKF/IC/2/3, para 77), USA (WIPO/GRTKF/IC/2/3, para 74)

[56] See European Community and its Member States (WIPO/GRTKF/IC/2/16, para 75), United States of America (WIPO/GRTKF/IC/2/16, para 74)

[57] See Ecuador (WIPO/GRTKF/IC/2/16, para 55), European Community and its Member States (WIPO/GRTKF/IC/2/16, para.75), Morocco (WIPO/GRTKF/IC/2/16, para 79), Peru (WIPO/GRTKF/IC/2/16, para 69), Singapore (WIPO/GRTKF/IC/2/16, para 66), Switzerland (WIPO/GRTKF/IC/2/16, para 83), Turkey (WIPO/GRTKF/IC/2/16, para 67)

- the IP rights and obligations set out in the Guide Contractual Practices should reflect the requirements of Prior Informed Consent which may apply to genetic resources;[58]
- the Guide Contractual Practices should recognize the sovereign rights of Member States over their genetic resources;
- the Guide Contractual Practices should provide for terms on access to and transfer of technology as established in the CBD;[59] and
- the Guide Contractual Practices should foresee the possibility of a special tribunal established to adjudicate issues surrounding contracts for access to genetic resource and benefit-sharing.[60]

31. The Committee is invited to take note of this document and, in particular, the Draft Intellectual Property Guidelines for Access and Equitable Benefit-sharing contained in the Annex.

[Annex follows]

[58] See (WIPO/GRTKF/IC/1/13, para. 106), Ecuador (WIPO/GRTKF/IC/2/3, para 55), Bolivia, Cuba, Dominican Republic, Ecuador, Panama, Nicaragua, Peru, and Venezuela (WIPO/GRTKF/IC/2/3, para 56)

[59] Algeria (WIPO/GRTKF/IC/2/3, para 78), Bolivia, Cuba, Dominican Republic, Ecuador, Panama, Nicaragua, Peru, and Venezuela (WIPO/GRTKF/IC/2/3, para 56), Venezuela (WIPO/GRTKF/IC/2/3, para 57)

[60] See INADEV (WIPO/GRTKF/IC/2/16, para 88)

ANNEX

DRAFT INTELLECTUAL PROPERTY GUIDELINES FOR ACCESS AND EQUITABLE BENEFIT SHARING

EXECUTIVE SUMMARY

International legal standards require that prior informed consent applies to access to genetic resources, and benefits from the utilization of genetic resources are shared equitably. Intellectual property (IP) issues arise as one element of this broader framework on access and equitable benefit-sharing.

Several options exist on how to manage IP issues and options so as to ensure prior informed consent and equitable benefit-sharing:

- these include choices variously to avoid IP rights and to transfer genetic resources subject to agreement not to take out certain IP rights;
- to vest IP rights in the custodian of the genetic resources or to jointly own such IP rights; or
- to give rights derived from the use of the resources to the user, subject to various conditions and safeguards, such as rights to receive benefits such as royalties and other payments, access to benefits of research, involvement in community-based development initiatives, contribution to various forms of appropriate social and economic development, and reporting and disclosure obligations.

Practical experience has shown a common need to understand the full range of options which have been taken by custodians, so as to strengthen the decisions of custodians of genetic resources about the best course to take to safeguard and promote their interests.

These draft guidelines are not intended to promote any particular choice to use IP rights, or to avoid their use, in the context of access and equitable benefit-sharing. These guidelines draw on reported experience from a range of stakeholders to illustrate the range of choices and thereby to enhance the practical information available to stakeholders assessing their options when considering access and benefit-sharing.

Some stakeholders have expressed concern about the use of IP rights in this context; others have used an array of mechanisms to identify their interests and to structure the benefit-sharing arrangements. In some cases, genetic resources are provided for research and evaluation only, with a requirement to negotiate further IP terms subsequently.

Any access and benefit-sharing arrangements should conform with the existing international framework – which is essentially set by the aforementioned legal instruments concerning genetic resources and by national legislation – not IP law in isolation. The present draft guidelines are therefore only supplementary and background materials and should not preclude any outcomes or developments in other fora, nor should they be used to interpret or limit rights and obligations within this framework.

These draft Guidelines provide practical information for providers and recipients of genetic resources and relevant policy and legal information. The present document introduces into the context of agreements on access and equitable benefit-sharing (Part I), sets out the main ideas behind the guidelines in its general provisions (Part II) and identifies the main preliminary steps for IP negotiations (Part III). In its main part, it develops the specific IP issues (Part IV) including overall IP issues (A), specific IP rights and issues (B) as well as

licensing issues (C). Further, it refers to Model IP Clauses (Part V) and adds some considerations for developing sectoral approaches (Part VI).

I. INTRODUCTION

When can these guidelines be used?

1. These draft guidelines provide background information for those who are considering whether, and how, to grant access to genetic resources which they own, control or have custody of. Negotiating and granting access to genetic resources, for research or commercial uses, can raise IP questions. Agreements reached on practical management of IP can influence the overall results of access to genetic resources, and how benefits arising from the access are created and shared equitably: this includes the decision of whether to use IP rights at all, and if so under what conditions. Yet access and benefit-sharing occur within a broader legal framework, and IP issues are only one component of the full range of practical and legal questions that may need to be addressed – in fact, IP issues do not arise at all in some access and benefit-sharing scenarios. So these guidelines should be seen only as supplementary and subordinate to the general principles and legal regimes that cover access and benefit-sharing for genetic resources. These guidelines have informal status only, and do not offer authoritative legal advice nor set a policy direction. They draw on practical experience in a very wide range of access and benefit-sharing scenarios, and provide illustrations of issues that have actually arisen in practice and the various approaches taken to resolving them.

What are genetic resources, traditional knowledge and intellectual property?

2. These draft guidelines are for general reference, so no precise definitions are intended, and the use of terms is not intended to have any legal effect. Contracts or agreements can settle on their own definitions of key terms, with reference, for instance, to the customary laws of indigenous and traditional communities. The definitions included in these guidelines may clarify the range of relevant subject matter for purposes of these draft guidelines.

   (a) The Convention on Biological Diversity (CBD) of 1992 defines *genetic resources* as ‘genetic material of actual or potential value’. It defines *genetic material* as ‘any material of plant, animal, microbial or other origin containing functional units of heredity’. Similarly, the Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food an Agriculture (ITPGR) of 2001 defines *plant genetic resources for food and agriculture* as ‘any genetic material of plant origin of actual or potential value for food and agriculture’ and defines *genetic material* as ‘any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity.’ This means material that contains the means for passing on characteristics from an ancestor to a descendent through reproduction, or allowing the entire organism to be reproduced. Samples of plants, cells, microbes and other materials can contain valuable genetic information that is useful in research and development – this includes modern biotechnology and genetic engineering, but can be just as important in the creation of products based on natural

extracts, the conventional breeding of new plants, and the use of genetic materials such as bacteria in industrial processes, in such traditional industries as baking and brewing, but also in new applications such as mineral processing and environmental management.

(b) "Traditional Knowledge" has no agreed international definition. TK "refers to the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources."[61] One general way of characterizing TK is knowledge which is:

- generated, preserved and transmitted in a traditional and intergenerational context;
- distinctively associated with the traditional or indigenous community or people which preserves and transmits it between generations; and
- integral to the cultural identity of an indigenous or traditional community or people which is recognized as holding the knowledge through a form of custodianship, guardianship, collective ownership or cultural responsibility. This relationship may be expressed formally or informally by customary or traditional practices, protocols or laws.[62]

"Traditional" and "tradition-based" refer to knowledge systems, creations, innovations which: have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and, are continually evolving in response to a changing environment. This does not mean that TK needs to be old, ancient or lacking in innovation, and there are many TK systems that are living, contemporary traditions in spite of their ancient roots.

(c) "Intellectual property" in one international definition includes "the rights relating to literary, artistic and scientific works, performances of performing artists, phonograms, and broadcasts, inventions in all fields of human endeavor, scientific discoveries, industrial designs, trademarks, service marks, and commercial names and designations, protection against unfair competition, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields."[63] Actual access and benefit sharing agreements or contracts may choose to define the scope of relevant "intellectual property" in a more limited way, consistent with the aims of the agreement.

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[61] Article 3 of the Protection of Traditional Knowledge: Revised Objectives and Principles. (WIPO/GRTKF/IC/17/5).

[62] Article 4 of the Protection of Traditional Knowledge: Revised Objectives and Principles. (WIPO/GRTKF/IC/17/5).

[63] Article 2(viii) of the WIPO Convention.

What is benefit-sharing and prior informed consent?

3. Genetic resources can provide an important input for research and the development of new products and processes, in an increasingly broad range of technological and industrial sectors. TK is often associated with genetic resources, and this can provide valuable insights into how genetic resources can be preserved, maintained, and used for the benefit of humanity. This leads to concern that when genetic resources are obtained or accessed for research or commercial purposes, the benefits from any research, development and commercial use should be fairly and equitably shared with the providers of the resources, and access to resources should be subject to the prior informed consent of the providers.

4. International legal regimes, and many national laws, have been developed to deal with these concerns, in particular since the negotiation of the CBD. They set a comprehensive framework for exercising prior informed consent and for arrangements for access and benefit-sharing including negotiated licenses, contracts or agreements. Typically, a provider of a resource (such as an indigenous community, a government agency, a research institution, or the owner of land on which the resource is exists) reaches an agreement with a resource user (such as a researcher or a company that wants to use the genetic resources.) Such agreements can refer to the intended use of the resources, any restrictions on the use, and the way any benefits resulting from the resource are managed and shared. An agreement or contract can be the practical expression of the *prior informed consent* that international standards require as the legal basis for access to genetic resources. Such agreements generally operate in line with other laws regulating the environment, public resources, indigenous and community rights and regional development, as well as general contract and property law. At the national, regional and community level, a range of laws, regulations and policies implement this framework, and govern directly how genetic resources are accessed and used. These regimes deal with many other issues apart from IP questions.

What is the role of IP in access and benefit-sharing?

5. The arrangements made for managing IP can be important in ensuring that an access agreement actually creates benefits from access to genetic resources, shares those benefits equitably, and respects the interests and concerns of the resource providers. When research is done on genetic resources, this can result in inventions that can be eligible for IP rights such as patents. Therefore, IP management in an access and benefit sharing agreement can greatly influence the degree to which the access provider and the resource recipient can achieve their goals and serve their mutual interests.

What are the typical IP issues to be managed?

6. Issues dealt with in agreements include the entitlement to seek IP in inventions and other results of research using the resources, ownership and licensing of any such derivative IP, responsibility for maintaining and exercising IP rights, and the arrangements for distributing any financial or other benefits resulting from this derivative IP. Agreements can also require the recipient of the resource to report on any IP that is applied for, and similar developments. Some agreements make access conditional on not seeking IP rights on the material received.

What is the scope of these draft guidelines in respect to genetic resources?

7. These draft guidelines are limited in scope, and only intended to provide information and guidance about intellectual property aspects of access to genetic resources. In contrast to the main elements of law and practical guidance relating to access to genetic resources in general, these guidelines provide supplementary and secondary information only. These guidelines are intended to provide practical information and support for those who choose to negotiate terms of access to genetic resources. However, they are limited to IP aspects only, and they are an adjunct and an aid, to be used as a resource, rather than stand-alone guidelines to negotiating and concluding contracts and agreements on access and benefit-sharing. Further, nothing in the draft 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.

What methodology has been used to develop these draft guidelines?

8. These draft guidelines draw on a wide range of inputs, based on practical experience, in line with the requirements established by the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the Committee). These include inputs from WIPO's Member States and from other stakeholders in response to questionnaires circulated under the authority of the Committee. The sample clauses contained in these guidelines as examples are meant to illustrate current licensing practices and are taken from model and actual agreements reported on in previous documents and updated by new submissions. They do not have any normative value but show different options for possible IP clauses.

What is the relationship to other instruments and forums?

9. The guidelines take into consideration the work of relevant international agreements and institutions such as the CBD, the FAO ITPGR, the FAO Code of Conduct on Germplasm Collection, and the recommendations of the World Summit on Sustainable Development ("WSSD") held in Johannesburg in September 2002 in relation to the need to develop practical measures to promote and safeguard the fair and equitable sharing of benefits arising from the use of genetic resources and associated TK, innovations and practices. While the guidelines takes into account these legal and policy frameworks, nothing in the guidelines shall prejudice the further evolution and implementation of these frameworks, or be construed as an interpretation of relevant instruments or a contribution to their implementation. In particular:

   – the CBD is developing an international regime governing the use of genetic resources, and this will be an important legal and practical consideration for providers and users of genetic resources;

   – the FAO ITPGR has developed a Standard Material Transfer Agreement (SMTA) concerning the plant genetic resources covered by that treaty.

II. GENERAL PROVISIONS

Who could use these draft guidelines?

10. These draft guidelines may 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. They describe some approaches that have been taken in practice, but do not seek to pre-determine actual choices on these approaches. The diversity of national law and of the practical interests of providers and recipients is likely to lead to a wide range of choices when actual provisions are negotiated and drafted. These guidelines may therefore support providers and recipients, but does not prescribe one template or set of choices.

What is the nature of these draft guidelines?

11. The draft guidelines are voluntary and illustrative only. They are no substitute for relevant international, regional or national legislation. They only concern the IP aspects of access and benefit-sharing, being supplementary and subordinate to the wider laws and policies that govern ownership, access and use of genetic resources.

What are the general conditions set by the CBD?

12. One general principle established under the CBD is that 'access [to genetic resources], where granted, shall be on mutually agreed terms' and 'shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.' Mutually agreed terms and prior informed consent provide the basic legal framework for access and benefit sharing for genetic resources under the national sovereignty of the many countries adhered to the CBD. Within this framework, drawing up a contract, agreement or licence is one way of expressing the 'mutually agreed terms'. The choice of terms is generally not significant in itself but whether the agreement is a general expression of intent, or is legally binding and under what jurisdiction it has effect.

What are the general conditions for legally binding agreements according to contract law?

13. In general, the terms and conditions of the contract, agreement or license relating to access to genetic resources define the purpose and permitted uses of the accessed resources, including the benefits that the provider is to receive from the recipient. In essence, a contract is a promise or undertaking containing generally mutual obligations of the provider and recipient that can be enforced by law. In some cases, a national law on genetic resources might specifically require that the provider and recipient agree on an access contract – and in that case, the law might lay down particular conditions that the contract or agreement has to comply with[64]. Even if there is no specific law for access and benefit-sharing, a contract is likely to be governed by general background laws such as the law of contracts and

[64] See document WIPO/GRTKF/IC/5/9, Section IV; e.g. Brazilian Provisional Measure No. 2.186-16, of August 23, 2001

competition law. For example, under many national laws of contract, a contract or agreement cannot be enforced if it has been obtained by coercion against the will of either party, or through deception or fraud.

How to negotiate the nature and terms of individual agreements?

14. These draft guidelines illustrate the various approaches that have been taken in agreeing on IP-related terms for access and benefit-sharing, but only as a general starting point. In any particular transaction and collaboration, the nature and terms of a contract can be tailored to fit the needs of the two partners to create an optimal partnership. In any event, in any potentially legally binding relationship, all parties should normally seek expert advice, with experience in the relevant national legal system (or systems), which can:

(a) Confirm that the agreement properly reflects the underlying access project or research relationship; and,

(b) Clarify whether the rights and obligations are reasonable, fair and legal, and whether and how obligations under the agreement can be enforced if necessary.

Such individual advice cannot be obtained from a consideration of the model or actual agreements of other institutions or organizations; the more the specific relationship under development is taken as the starting point for contractual negotiations (rather than other agreements developed in other contexts), the more likely that the resulting agreement will be workable and mutually beneficial.

Need for additional expert legal advice

15. These draft guidelines cannot substitute for specialized legal advice. Prior to entering into any legally binding contractual arrangement setting out mutually agreed terms of access to genetic resources and benefit-sharing, all contracting parties should seek expert legal advice. This is especially important for resource providers who may have limited access to legal advice – effective availability of expert legal advice, including on IP issues, may be one important aspect of ensuring that access is based on prior informed consent. In particular, Indigenous and local communities should draw on the possibility of getting expert legal advice for indigenous matters.

III. PRELIMINARY AND BASIC STEPS FOR THE NEGOTIATIONS

16. It is important to prepare negotiations in advance and parties may consider some of the following indicative and illustrative preliminary steps and factors of negotiations to enhance a mutually agreeable and practically workable agreement. Negotiations concerning access to genetic resources should aim to identify and promote the mutual interests of the two parties to the agreement – provider and recipient – so that the agreement captures and expresses a common understanding of shared interests and objectives. In some negotiations involving parties with diverse backgrounds, the identification of interests can entail building respect, trust and understanding for the values and cultural backgrounds. This applies as well to settling the IP provisions within an agreement. Before

negotiations or discussions occur between a provider of genetic resources and a potential recipient seeking access to the genetic resource, both parties should seek to understand and acknowledge the legitimate interests and objectives of the other party. Then they should aim in the negotiations to find an approach to IP issues that promotes the common interests of the two parties. The final understanding reached must be good for both parties if it is to form the basis for a lasting, beneficial relationship and mutual trust.

A. STEP 1: CONSIDERING A PRELIMINARY CONFIDENTIALITY AGREEMENT

17. Potential recipients and providers may enter into a preliminary confidentiality agreement to explore potentially common interests and to conduct the assessment of resources. If they then identify mutual interests, a separate access and benefit-sharing agreement may then be negotiated. That subsequent agreement could address ownership of IP rights currently existing or that arise in the future, rights to license the IP, and benefit-sharing arising out of any licensing agreement. Preliminary confidentiality agreements are important to protect confidential information during the assessment and negotiations.

B. STEP 2: DEVELOPING A SHARED UNDERSTANDING

18. One key to an equitable and enduring partnership, and appropriate provisions concerning IP, is a shared understanding of the value of the contributions that are made by each party – on the one hand, the value of genetic resources (and eventually associated TK) that are being provided and, on the other hand, the value of research, development, risk management and investment that is involved in the use of the resource. Each party may need to understand the limitations of their contributions to the potential arrangement, as well as the valuable attributes of their contributions. It will be helpful, for instance, for both parties to recognize the different expectations and perceptions of value that each brings to the discussions.

Evaluation and understanding of the situation of the provider

19. A recipient of genetic resources and associated TK may need to understand that the value of a genetic resource or insight into the workings of biological material (including traditional knowledge) may not be limited to monetary value. What is viewed by the recipient in simple terms as a raw input for research may be seen by the custodian and provider as a vital part of their heritage, cultural identity and spirituality. The resource and TK, for instance, may be associated with spiritual or cultural values of the provider that cannot easily be defined in economic terms or within a brief time-frame. Genetic resources may be the result of many generations of conservation, selection and development by indigenous and local communities. If the resource provider is a government body, a public agency or a community, broader public interests - e.g. sustainable resource management, environmental protection, social equity, appropriate grass-roots development and technology transfer – are likely to be valued more highly than more immediate technological or commercial goals. Non-monetary and longer-term benefits may be preferred over short-term or monetary benefits.

20. Understanding of the value and use of genetic resources, and associated TK, from the perspective of the public and community interests of the provider, may be the key to reaching an equitable agreement on IP. Indigenous communities and scientists working in academic institutions alike may have committed years, decades or a lifetime of work to arrive at the genetic resource or insight into a particular biological component. Both the resource and the knowledge of its present utility may have developed over generations. The following Sample Clause 1 exemplifies how the recognition of value could be reflected in the agreement:

> Sample Clause 1: Recognition of value of research material
>
> "*This Research Material represents a significant investment on the part of provider, and is considered proprietary to provider, recipient's investigator therefore agrees to retain control over this Research Material, and further agrees not to transfer the Research Material to other people not under her or his direct supervision without advance written approval of provider*".[65]

21. One element of the evaluation of the contribution of provider will be whether the provider is giving access to traditional knowledge increasing the chances of a valuable invention. Such contribution should be evaluated carefully.

Evaluation and understanding of the situation of the recipient

22. A provider of genetic resources will also benefit in negotiations from recognizing and understanding the way a potential recipient may evaluate the resources and associated TK. The factors that may be used include:

(a) *alternative source* factor: what alternative sources exist for the material of interest and what are the costs and conditions of access through those alternative sources?

(b) *proximity to market* factor – the cost, in time, money, and scientific or personnel resources, of R&D investments needed to fashion a product that might be saleable;

(c) *risk of technical failure* factor – what are the prospects for arriving at a revenue producing product from a scientific standpoint?

(d) *risk of regulatory preclusion* factor – what are the prospects for and costs of obtaining regulatory approval to market a final product?

(e) *alternative investment opportunity* factor - do other investment opportunities exist that offer greater returns or fewer risks?

(f) *authority to consent* factor - is the provider in a position to give prior informed consent, and is consent also required from other parties or government authorities?

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[65] Model Material Transfer Agreement (MTA) of the Korean Research Institute of Bioscience and Biotechnology, Clause 6

Both parties to recognize and understand these different perspectives can increase the likelihood that expectations will be reasonable and that relationships will form that contribute to positive outcomes.

Mutual understanding of situation and expectations of each party

23. Reaching agreement on the value and level of contribution of each party to the access and benefit-sharing arrangement will be vital in ensuring an equitable and effective outcome. There is a wide range of potential factors to be discussed and weighed when assessing the relative contribution of the various parties for a mutual understanding. For example, is a bare resource being provided, or is there considerable associated TK which provides an important lead for researchers? Could associated TK contribute so directly and so significantly to an invention based on the resource that the TK provider is actually a co-inventor? Is the user of the resource expected to invest heavily in research and development, or is the commercial or technological use of the resource already proven in principle with little additional investment required? What kind of products are intended to result from the research and development – for instance, simple reagents for further research, finished medical products, or industrial materials? Do the genetic resources contribute directly to the finished products, or do they provide one indirect input? Is the value of the genetic resource proven and well established, or is its potential unclear? Should there be an agreement to return to the issue once the actual value of the resource and its potential applications are better known? For an example, see Sample Clause 2:

Sample Clause 2: Mutual understanding

"*DTP/NCI has an interest in investigating plants, terrestrial and marine microorganisms and marine macro-organisms from [Source Country], and wishes to collaborate with the [Source Country Organization ("SCO")] in this investigation. DTP/NCI will make sincere efforts to transfer knowledge, expertise, and technology related to drug discovery and development to [SCO] in [Source Country] (as the agent appointed by the [Source Country] Government), subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology. [SCO], in turn, desires to collaborate closely with the DTP/NCI in pursuit of the investigation of [Source Country]'s terrestrial plants, marine macro-organisms and microorganisms, and selected synthetic compounds subject to the following conditions and stipulations of this Memorandum of Understanding (MOU)*".[66]

C. STEP 3: PRIOR INFORMED CONSENT

24. The need for prior informed consent from the appropriate individuals and institutions should also be accounted for. For potential users of genetic resources, this includes ensuring legal compliance with any access and benefit-sharing regimes that national governments, local authorities or local custom have established. Detailed guidelines for such prior informed consent procedures have been spelled out in the Bonn Guidelines and are contained in several guidelines

[66] Memorandum of Understanding between [Source Country Organization] and the Developmental Therapeutics Program, preamble

and model agreements[67]. For an example of a model prior informed consent application, see Sample Clause 3:

Sample Clause 3: Prior Informed Consent Application

"*(Date) (Name and address of the PIC-provider) Dear (.....),*
According to article 15 of the Convention on Biological Diversity (CBD) stating that «the authority to determine access to genetic resources rests with the national governments and is subject to national legislation » and that «Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention », as well that «access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources »; and, as ratified by (Name of the Country where one wants to access MGRs), I would like to get access to (Name of the field survey area), as well as to its genetic resources, more specifically samples or isolates from (name or description of group of plant, animal or microbial resources), with your prior informed consent (PIC), during the period and under the conditions specified in annex (copy of MTA if any; copy of authorisation of third party if any). (Name, address and signature of the PIC-applicant)".[68]

D. STEP 4: REVIEWING RESOURCES AND SETTING GOALS

25. Before engaging in negotiations on access and benefit-sharing, a provider of genetic resources and associated TK may need to identify and review systematically the assets it can potentially offer. This assessment may result in an inventory, which could separately account for physical resources and knowledge resources. The legal regimes governing physical resources and knowledge resources may differ, and their legal status are usually distinct, from both IP and valuation standpoints. The assessment could be supplemented by an analysis of the relevant international, regional and national laws and regulations, including any *sui generis* legislation on the protection of TK and, where applicable, relevant customary laws in those countries where IP rights may be developed and exploited.

Inventory process and potential IP outcomes

26. The inventory process should assist the resource provider to identify the aims and objectives of the intended access, and the uses to which the genetic resources and related information (including TK) may be put. It may also identify what the provider does not want to give access to, or what resources could be held in reserve for possible later access, if the partnership develops successfully. The potential IP outcomes of such uses can then be broken down into individual components. This should ensure that, right from the start, the specific IP implications of any access and use have been identified and that, subsequently, any IP rights and benefits arising from the exploitation of those resources can be properly apportioned and managed. This creates an opportunity for the access

[67] For an example, see Micro-Organisms Sustainable Use and Access Regulation International Code of Conducted (MOSAICC), Updated September 2009, Section 1.1, available at: http://bccm.belspo.be/projects/mosaicc/docs/code2009.pdf

[68] MOSAICC, September 2009, *op.cit.*, page 23

provider to identify and achieve broader goals. For instance, this might entail obliging the recipient through the access contract to disclose the origin of genetic resources in patents resulting from the use of the resources, or restricting permitted use to activities compatible with the cultural values of the provider, or ensuring third party access to research results for non-commercial uses or for use in developing countries.

E. STEP 5: CONSIDERING DIFFERENT FACTORS AFFECTING AGREEMENTS

27. In practice, there are many different scenarios involving access to and use of genetic resources and associated TK. These different factors will affect the elements of agreements. Access and benefit-sharing scenarios can differ in terms of:

(a) *Legal jurisdictions and particular national laws applicable* which may govern the contractual relationship between the parties. This is in line with the sovereign rights of States over their natural resources recognized under the CBD, and the principle that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. An analysis of the relevant international, regional and national laws and regulations, including any *sui generis* legislation on the protection of TK and, where applicable, relevant customary laws in those countries where IP rights may be developed and exploited may be a supplementary tool to consider the factors which will affect the agreement.

(b) *Providers and recipients:* These 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 TK 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.*) For an example, see Sample Clause 4:

Sample Clause 4: Definition of Provider and Recipient

"*PROVIDER: Organization providing the ORIGINAL MATERIAL. The name and address of this party will be specified in an implementing letter. […]*
RECIPIENT: Organization receiving the ORIGINAL MATERIAL. The name and address of this party will be specified in an implementing letter".[69]

(c) *Genetic resources:* this may embrace a wide range of genetic materials, of plant, animal or microbial origin: genetic material may have clear actual value; its potential value may be high; its value may be untested or uncertain; or it may have unforeseen, surprising or unpredictable uses and values in different sectors; individual agreements may include other

[69] Uniform Biological Material Transfer Agreement, dated March 8, 1995 for the Transfer of Materials between Non-Profit Institutions and an Implementing Letter for the Transfer of Biological Material

materials as defined by the scope of agreement. For examples of different approaches, see Sample Clauses 5 and 6:

Sample Clause 5: Scope of material

"*Scope of Agreement. This Agreement applies to the use, handling, sale, distribution and any disposition of the Material, Replicates, and Derivatives. For the purpose of this Agreement, "Material" means any material or portion thereof shipped to the Purchaser. For the purpose of this Agreement, "Replicates" means any biological or chemical material that represents a substantially unmodified copy of the Material. Replicates include but are not limited to material produced by growth of cells or microorganisms or amplification of Material. For the purpose of this Agreement, "Derivative" means material created from the Material that is substantially modified to have new properties*".[70]

Sample Clause 6: Scope of material

"*'Genetic Resource(s)'* means material of non-human animal, plant or microbial origin containing functional units of heredity".[71]

(d) *Agreed or licensed uses of the genetic material and associated TK:* this may define certain uses which are specifically not permitted, or may define conditions governing certain uses, or both: this may range over commercialization (including realizing the market potential of the genetic material and/or TK); research with a commercial objective (in the pharmaceutical, food and agriculture, horticulture, cosmetics and other industries); or scientific or academic research only; it may include research, selection and development for food and agriculture (in particular within the framework of the FAO ITPGR). Sample Clause 7 gives an example of an agreed and licensed use:

Sample Clause 7: Agreed or licensed use of genetic material

"*Subject to the terms and conditions of this agreement and any statutory, regulatory or other restriction imposed by law or any third party interest, recipient may use the material in any lawful manner for academic research, teaching or quality control purposes. Any commercial use of the material requires the prior written authorization of the provider. Such approval will not be unreasonably withheld*".[72]

(e) *Time frames* within which a particular contract or license may operate: This may set an absolute limit for the licensed use, or establish a timetable for the licensed use, with certain milestones that should be met, and subsequent obligations (such as an agreement to negotiate further terms in the event, for instance, that a product is approved for commercialization).

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[70] Material Transfer Agreement, American Type Culture Collection (ATCC), Art.1.

[71] Model Material Transfer Agreement (MTA) of the Biotechnology Industry Organization (BIO).

[72] Model Transfer Agreement (MTA): Terms and Conditions of limited non-exclusive license model agreement to use genetic material of the Culture Collection of Dairy Microorganisms (CCDM) of the Czech Republic, Crop Research Institute (CRI), Clause 5

For an example of time frames set by a model project, see Sample Clause 8:

Sample Clause 8: Time Frames

"*The Hania plant (Withania Somnifera) material will be taken from natural habitat of Karimabad for R&D pupopses for 5 years and commercial purposes for next 20 years with permission of the local government , if any. … After expiration of 25 years the botanical garden will be sole property of local government alongwith all its moveable and immoveable property*".[73]

28. Such factors will affect the basic elements of the contract, but will also define and shape the way in which any IP issues are dealt with in a contractual relationship. In some scenarios, there may be no role at all for IP rights. However, an initial agreement may concentrate on non-IP related issues of benefit-sharing, such as research cooperation, evaluation of resources, training and education and technology transfer, and the parties may agree to negotiate a separate commercialization package (including agreement on ownership of IP, right to license the IP, benefit-sharing arising out of any licensing agreement, etc.) at a later date, once initial research leads to commercial possibilities. Alternatively, IP rights may have a role to play right from the start of a partnership, often as an integral part of a specific benefit-sharing package, with identifiable short, medium and long-term returns. Finally, IP rights may be incorporated into a distinct series of licensing terms and conditions that reach beyond the field of access and benefit-sharing, and embrace the wider legal and working relationship of the parties.

F. STEP 6: CONSIDERING DIFFERENT TYPES OF AGREEMENTS

29. In practice, negotiators are normally advised to think first about the practical arrangement or partnership that they want to enter into, and then to think about how that arrangement should be expressed in legal terms. This is often more effective than limiting the range of cooperation and sharing of benefits to a pre-existing model. Earlier agreements and precedents can be used as guidance on the options, without pre-determining the actual choices made by the provider and recipient in any scenario. For illustration, contractual scenarios relevant to genetic resources range over the following broad categories. Many actual agreements are, in fact, a combination of several of these categories, depending upon the individual circumstances of the collaboration. The following types of agreements may provide guidance:

(a) *Letters of Intent or Heads of Agreement* recording preliminary agreement on the overall framework of a proposed collaboration, including any commercial arrangements that may apply, and to ensure that the future negotiations on the details of a contract or license have a solid basis of understanding. For an example of a letter of intent setting a preliminary framework agreement

[73] Model project on "Genetic Modification of hyaluronidase inhibitor glycoprotein (WSG) in the roots of Withania Somnifera (Hania plant) for Anti Vanum Treatment" between the Astra Zeneca (Medicine Company), UK, the National Institute of Health (NIH),Islamabad and the Local Government, Karimabad (Hunza Valley, Pakistan)

between a recipient and a provider on plant screening as a basis for further negotiation on possible commercial applications, see Sample Clause 9:

Sample Clause 9: Letter of Intent

"*Letter of Collection*
The Developmental Therapeutics Program ("DTP"), Division of Cancer Treatment and Diagnosis ("DCTD"), National Cancer Institute ("NCI") is currently investigating plants, microbes, and marine macro-organisms as potential sources of novel anticancer and AIDS-antiviral drugs. … While investigating the potential of natural products in drug discovery and development, NCI wishes to promote the conservation of biological diversity, and recognizes the need to compensate [Source Country, SC] organizations and peoples in the event of commercialization of a drug developed from an organism collected within their borders.
As part of the drug discovery program, DTP has contracts with various organizations for the collection of plants, microbes and marine macro-organisms worldwide. DTP has an interest in investigating plants, microbes and marine macro-organisms from [Source Country], and wishes to collaborate with the [Source Country Government ("SCG") or Source Country Organization(s) ("SGO")] as appropriate in this investigation. The collection of plants, microbes, and marine macro-organisms will be within the framework of the collection contract between the NCI and the NCI Contractor ("Contractor") which will collaborate with the appropriate agency in the [SCG or SCO]. The NCI will make sincere efforts to transfer knowledge, expertise, and technology related to drug discovery and development to the [appropriate Source Country Institution ("SCI")] in [Source Country] as the agent appointed by the [SCG or SCO], subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology. The [SCG or SCO], in turn, desires to collaborate closely with the DTP/NCI in pursuit of the investigation of its plants, microbes and marine macro-organisms, subject to the conditions and stipulations of this agreement". [74]

(b) *Confidentiality or Non-Disclosure Agreements* requiring the recipient of information to keep it confidential, such as information concerning source of genetic resources, associated TK or know-how, which may be used in gaining access to genetic resources for evaluation purposes, developing a research collaboration, or as a condition of employment; such agreements frequently limit the purposes for which such information can be used – depending on the circumstances, this may include limiting its use to evaluation, research, or non-commercial purposes, or limiting it to certain agreed purposes. See Sample Clause 10 on non-disclosure of confidential information including TK and Sample Clause 11 on confidentiality on information relating to patents).

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

Sample Clause 10: Non-disclosure Agreement

"*The confidential information including all intellectual property such as, traditional knowledge, practices etc shall remain the property of disclosing Party, even after the verification by recipient. The recipient agrees to hold all confidential Information in trust and confidence, both during and after the term of this agreement and agrees not to disclose to any person, firm or corporation, company subject specialist and / or use such confidential information in any manner*".[75]

Sample Clause 11: Confidentiality Agreements:

"*Company agrees not to disclose any portion of the Application(s) to any third party without prior written permission from PHS, shall use reasonable care to maintain the confidentiality of the Application(s) with at least the same degree of care as is exercised in respect of Company's own proprietary information, and shall disclose the Application(s) only to those of Company's employees who have a need to review the Application(s) for the purposes specified in paragraph 4 below*".[76]

(c) *Material Transfer Agreements (MTAs):* common tools in commercial and academic research partnerships involving the transfer of biological materials, such as germplasm, microorganisms and cell cultures. They are used for exchange of materials in various contexts – exchanges between research institutions, and setting conditions for access to public germplasm collections or seed banks, and access by a researcher to *in situ* genetic resources, where the agreement will be between the research institution and the access provider. In most MTAs, a provider agrees to give identified physical material to a recipient, and the recipient agrees to restrict the uses that may be made of that material, and often of any improvements or derivatives. An example of the main clause of a standard MTA is contained in Sample Clause 12 as follows:

Sample Clause 12: Material Transfer Agreement

"*The provider is willing to transfer the material to recipient and to grant recipient a limited non-exclusive license to use the material under the terms and conditions specified in this Material Transfer Agreement (MTA). The recipient accepts the terms and conditions of this MTA by placing an order with the provider*".[77]

(d) *Licensing Agreements:* 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 TK or other IP rights. The following Sample Clause 13 gives an example:

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[75] Non-disclosure agreement between National Innovation Fund (NIF) and recipient

[76] Confidentiality Agreement NIH, available at: http://www.ott.nih.gov/pdfs/cda.pdf

[77] Model Transfer Agreement (MTA) on Plant Genetic Resources for Food and Agriculture (PGRFA), recommended model for institutions participating in the "National Programme on Plant Genetic Resources and Agro-biodiversity Conservation and Utilization" of the Czech Republic, Czech Gene Bank, Crop Research Institute (CRI) and providing PGR to users.Clause 3.1

Sample Clause 13: Licensing Agreement

"*Harvard hereby grants to licensee and licensee accepts, subject to the terms and conditions hereof, in the territory and in the field:*
(a) an non-exclusive commercial license under patent rights, and
(b) a non-exclusive commercial license to use biological materials
to make and have made, to use and have used, to sell and have sold the licensed products, and to practice the licensed processes, for the life of the patent rights. Such licenses shall not include the right to grant sublicenses".[78]

(e) *Research Agreements or Research and Development Agreements*: agreements that define various inputs to research or to research and development, including financial, material (including genetic resources) and intellectual contributions, specify various responsibilities in relation to the conduct of research and development of new products or processes, and set out how the monetary and non-monetary benefits from this research and development should be managed and shared. Some agreements are part of wider Co-operative Research and Development Agreements (CRADAs) as a common tool in biotechnology research. In essence, the parties agree to contribute various resources, such as existing IP, personnel, research facilities, in the collective pursuit of a shared research and development objective. For an example of a research agreement, see Sample Clause 14 and for a Co-operative Research and Development Agreement, see Sample Clause 15:

Sample Clause 14: Research Agreement

"Provider agrees to transfer to recipient's investigator named below the following Research Material: …
This Research Material will only be used for research purposes by recipient's investigator in his/her laboratory under suitable containment conditions. This Research Material will not be used for commercial purposes including for the avoidance of doubt for the production or sale of any products or for clinical use, for which a commercialization license may be required and recipient will not file patents on the Research Material of its uses or any material developed using the Research Material".[79]

[78] Non-exclusive License Agreement (sample) - Harvard College, United States of America. Section III

[79] Model Material Transfer Agreement (MTA) of the Korean Research Institute of Bioscience and Biotechnology, Clause 1 and 4

Sample Clause 15: Co-operative Research and Development Agreement

"*The Hania plant (Withania Somnifera) material will be taken from natural habitat of Karimabad for R&D purposes for 5 years and commercial purposes for next 20 years with permission of the local government , if any. The local government will specify a 50 hectare land area where botanical garden for experimental work on Hania plant will be developed with technical support of NIH and financial support of Astra Zeneca. After expiration of 25 years the botanical garden will be sole property of local government alongwith all its moveable and immoveable property*".[80]

IV. MAIN CONSIDERATION OF IP ISSUES

30. Once the preliminary steps and main overall considerations for access and equitable benefit sharing agreements have been taken into account, the main consideration of IP issues could be guided by the following overall IP issues (Part A), specific IP rights (B) and the exploitation of IP rights by licensing (Part C).

A. OVERALL IP ISSUES

31. The different elements of the overall IP issues are guided by the mutual understanding of the agreement developed by the parties in previous steps and by the goals set after assessment. In addition, they will depend on the type of agreement and the different factors affecting the agreement. In general, there is a range of IP issues which are common to all negotiations of IP Clauses set out in this section. These IP aspects comprise general questions of development and management of IP (Cluster 1), specific practical aspects (Cluster 2), the need for a project planning related to IP management (Cluster 3), the sharing of benefits arising from the exploitation of IP rights (Cluster 4) and the need for specific IP terms and dispute settlement (Cluster 5).

Cluster 1: General IP questions

32. Among the IP questions confronting the negotiators of access and benefit-sharing agreements are:

(a) what IP could result from the access to the genetic resources?

(b) what conditions or restrictions should apply to seeking and obtaining IP rights?

(c) how should those IP rights be owned, exercised, maintained and licensed?

[80] Model project on "Genetic Modification of hyaluronidase inhibitor glycoprotein (WSG) in the roots of Withania Somnifera (Hania plant) for Anti Vanum Treatment" between the Astra Zeneca (Medicine Company), UK, the National Institute of Health (NIH),Islamabad and the Local Government, Karimabad (Hunza Valley, Pakistan)

(d) what approach to obtaining, holding and exercising rights best promotes a mutually beneficial outcome, and the equitable sharing of benefits from the permitted access?

It is crucial to consider in advance what IP is likely to result from the intended access. If access to genetic resources is intended for applied research, it is likely to have IP implications. This is especially so if research collaboration is aimed at developing a commercial product or process. Potential IP on research outcomes and commercialization activities could include a range of IP rights, depending on the direction taken in research and development: these could include patents, plant variety rights, trademarks, geographical indications, designs, trade secrets, and copyright.

Distinction between IP potentially covered and actually covered or excluded

33. The parties may therefore need to review the potential IP resulting from the permitted access, and in particular:

(a) *potential IP*: what subject matter could potentially be covered by IP,

(b) *actual IP*: what elements of this material should actually be covered by IP (for instance, new products created by the research), and what elements should be excluded (some material transfer agreements, for example, oblige the recipient not to seek IP rights on the transferred material, or require further negotiation and agreement at the stage when basic research begins to deliver outcomes).

Cluster 2: Specific practical IP questions

34. These basic questions then lead to specific practical IP questions such as:

(a) *Right to application*: who will decide whether to acquire IP rights on various categories of subject matter; what kind of consultation and further agreement may be necessary before IP rights are acquired and exercised, if at all;

(b) *Ownership*: who will have ownership of IP rights;

(c) *Licensing*: licensing arrangements that should apply to ensure access to new technologies;

(d) *Payment*: payment for acquisition and maintenance of IP rights;

(e) *Enforcement*: who will police and enforce IP rights in the market place;

(f) *Sublicensing*: participation in decisions on sublicensing;

(g) *Performance standards*: ownership or licensing implications if certain performance standards are not met (for example, if the party that gains access to the resources decides not to develop the resources, or takes too long to do so, then the party giving access may wish to reserve rights over intellectual property and any research outcomes);

(h) *Reporting and disclosure*: obligations to report on any actions taken to take out IP rights, and obligations to disclose the source or conditions of access to the genetic resources.

Additional aspects related to IP

35. It might be useful to consider additional aspects related to IP going beyond management of IP rights themselves. If the research activities are wholly academic in nature, and are not aimed at the development of new products or processes, it is nonetheless likely that the parties will wish to create and publish articles and associated data, giving rise to copyright in those publications and related transfer or licensing issues. Privacy and confidentiality issues also may apply – a traditional community may make access condition on non-disclosure of certain traditional knowledge, for instance, and a resource provider may require that the specific origin of a rare or endangered genetic resource be kept confidential. Furthermore, academic research projects may wish to provide, or to use, genetic material that is already subject to third party IP protection. Appropriate warranties may need to be sought or given, for instance, a warranty that the provider or licensor holds all legal right, title and interests in and to those IP rights. Alternatively, the provider or licensor may assert that it does not extend any warranties that the use of the material will not infringe any patent, copyright, trademark, or other proprietary rights. For an example of a clause on publications and confidentiality, see Sample Clause 16:

Sample Clause 16: Additional confidentiality aspects

"*In all oral presentation or written publications concerning the Research Project, recipient will acknowledge provider's contribution of this Research material unless requested otherwise. To the extent permitted by law, recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of provider's written information about this Research Material that is stamped "confidential", except for information that was previously known to recipient or that is or becomes publicly available or which is disclosed to recipient without a confidentiality obligation. Recipient may publish or otherwise publicly disclose the results of the Research Project, but if provider has given confidential information to recipient such public disclosure may be only after provider has had thirty (30) days to review the proposed disclosure*".[81]

36. IP rights are territorial in nature, which means that they can be owned or exercised discretely in various countries. So the decisions made on these questions can specify different arrangements for different territories. For example, the access provider could choose to retain IP rights in the country of origin, but might agree to the partner owning IP rights in other markets. An agreement might specify that licenses be automatically granted to third parties if the recipient fails to meet certain agreed performance criteria, such as making a new product available in developing countries at a preferential price.

[81] Model Material Transfer Agreement (MTA) of the Korean Research Institute of Bioscience and Biotechnology, Clause 5

Joint ownership of IP Rights

37. Joint ownership of IP rights is one legal option, and may be preferred as one way of ensuring that the provider retains a distinct stake in the outcomes resulting from the access. On the other hand, joint ownership can lead to unexpected practical problems and limitations, and may not always be an appropriate benefit-sharing outcome or mechanism. For example, joint ownership does not necessarily create an entitlement to receive benefits from the other owner's exploitation of the common IP rights. In some jurisdictions, joint ownership of patent rights does not require one owner to share economic benefits with the other owner. In cases of joint ownership, the provider and user of the resources should consider how the responsibilities flowing from co-ownership of IP rights will be apportioned, as ownership generally brings with it the costs and responsibilities of securing and maintaining rights, as well as enforcing them;

Cluster 3: Project planning for potential IP aspect

38. For a research relationship involving genetic resources, initial planning of the project should consider the likely outcomes of the collaboration and how IP rights in those outcomes should be handled. This should ensure that, right from the start, any IP rights and potential benefits associated with them can be properly managed. Progressive decisions on IP could be programmed to be taken at key points – for instance, an initial evaluation phase, a review of research proposals and assessment of specific research outcomes. Prospective partners should build into overall project planning of different IP issues such as:

(a) What are the possible IP outcomes that could arise from the proposed collaboration?

(b) How important is ownership of these IP rights to the collaborators? What about ownership of improvements and future developments?

(c) How will benefits be shared arising from the successful exploitation of any IP? Who will negotiate and agree the terms of any subsequent licensing arrangement?

(d) What applicable legislation must be taken into consideration when analyzing the above, including relevant international, regional or national laws or regulations, including, where applicable, sui generis legislation on the protection of TK and customary laws?

Cluster 4: Sharing of benefits arising of the exploitation of IP rights

39. The crafting of IP provisions in an access agreement can help create benefits resulting both directly and indirectly from the access to genetic resources, and can be integral to ensuring the benefits are shared effectively and equitably. Some benefits may arise directly from the successful creation and exploitation of IP rights, such as through royalties from licensing IP. But benefits can extend beyond simple monetary payments, or the ownership and licensing of IP. The Bonn Guidelines provide an illustrative list of diverse possible monetary and

non-monetary benefits from access to genetic resources: this list is attached to these draft guidelines as Appendix I.

Broad understanding of benefits

40. When the access provider is a government agency, a public institution or other authority (such as a national park authority), or a community organization, a broader conception of benefit-sharing may be more consistent with their interests, values and objectives. For such providers, benefits may be assessed in terms of local development, enhanced environmental management, biodiversity conservation, access to technologies in addition to those resulting from the access, transfer of technologies to developing countries, investment in local research and economic activities, and favorable or social marketing arrangements for agreed derivative products and processes. The need to understand the partners' different value systems applies not just to assessing the values of contributions or inputs to the collaboration: it also applies to assessing the importance and value of prospective benefits. IP provisions of an agreement can be structured to support many of these broader goals, and for this reason, the full range of potential benefits should be reviewed and kept in mind when the specific IP provisions are negotiated. An agreed approach to IP provisions may flow from a comprehensive assessment of the full range of potential benefits, and ways of apportioning and sharing them. Benefits could be monetary or non monetary as follows:

(a) Specific monetary benefits flowing from the exploitation of IP rights could include: license fees, in the event of a licensing of the IP rights to a third party or the development of, for instance, a fee-paying database; the sale price, in the event of an assignment or sale of the IP right to a third party; royalties, in the event of a successful commercialization of the IP rights, whether as a result of sale, licensing or joint venture; salaries, where provider country nationals are involved in the exploitation of the IP rights; monetary benefits may vary between different sector. See Sample Clause 17 below:

Sample Clause 17: Monetary benefit sharing[82]		
"Purpose of the Product	*Gross Exploitation Revenue received in one calendar year ($ Australian Dollars)*	*Threshold Payment (% of gross Exploitation Revenue)*
Pharmaceutical, Nutraceutical or Agricultural	*< 500 000* *500 000 – 5 000000* *> 5 000 000*	*0* *2.5* *5.0*
Research	*> 200 000* ***or*** *< 100 000* *100 000 – 3 000 000* *> 3 000 000*	*2.5* *0* *1.0* *3.0*
Industrial, Chemical, Diagnostic or Other	*> 200 000* ***or*** *< 100 000* *100 000 – 3 000 000* *> 3 000 000*	*1.5* *0* *1.0* *2.0*"

(b) Specific non-monetary benefits flowing from the exploitation of IP rights could include: responsibility for filing, maintenance and enforcement of those IP rights; responsibility for the negotiation of any subsequent joint ventures, assignments and/or licensing agreements; capacity building, such as IP-related training and education. Sample Clauses 18 and 19 provide examples of different options:

Sample Clause 18: Non-monetary Benefit-sharing
"*Non-Monetary Benefits include:*
(a) investment in the capacity of the Queensland-based biotechnology industry;
(b) technology transfer to Queensland-based entities;
(c) creation of employment in Queensland;
(d) formation of collaborative agreements with Queensland-based entities;
(e) investment in Queensland-based entities;
(f) investment in research and development infrastructure in Queensland;
(g) conducting field and clinical trials in Queensland;
(h) undertaking commercial, production, processing or manufacture in Queensland;
(i) creation of alternative industries or crops in Queensland;
(j) improved knowledge of Queensland's biodiversity;
(k) improved knowledge of Queensland's natural environment; and
(l) lodgement of voucher specimens with the Queensland Museum or Queensland Herbarium".[83]

[82] Model Access and Benefit Sharing (ABS) agreement between Australian Government and access party

[83] Model Biodiscovery Benefit-Sharing Agreement prepared by the State of Queensland, Australia to facilitate the development of the Queensland Biodiscovery Industry, Recital

Sample Clause 19: Benefit-sharing

"*As mentioned earlier a separate chapter for Benefit Sharing has been included in the Contract. Following are the main points of this chapter regarding non-monetary benefti sharing:-*
(1) The technical expertise of local people and farmer community will be prefered for development of 50 hectare Botanical Garden in Karimabad.
(2) The agricultural graduates and botanical experts of local area will be prefered for research work on Hania plant in the said Botanical Garden and they will be trained by experts of NIH and Astra Zeneca to develop their Negotiation capacity.
(3) Special IP training courses will be conducted for officials of Local Government to develop their capacities for royality and other arrangements.
(4) The technology should be transferred automatically to the Local Government after the expiration of 25 years of the contract".[84]

Cluster 5: Dispute settlement

41. Agreements have to anticipate the need for dispute settlement in the case of general disputes, and there should be an overall dispute settlement provision in the agreement, covering all aspects, not merely IP-related provisions. The various mechanisms for resolving disputes, such as mediation, arbitration and litigation (including the jurisdiction that applies) should be considered and agreed upon, with a view to what is appropriate and effective (especially from the perspective of resource providers if they are confronted with limited capacity in terms of effective use of formal legal systems). Alternative dispute settlement measures such as arbitration and mediation may take account of customary law interests and custodial responsibilities. Where access and benefit-sharing agreements are stipulated under specific national regimes, there may be mandatory requirements for dispute settlement.

Shared understanding on specific terms to avoid disputes

42. As a rule, the more the specific terms of an access agreement are based on a shared and full prior understanding of the nature of the access and benefit-sharing partnership and the intended use of the resources, the less is the likelihood of disputes relating to IP provisions. Some IP issues may require specific dispute settlement: for instance, there may be provisions for arbitration on whether or not to proceed with IP protection for a particular innovation, whether or not a research outcome is derived from the accessed genetic resource and is therefore covered by the agreement, and when certain obligations may be triggered, such as an agreement to license IP to a third party in the event that the recipient does not meet certain performance standards. Different options for IP clauses on dispute settlement are provided by Sample Clause 20 and 21:

[84] Model project on "Genetic Modification of hyaluronidase inhibitor glycoprotein (WSG) in the roots of Withania Somnifera (Hania plant) for Anti Vanum Treatment" between the Astra Zeneca (Medicine Company), UK, the National Institute of Health (NIH),Islamabad and the Local Government, Karimabad (Hunza Valley, Pakistan)

Sample Clause 20: Dispute Settlement

"*A.17 ARBITRATION*
Applicable to agreements with private parties in India
A.17.1 Except as hereinbefore provided, any dispute arising out of this Agreement, the same shall be referred to the arbitration of two arbitrators, one to be appointed by each party to the dispute, and in case of difference of opinion between them to an umpire appointed by the said two arbitrators before entering on the reference, and the decision of such arbitrators or umpire, as the case may be, shall be final and binding on both parties. The venue of arbitration shall be at such place as may be fixed by such arbitrators or umpire and the arbitration proceedings shall take place under the Indian Arbitration Act, 1940.
A.17.2 Any legal appeal over the arbitrators' award arising out of or in any way connected with this agreement shall be deemed to have arisen in Thiruvananthapuram and only the courts in Kerala shall have the first jurisdiction to determine such matters."[85]

Sample Clause 21: Dispute Settlement

"*Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be submitted to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be ... The language to be used in the mediation shall be ...*

If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the mediation within [60][90] days of the commencement of the mediation, it shall, upon the filing of a Request for Arbitration by either party, be referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules. Alternatively, if, before the expiration of the said period of [60][90] days, either party fails to participate or to continue to participate in the mediation, the dispute, controversy or claim shall, upon the filing of a Request for Arbitration by the other party, be referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules. The arbitral tribunal shall consist of [three arbitrators] [a sole arbitrator]. The place of arbitration shall be ... The language to be used in the arbitral proceedings shall be ... The dispute, controversy or claim referred to arbitration shall be decided in accordance with the law of ...".[86]

[85] Know How Licencing Agreement between The Tropical Botanic Garden and Research Institute, Kerala, India (TBGRI) and The Arya Vaidya Pharmacy (Coimbatore) Ltd, Coimbatore, India (the PARTY), dated November 10th, 1995

[86] See WIPO publication No. 446(E): WIPO Arbitration and Mediation Center, Recommended WIPO Contract Clauses and Submission Agreements

B. SPECIFIC IP RIGHTS AND ISSUES

Patents

43. A research project based on access to genetic resources may have as its clear intention the discovery of a patentable invention and the subsequent licensing and commercial development of that patent. Alternatively, an academic collaboration may inadvertently or unexpectedly result in a patentable invention. The following is a non-comprehensive list of some of the patent-related issues that prospective partners may wish to consider as part of their initial assessment of IP issues,

Is this a project which may result in the creation of a patentable invention?

44. In order to answer this question, consideration will need to be given to the scope of the research to be carried out. Are the resources, and any related information, to be accessed for academic research purposes only, or will they be used in order to create, if possible, a product or a process that provides a new way of doing something, or offers a new technical solution to a known problem? Such a product, process or solution may be eligible for patent protection. The following guidelines set out different options provided in Sample Clause 22:

Sample Clause 22: Different purposes of agreements

"*The recipient and the provider distinguish the following categories of use of MGRs:*
Category 1: Use for test, reference, bioassay, and control (covering only their use within the framework of the corresponding official (inter)national test-, bioassay and control protocols); use for training and research purposes;
Category 2: Commercial use. Commercial use of MGRs includes but is not limited to the following activities: sale, patenting, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or licence, product development and seeking pre-market approval.
For category 1 uses:
The recipient will not claim ownership over the MGRs received, nor seek intellectual property rights over them or related information. If the recipient wishes to utilise or exploit such organisms commercially he will first inform the provider; when applicable, suitable and adequate recompense to those entitled to be rewarded, and the country of origin will be discussed in the spirit of the Convention on Biological Diversity.
The recipient will ensure that any individual or institution, to which the recipient makes samples of the MGRs available, is bound by the same provision.
For category 2 uses,
In order to ensure adequate benefit sharing with the country of origin and « names of those entitled to be rewarded », according to the principles of the Convention on Biological Diversity, the recipient will immediately inform the provider and the country where the MGRs were originally accessed, of the intended commercial use(s) of the MGRs and/or derived technology and/or related information. The terms upon which benefit sharing with the stakeholders takes effect are laid down in annex.
For all categories of uses, The recipient will mention the provider, the strain reference number and the country of origin in publication presenting scientific results and related information resulting from the use of the MGRs".[87]

General conditions of patentability and specific national and regional legislation

45. The rules for patent protection vary between different national and regional patent laws. An invention is generally required to be industrially applicable (or useful), new (or novel) and non-obvious (or involve an inventive step), and the invention has to be disclosed in the patent application according to certain standards. There are differences between different laws on what technical subject matter can be protected, including in areas potentially relevant to inventions based on genetic resources. For instance, patent laws may exclude discoveries of materials or substances already existing in nature, scientific theories, plant or animal varieties, or essentially biological processes for the production of such plant and animal varieties, other than microbiological processes, as well as inventions that would contravene public order or morality if they were commercially exploited. So, in many countries, the choice has been made to exclude certain categories of invention that can be directly relevant to the use of genetic resources. Access and benefit-sharing agreements should acknowledge and respect the different scope of patentable subject matter that different national and regional systems provide for.

[87] MOSAICC, Septmeber 2009, *op.cit.*, page 20

Should patent protection be obtained?

46. When drafting any contractual arrangement, the scope of the proposed use of the genetic resources and any related information should be clearly defined. This should also clarify whether it is intended for IP rights to be obtained as a result of this use. For instance, if the research is for specified academic purposes only, consideration could be given to both clearly defining the permitted research under the contract and also including a clause stating that no IP rights may be obtained over any genetic resources, progeny or derivatives transferred under the agreement, without the further agreement of the original provider of the material or related information. Such a clause could protect the original grantors of the resources and knowledge in the event of an inadvertent discovery of a potentially patentable invention by an academic researcher. A clear understanding should be reached about seeking patent protection for inventions derived from the access and use of genetic resources, in the framework of a broader understanding of how equitable sharing of benefits should proceed. The access provider may wish to restrict or otherwise place conditions on the use of patents on inventions that result from access to the resources. A range of options have been used in practice, including:

Options for the use of patents

- *precluding any IP rights* on any developments based on the access to the resources, as a contractual condition of access (for instance, in MTAs granting access for evaluation purposes or pure research only);

- *providing for reporting and consultation* in relation to any developments based on the access to resources (so that the user of the resource needs to disclose any potentially patentable invention to the resource provider, when a decision is made as to whether to patent the invention and if so, how and in whose name, and subject to what conditions);

- *affirming the right of the user of the resource to seek patents on certain defined inventions*, but making this right subject to appropriate arrangements for sharing benefits from the patents and from the use of the resource more generally (see also the option of co-ownership of any patents, discussed below); these may include obligations to share or pool research results, to provide open access for non-commercial use, research or breeding, to provide preferential access to developing countries or for humanitarian purposes, and to grant licenses in various circumstances consistent with the goals and interests of the resource provider;

- *reserving rights*, so that if the user of the resource elects not to proceed with research or development, or otherwise fails to generate the expected benefits from the resource, the resource provider might retain an entitlement to take control of new technologies developed under the mutual agreement;

- *providing for some research outcomes to be published defensively* and for the general public to access them – that is, published so as to ensure they are in the public domain, and preclude any other party from seeking IP rights on them, to preserve ‘freedom to operate’ for such technologies;

- *imposing other conditions concerning patents*, such as obliging the user of the resource to mention the source of the genetic resource or conditions of

access in any patent application concerning inventions resulting from the access to the resource;

– *clarifying the scope of research* that the user of the resource may be entitled to undertake, and the implications for IP ownership, such as further development and improvement of the original invention, and applied research to enable industrial use of the invention.

These are only some of the options that can be chosen by the two parties to the access and benefit-sharing arrangement, and finding the right balance of interests that is both equitable and effective in achieving mutual benefit may involve exploring all these options.

If so, who may own such an invention?

47. In contrast, if the research has as its clear objective the discovery and development of a product, process or technical solution that may be eligible for patent protection, then, as part of an IP audit, consideration should be given to ownership of any resulting patent. Typically, co-ownership accrues with co-inventorship. Nonetheless, the parties can agree that any patent will be jointly owned by the partners, regardless of contribution to the invention. Other, more varied arrangements are also used: for instance, patent rights on resultant inventions could be granted to the recipient, subject to further benefit-sharing, except in the territory of the provider, where patents could be jointly owned or owned by the provider.

Some further practical considerations may arise:

(a) *Employees' inventions*: In research and educational institutions, such as universities, the employer may be deemed to be the owner of an invention, when the invention is produced by an employee (such as a professional researcher or academic) within the scope of his or her employment. However, this rule may not apply to students involved in a research project on biological material, and they may have distinct rights to an invention, which should be taken into account in structuring IP provisions in an agreement;

(b) *Provider*: The grantor of access to the biological material and to any associated information may have retained certain contractual rights in relation to ownership of, development and licensing of any patent arising out of research carried out on the material or associated information;

(c) *Sponsoring organization*: A sponsoring private organization or government body may make certain demands on the ownership and use of any patents arising out of research collaboration, even if the researcher retains the basic entitlement to obtain patent rights.

Approaches to ownership of patents

48. Ownership can provide reassurance to the providers that they will retain a say over how the resources and any new technology derived from the genetic resources are developed, used and disseminated. On the other hand, ownership of patents

derived from access to genetic resources is unlikely in itself to generate tangible or sufficient benefits, in the absence of a strategy for managing actively a patent portfolio. One practical consideration is that maintaining and exercising a patent portfolio, potentially in several countries, can be complex and entail significant investment. Normally, a patent owner bears the financial and administrative obligations to maintain and to enforce that patent, although contractual agreements can provide for other arrangements.

49. Joint ownership of patents is one possibility, but the implications of various ways of structuring ownership should be considered in advance. In cases of joint ownership, the parties will need to consider how certain responsibilities are shared, such as making and maintaining a patent application, enforcing the patent in the event of infringement, and negotiating and agreeing the terms of any subsequent licensing arrangement - the organization that carries out research on genetic material may not be competent to develop a commercial product arising out of any successful research, so third parties may need to be involved. How these detailed arrangements are settled should be determined with reference to the overall arrangements set for access and benefit-sharing. For instance, some agreements require that any licensing of patents derived from the access to genetic resources should refer back to the original access and benefit-sharing agreement.

50. In some jurisdictions, if there is more than one owner of IP, then the consent of the other owner(s) must be obtained for an assignment or license; i.e. the agreement of all owners is required for effective development and exploitation of the patent. In other cases, unless the joint owners have agreed differently, each one is free to use the patented invention without being accountable to the others. It may be difficult to arrange three-way partnerships between potential licensees and third parties.

51. For this reason, it can be more practical for one co-owner to license or sell his or her interest in the patent to the other co-owner, subject to continuing access to the technology, payment or other conditions. In some cases, it may be more advantageous to concede ownership of any resulting patent in return for other benefits, such as a free license to use the patented product, process or technical solution, or broader benefits such as guarantees of access to technology for certain third parties, such as public authorities, developing country enterprises or non-commercial researchers.

Summary of issues

52. The following points summarize the patent-related issues that may be considered:

(a) *Patentable invention*: Will access to the genetic resources and related information result in the creation of a patentable invention? If not, and where the aim of the access is academic research only, this should be clearly stated in any contractual arrangement, and the purposes of the access clarified accordingly. What is patentable can vary considerable between different countries. What the access provider and the user of resources believe should be patented will also vary, depending on their perspectives and interests.

(b) *Party obtaining patents*: What are the agreed arrangements concerning the obtaining of patents for any inventions resulting from the access? How do the access provider and user of the resources agree that patents should be obtained – are there requirements to report on inventions, to agree on specific patenting arrangements, or a general approach for all inventions resulting from the access?

(c) *Ownership of patents*: If so, who will be the owner(s) of the resulting patent? Will ownership be dependent upon such issues as the value of the contribution of genetic resources and TK, the level of scientific contribution and other contributions? Will the patent be jointly owned by the provider and user, regardless of contribution to the invention? Or will the access provider retain ownership? Consideration may need to be given to the demands of a sponsoring private organization or government body on the ownership and use of any patents arising out of the collaboration.

(d) *Joint ownership*: In cases of joint ownership of a patent, how will responsibilities flowing from the co-ownership be apportioned? For instance, relating to filing, maintenance and enforcement. Where will the resources come from to carry out these activities?

(e) *Exploitation model of patent*: What is the most appropriate model for the exploitation of the patent and for the use and dissemination of the new technology developed – for instance, a license, assignment or joint venture? Who will negotiate and agree the terms of any subsequent arrangement to exploit the patent? The parties could negotiate licenses to commercialize the research outcomes, or a separate commercial or industrial partner could be brought in once the research outcomes were proven.

(f) *Sharing of benefits*: How, when and between whom will any monetary or non-monetary benefits arising from the commercial exploitation of the patent be apportioned? The provider of access to the genetic resources and any related information may retain certain contractual rights in relation to the sharing of benefits, regardless of ownership of the patent itself. Licensing royalties could be shared with the provider; alternatively, the provider may prefer to receive more immediate, short term benefits. In any event, consideration may need to be given to the establishment of specific structures or procedures to ensure that agreed benefits flow back to the provider; for instance, contract monitoring provisions and a benefit-sharing trust fund.

(g) *Confidentiality*: How will the parties maintain confidentiality? The principle of confidentiality plays a central role in the patent system and the leaking of any confidential information into the public domain can adversely affect the securing of future patents. It is therefore vitally important that confidentiality is maintained until adequate protection is in place. Consideration should also be given to agreeing terms related to publications, in order to ensure that prior publication does not destroy any future patent rights. For an example, see Sample Clause 23:

Sample Clause 23: Confidentiality Clause

"*The test results will be kept confidential by all parties, with any publication delayed until DTP/NCI has an opportunity to file a patent application in the United States of America on any active agents isolated. Such application will be made according to the terms stated in Article 6*".[88]

(h) *IP warranties*: In carrying out the research, what use may be made of material or data covered by IP owned by others? Do warranties need to be sought, or given, relating to such IP? For an example to exclude such warranties, see Sample Clause 24:

Sample Clause 24: Potential IP of third parties

"*Use of the material may be subject to intellectual property rights. No express or implied licenses or other rights are provided herein to the recipient under any patents, patent applications, trade secrets or other proprietary rights. In particular, no express or implied licenses or other rights are provided to use the material or any related patents for commercial use*".[89]

Trademarks and geographical indications

53. The following issues relating to trademarks and geographical indications may be considered:

(a) *Trademark*: Will access to the genetic resources and related information result in the creation of goods or services, which could be identified by a distinctive sign linking the goods or services back to the provider of the genetic resources? For instance, a word in a local dialect describing the resources in question, or a particular tribal symbol. See sample clause 25:

Sample Clause 25 Trademark protection

"*The medicine will be given a special commercial name "Astra-Hania" or "Hanio-Zeneca" and trade mark registration will be applied in Pakistan, UK and other target countries/regions at the end of the 2nd year of Contract*".[90]

(b) *Prior informed consent*: If so, does permission need to be sought to use such a word or symbol and, if so, from whom and on what mutually agreed

[88] Model Letter of Collaboration between the Developmental Therapeutics Program Division of Cancer Treatment/Diagnosis National Cancer Institute, United States of America (DTP/NCI) and a Source Country Government (SCG)/Source Country Organization(s) (SCO), Clause A.2

[89] Model Transfer Agreement (MTA): Terms and Conditions of limited non-exclusive license model agreement to use genetic material of the Culture Collection of Dairy Microorganisms (CCDM) of the Czech Republic, Crop Research Institute (CRI), Clause 7

[90] Model project on "Genetic Modification of hyaluronidase inhibitor glycoprotein (WSG) in the roots of Withania Somnifera (Hania plant) for Anti Vanum Treatment" between the Astra Zeneca (Medicine Company), UK, the National Institute of Health (NIH),Islamabad and the Local Government, Karimabad (Hunza Valley, Pakistan)

terms? What limitations on the use, for instance to reflect cultural concerns, should be imposed?

(c) *Ownership*: Who would own such a trademark? Who would be responsible for the cost of development, registration and upkeep of a trademark, including payment of renewal fees and enforcement?

(d) *Exploitation model*: What would be the most appropriate commercial model for the exploitation of the trademark? It is common practice for trademark owners to license third parties, who operate in different countries, to use their trademarks in those countries. Could the trademark be assigned?

(e) *Benefit sharing*: How would any benefits arising from the ownership, use and licensing of the trademark be apportioned? The provider of access to the genetic resources and any related information may retain certain contractual rights in relation to the sharing of benefits, regardless of ownership of the trademark itself.

(f) *Geographical indication*: Are the genetic resources associated with a geographical indication? For example, are the resources linked with a traditional product that is distinctive of the geographical location where the resources are found? Are the genetic resources to be used for a product that has a quality, reputation or other characteristic that is essentially attributable to its geographical origin? What arrangements should be made to respect existing geographical indications, or to seek appropriate protection for geographical indications?

Copyright

54. Copyright may arise when information about genetic resources is recorded, and when accounts of TK are written down or otherwise recorded. Agreement at the time of access on ownership and use of this copyright may be an important question in ensuring an appropriate overall arrangement that reflects the interests of the two parties. The following copyright-related issues may therefore be considered:

(a) *Copyright*: Will access to the genetic resources and related information result in the creation of original materials that may be eligible for copyright protection, such as texts, technical drawings or databases? If TK relating to Genetic Resources is recorded, in an article or book, for instance, how will rights and benefits associated with that record be allocated? Particular consideration may need to be given regarding the IP rights in databases. The structure of a database may have IP protection in its own right, without prejudice to any copyright in the information contained in the database.

(b) *Ownership*: Who will own the copyright in works that contain TK about genetic resources? In many research institutions, such as universities, the employer, and not the employee/author, is deemed to be the author of a work prepared by an employee within the scope of his or her employment. However, an access agreement may pre-emptively assign ownership of the copyright to the provider of the TK.

(c) *Joint authorship*: In cases of joint authorship, how will responsibilities flowing from co-ownership of copyright be apportioned? Can copyrighted material produced from the collaboration be assigned or otherwise licensed to third parties? If so, on what terms? Consideration may need to be given to entering into a partnership agreement over the management of the joint rights.

(d) *Publication*: Where, and in what format, will the works be published? As a condition of publication, an author may be obliged to sign a Copyright Transfer Agreement, transferring ownership of the copyright to the publishing house. This is standard practice in serials and journals publishing and is designed to ensures maximum international protection against infringement, libel or plagiarism. This will not affect the author's moral rights. For an example see Sample Clause 26:

Sample Clause 26: Sample Clause on Publication

"*You agree to acknowledge the source of the Biological Material in any publications reporting on your use of it*".[91]

(e) *Benefit sharing*: How will monetary and non-monetary benefits arising out of publication of copyright works be shared? The provider of access to the genetic resources and any related information may retain certain contractual rights in relation to the sharing of benefits, regardless of ownership of the copyright itself.

(f) *Third party rights*: What use may be made of material or data covered by third party IP? Do warranties need to be sought or given relating to third party IP?

Plant Variety Rights

55. Plant varieties represent an important form of plant genetic resource. A plant variety is generally defined as the lowest level of taxonomy (or classification) within the plant kingdom – in other words, a group of plants that is distinct from all other groups of plants within a given species. Thus, a plant variety results from the lowest sub-division of the species.[*]

56. Plant varieties are relevant to access and benefit-sharing in at least two possible ways:

- the genetic resources that are accessed may be plant varieties; and
- because the access to genetic resources may provide genetic inputs to plant breeding that creates new plant varieties.

[91] National Science Foundation draft letter Uniform Biological Material Transfer Agreement, Non-profit to Non-profit, Art. 4, Quoted in Barton, John and Siebeck, Wolfgang. *Material transfer agreements in genetic resources exchange – the case of the International Agricultural Research Centres*. International Plant Genetic Resources Institute, May 1994, page 23

[*] For details on the nature of plant varieties, see http://www.upov.int/en/about/upov_system.htm#what_is_a_pv

In both cases, there are potential IP questions that should be considered before agreement is reached on the terms of access and benefit-sharing.

What is plant variety protection?

57. IP protection has been developed specifically for new plant varieties. Different national systems provide protection through distinct, *sui generis* rights (termed 'plant breeder's rights' or 'plant variety rights'), patents on plant varieties, or both. *Sui generis* plant variety protection is available in many countries. The International Union for the Protection of New Varieties of Plants (UPOV), through the UPOV Convention, provides the only internationally harmonized system of plant variety protection in place. It comprises currently 68 member States. The UPOV Convention offers protection to the breeder of a new plant variety, in the form of a "breeder's right", if the variety satisfies the conditions set out in the UPOV Convention. In particular, the variety must be new, distinct, uniform and stable and must be designated by an appropriate denomination. When contractual arrangements for access to genetic resources relate to territories covered by the UPOV Convention, they should take account of the implications of the UPOV Convention for access to genetic resources, prior informed consent, and benefit-sharing, with regard to the "breeder's exemption", subsistence farmers and farm-saved seed.[*]

58. The following specific issues concerning plant variety rights may need to be agreed depending on the nature of access to genetic resources and their intended use:

(a) *Plant variety*: Will access to the genetic resources and related information result in the development of a new plant variety(ies), through breeding or other research activities?

(b) *IP Protection*: What IP protection may be available for this new variety (ies)? This differs according to the approach taken in national laws. Generally, some form of *sui generis* plant variety right is available. Some countries provide for patent protection of new plant varieties, in addition to plant variety rights or as an alternative.

(c) *Conditions*: In what circumstances is it agreed that IP protection should be obtained for new plant varieties resulting from the access to genetic resources?

(d) Ownership: Who will own the rights for any new plant variety, and how will this differ according to different territories? Will ownership be dependent solely upon contribution to plant breeding? Or will the IP be jointly owned by the provider and user, regardless of contribution to the breeding of the new variety? In cases of joint ownership, how will responsibilities for management and enforcement be apportioned and funded?

(e) *Exploitation model*: How may the plant variety right be commercially exploited, in what territories, and by whom? What forms of licensing the right are agreed as a condition of the original access?

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[*]These matters are explained in the "Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the CBD," available at: http://www.upov.int/en/news/2003/pdf/cbd_response_oct232003.pdf

(f) *Benefit-sharing*: How may any benefits arising from such commercial exploitation be apportioned? As for other areas of IP derived from genetic resources, the provider of access to the genetic resources and any related information may retain certain contractual rights in relation to the sharing of benefits, regardless of ownership of the IP right itself.

Trade Secrets

59. The following issues may arise in relation to confidential or undisclosed information (such as TK which is required by customary law to be disclosed only to certain people, only for certain purposes, or only in certain circumstances):

(a) *Confidential information*: Will access to the genetic resources and related information result in access to confidential information that may require careful handling and appropriate protection?

(b) *Possible Terms for Confidentiality Agreements*: If so, then as a matter of priority, the provider and user of the information should contemplate entering into confidentiality agreement, to protect such information. Such an agreement could include the following terms:

(i) a description of the *information covered* by the agreement;
(ii) the *nature of the protection* required;
(iii) the *scope of the permitted disclosure* (who is authorized to get access to the information, including the need to put in place confidentiality obligations that cover the relevant employees or contractors of the institution receiving the confidential information);
(iv) the *scope of permitted use* (for technical or commercial evaluation; for non-commercial research; or for the development of a particular commercial product);
(v) *ownership and management of any further IP rights* that are created as a result of access to the confidential information, such as in the evaluation or testing process;
(vi) *time limitations* on the permitted use of the confidential information; and
(vii) *monitoring and reporting* on the use of the confidential information.

C. EXPLOITATION OF IP RIGHTS: LICENSING

How to commercialize IP rights?

60. An IP right does not in itself provide an economic benefit to anyone. For instance, the grant of a patent does not, *per se*, mean that an invention has an economic value and will be commercially viable. Furthermore, commercialization of an IP right, such as a patent, can involve a considerable amount of commercial risk, which may not be acceptable to smaller companies and dedicated research institutions, such as universities. Because of these considerations, many users of genetic resources choose not to commercialize IP rights themselves, but elect between different options to manage those rights so as to get the commercial

benefits of their research. Options could include licensing, assignment and joint ventures.

Licensing Agreements

61. Licensing agreements are a particularly common way to exploit IP rights related to genetic resources and related information, including TK. A license agreement is an agreement to permit an inventor to license an IP right, such as a patent or trademark, to others to develop and use commercially, whilst retaining ownership and control of the IP right itself and gaining benefits, such as financial royalties from the commercial development and use. In the event of access for the purposes of commercial or industrial application, a license agreement shall be signed in which terms are provided that ensure due reward for the said access, and in which the equitable distribution of derived benefits is guaranteed.

Checklist of licensing issues

62. Many providers and users of genetic resources may elect not to address the specific detail of exploitation of IP rights until an IP right has been created, and its potential commercial viability and value has been assessed. However, as part of an IP audit, it may nonetheless be useful to consider the following licensing-related issues, within the context of applicable international, regional or national laws or regulations. Some of these issues may need to be left open at the initial stage, and settled in detail only when the nature and potential of the results of research and development derived from the genetic resources are better known:

(a) Definitions and Scope: What IP rights arising out of the collaboration may, or may not, be licensed? For instance, the right to use a patented process to produce a specified product, but not the associated trademark; (define the IP rights being licensed, such as patents or know how, the purpose of the license and the permitted scope of the licensed use);

(b) Ownership of the IP rights that are being licensed (who retains ownership? In the case of joint ownership, who is entitled to grant licenses, under what conditions?); see Sample Clause 27 as an example:

Sample Clause 27: Ownership of IP rights

"*Subject to Section 4 (License) it is understood that the AAFC Inbred Line(s) belong to Agriculture and Agri-Food Canada and that all intellectual property rights related to the AAFC Inbred Line(s) are vested and shall continue to be vested in Agriculture and Agri-Food Canada*". [92]

(c) Grant of licensed rights. The license needs to set out the exact rights that are (and are not) being granted. For instance, the right to use a patented process to produce a specified product, but not the associated trade mark. The use could be limited to research, or non-commercial, purposes;

[92] Exclusive Variety License Agreement between her Majesty the Queen in Right of Canada, as represented by the Ministry of Agriculture and Agri-Food (AAFC), and the Company, Clause 1

(d) Type of licence: What kind of license may be granted? Sole, exclusive or non-exclusive? The kind of license granted will influence the scale of royalties, or other payments, made by the licensee. In which territory(ies) will the license apply? Can a sub-license be granted so that a third party may also use the IP rights in question. If so, to who, and on what terms or conditions? It is important to clarify which one of these options applies to the IP right in question (will the licensor retain the right to use the covered invention, is the license required to be registered with appropriate national authorities, if so, by who?). The kind of license granted will influence the scale of royalties, or other payments, made by the licensee. For an example, see Sample Clause 28:

Sample Clause 28: Scope and Type of Licence

"*Harvard hereby grants to Licensee and Licensee accepts, subject to the terms and conditions hereof, in the Territory and in the Field:*
(a) an exclusive commercial license under patent rights, and
(b) a license to use biological materials […]".[93]

(e) Territory. In which territory(ies) does the license apply?

(f) Sub-licenses. Can a sub-license be granted so that a third party may also use the IP rights in question. If so, to who, and on what terms or conditions?

(g) Diligence and Milestones. Do clear milestones need to be identified? If a licensee gains an exclusive license, subject to royalty payments on profits, and then does not use the technology for several years, then some of the value of the IP is effectively lost to the licensor. So, licenses will often include obligations on the licensee to develop and apply the licensed technology within a certain time scale. Where possible, certain defined points or milestones should be identified. If a licensee gains an exclusive license, subject to royalty payments on profits, and then does not use the technology for several years, then some of the value of the IP is effectively lost to the licensor. Licenses will often include obligations on the licensee to develop and apply the licensed technology within a certain time scale. An obligation to use best efforts as contained in Sample Clause 29 would be one option:

Sample Clause 29: Best Efforts to Sell

"*The Company shall use its best efforts to sell the Licensed Product(s) to the end-users and sub-licensees. This obligation includes the twin duties of filling demand and creating demand for the Licensed Product(s). Nothing in the License Agreement authorizes the "shelving", deferral of, or otherwise enfeebled sales efforts or other activities which neither create demand nor fill demand for the Licensed Products, and any such activities are a material breach of the License Agreement*".[94]

[93] Non-exclusive License Agreement (sample) - Harvard College, United States of America, Article III, 3.1(a)

[94] Exclusive Variety License Agreement between her Majesty the Queen in Right of Canada, as represented by the Ministry of Agriculture and Agri-Food (AAFC), and the Company, Clause 4.1

(h) Payments and Pricing. There are many potential models for payment. It is always difficult to establish a value for IP, especially where it relates to unproven technology that will require a licensee to take a considerable commercial risk. Many licensing agreements consist of a mixture of lump sum payments and royalties, based on the extent of use of the technology. The need to monitor the use of the invention and to ensure that royalties are paid, as well as checking on diligence and milestone obligations, can lead to requirements for record-keeping, access to accounts etc. The approach taken to agreeing payments and pricing should be realistic, reflecting possible regulatory delays (especially in the biotechnology industry), and the fact that returns to the licensee can take many years to realize.

(i) *Benefit sharing*: How will benefits flowing from the exploitation of the IP right be apportioned? It is always difficult to establish a value for IP, especially where it relates to unproven technology that will require a licensee to take a considerable commercial risk. Many licensing agreements consist of a mixture of lump sum payments and royalties, based on the extent of use of the technology. The approach taken to agreeing payments and pricing should be realistic, reflecting possible regulatory delays, especially in the biotechnology industry, and the fact that returns to the licensee can take many years to realize. Providers of genetic resources and related information may prefer to receive more certain up-front payments, rather than longer-term less certain returns.

(j) Confidentiality. There may be a distinct confidentiality agreement, or obligations as to secrecy may be incorporated into the license agreement itself. It may be important to agree the rights of the inventor(s) to publish their research;

(k) Copyright. The license may set out the copyright provisions covering any manuals or other documentation received, and used, as part of the licensing package;

(l) Ownership of improvements, grant-back rights and assign-back rights: Who will own IP rights relating to improvements and adaptations to the licensed technology, whether arising from the licensed use of the technology or made by the licensor to the original technology? It is often important to agree who will own IP rights relating to improvements and adaptations to the licensed technology (whether arising from the licensed use of the technology or made by the licensor to the original technology). A ‘grant-back’ clause may give access to a licensor to improvement made by a licensee. However, an exclusive ‘grant-back’ clause may be viewed under national law as anti-competitive commercial behavior. An assign-back clause would entitle the licensor to ownership in patents on any improvements. An example of a grant-back license to the licensor for improvement on the technology is contained in IP clause 30:

Sample Clause 30: Grant-back license:

"Recipient will give provider a non-exclusive, royalty-free license under any inventions it may patent that derive from the transferred material or improvements or derivatives thereof".[95]

(m) Cross-licenses. Under a cross-license, A grants B a license to use A's IP, and B grants A a license to use B's IP.

(n) Required Performance. A licensor (especially when granting an exclusive license) may wish to set specific performance targets in order to ensure a certain level of performance from the license agreement. For instance, minimum sales levels. A licensor may be expected to provide the licensee with assistance to exploit the IP effectively (such as training and technical support and advice); the licensee might need to submit an exploitation plan an report on business;

(o) Publication of Research. Terms related to publications may monitor developments in the technology and the licensed activities, and ensure that prior publications does not destroy any future patent rights;

(p) Maintaining and enforcing IP rights. Consideration will need to be given as to who may be responsible for ensuring that renewal fees are paid, and the respective roles of the parties in relation to enforcing the licensed IP rights. The licensor and licensee will need to agree who is responsible for ensuring that patent renewal fees are paid, and their respective roles in relation to enforcing the licensed IP rights; see sample clause 31:

Sample Clause 31: IP enforcement

"*Licensee shall have the right to prosecute in its own name and at its own expense any infringement of such patent, so long as such license is exclusive at the time of the commencement of such action*".[96]

(q) Duration of license; Termination; Dispute resolution; and Choice of law. A license will typically include provisions addressing all of these points.

(r) Other issues: these may include a guarantee clause (with provisions on liability and validity of authorizations, including prior informed consent under applicable law), provisions concerning challenges to validity of the IP rights (noting that competition law may not permit this), provisions concerning termination of the agreement before maturity, and provisions for amendment of the terms of the agreement including cases of changed circumstances (force majeure).

[95] Example Material Transfer Agreement, in: Barton/Siebeck, *op.cit.*, page 21

[96] Exclusive License Agreement (sample) - Harvard College, United States of America. Section VIII 8.1

V. MODEL IP CONTRACTUAL CLAUSES

63. Once answers have been established to the questions raised by the IP assessment, and negotiations have been carried out to reach mutually agreed terms of access and benefit-sharing, appropriate contractual terms and conditions reflecting these negotiations can be drafted. The IP aspects of these negotiations can be included either as part of a wider benefit-sharing package or as stand-alone IP clauses.

64. Examples of actual and model IP clauses in contracts and licenses concerning IP, access to genetic resources and benefit-sharing can be found in the WIPO Contracts Database at: http://www.wipo.int/tk/en/databases/contracts/index.html. The information contained in the WIPO Contracts Database should be viewed as a general starting point, to be interpreted according to the individual circumstances of a particular collaboration.

65. In any event, prior to entering into a legally binding contractual arrangement, all parties should seek expert legal advice from a practitioner with experience in the relevant legal issues, including IP rights, and national legal system, or systems, in question.

VI. SECTORAL APPROACHES

66. IP clauses in agreements on access to genetic resources and equitable benefit-sharing should take into account the realities of different sectoral activities, in particular distinguishing between commercial and non-commercial use of genetic resources. Even if genetic resources are used in a wide range of different sectors and subsectors, a few main sectors for the utilization of genetic resources could be identified in order to classify the utilization and to draw on the different circumstances, needs and purposes of activities of these main sectors. Therefore, sectoral approaches for IP guidelines on access and benefit-sharing could be developed. The most relevant sectors for IP and access and benefit-sharing are: pharmaceuticals and biotech, food and agriculture, non-commercial research, as well as genebanks and ex situ conservation (Microbial Resources Centers) These sectors had been identified by a meeting of a Group of Legal and Technical Experts on Concepts, Terms, Working definitions and Sectoral approaches in Windhoek, Namibia in December 2008 mandated by the Conference of Parties of the CBD.[97] The following considerations are based on the conclusions of the legal and technical experts.

67. Some sectors handle very large numbers of samples and access should be facilitated through the development of model clauses for potential inclusion in MTA. Optional clauses could leave flexibility for both provider and user in establishing the mutually agreed terms. A wide range of national and international voluntary codes

[97] Compare Report of the Meeting of the Group of Legal and Technical Experts on Concepts, terms working definitions and sectoral approaches, UNEP/CBD/WG-ABS/7/2; see as well sectors mentioned in document WIPO/GRTKF/IC/1/3 para 37: “include public sector research institutions as well as private sector initiatives, in both the pharmaceutical and agricultural sectors as well as genebanks and other ex-situ collections of genetic resources”

of conduct and best practices exists, many of which are included in WIPO's online database. These have been developed in different sectors using genetic resources, including by the FAO ITPGRFA, the biotech industry or pharmaceutical companies, as well as the research community, botanical gardens, microbial collections.[98]

68. The present draft guidelines apply to all different sectors. However, some brief consideration of sectoral approaches could be added relevant to each sector:

A. PHARMACEUTICAL, BIOTECH AND COMMERCIAL USE

69. Some characteristics of access and benefit sharing in the pharmaceutical, biotech and commercial sector have been identified by experts,[99] which are important as well for IP clauses. The pharmaceuticals and commercial biotechnology sector uses mainly genetic resources of plants, animals and microbes in material transfer agreements and collaboration agreements. The benefits could be both monetary (up-front payments for samples, milestone payments, royalty payments) and non-monetary (technology transfer, equipment, education of health professionals on diseases, treatment and pharmaceuticals, scientific collaboration, training including student exchange and scholarships, information exchange and sharing of research results). In general, activities in this sector are conditioned by a high risk and high investments, long research and development cycles and low probability of success. Therefore, it exists a critical need for legal certainty over a long period of cooperation and a need for reliability of material delivery over course of research. Sometimes it is not possible to communicate successes due to confidentiality requirements and industry competition. Another significant characteristic is that the pharmaceutical industry, for instance, acquires genetic resources mainly from *ex situ* collections and others mainly through intermediaries such as culture collections. Only a few pharmaceutical companies directly access genetic resources from *in situ* conditions.[100]

70. Therefore, agreements in the pharmaceutical sectors are mostly of commercial nature and therefore provide for clear IP protection on the possible results of research and development. IP protection may be sought for inventions of the recipient in the course of research and development. The commercialization maybe subject to another agreement. Agreements mostly provide for some clauses in respect to reporting on the commercialization. For an example, see Sample Clauses 32 and 33.

[98] See UNEP/CBD/WG-ABS/7/2

[99] See UNEP/CBD/WG-ABS/7/2

[100] See UNEP/CBD/WG-ABS/7/2

See Sample Clause 32: Patent protection for recipient's inventions

"*The [Transferee] shall not seek patents or plant variety protection rights in the Materials as such as they are listed in Article 2 (i.e., materials in the form they are transferred to the [Transferee]). The [Transferee] may apply for the grant of patents claiming inventions developed using samples of the transferred Materials, including inventions embodied in modified forms of the materials, or for the grant of plant variety protection claiming varieties developed using samples of the transferred Materials*". [101]

Sample Clause 33: Commercialization

"*If the Organisation proposes to undertake Commercialisation which is required pursuant to clause 8.2 to be authorised under a Commercialisation Plan, the Organisation may submit a draft Commercialisation Plan to the Department which must provide to the reasonable satisfaction of the Department, full details of:*
(i) all Commercialisation proposed to be authorised under the Commercialisation Plan;
(ii) all benefits (including Non-Monetary Benefits) for Queensland of the Commercialisation proposed to be authorised under the Commercialisation Plan; and
(iii) any aspect of the Commercialisation proposed to be authorised under the Commercialisation Plan which is proposed to occur outside of Queensland.[102]

B. FOOD AND AGRICULTURE

71. Agreements in the agricultural sector face the following realities,[103] which may be reflected in the design of IP clauses. The sector mainly uses crops, farm animals, forestry, fisheries, micro-organisms and insects related to food and agriculture, and their wild relatives primarily for breeding and selection, propagation and cultivation of the genetic resource in the form received but as well for conservation and other uses. The ITPGRFA and SMTA provide facilitated access to PGR including detailed benefit-sharing and dispute settlement provisions. For access to animal and microbial genetic resources no such standard agreements exist. In addition, many different and highly sophisticated exchange systems and material transfer agreements for access major *ex situ* collections exist. Input materials are generally available free of restrictions for further research and breeding and large *ex situ* collections exist. The sector continuously reuses its own genetic resources for the generation of new products and needs access to a wide range of different genetic resources. Therefore, wide facilitated access is so useful and prevalent in the agricultural sector. In some instance particular MTAs are negotiated.

72. Some access and benefit-sharing agreements related to food and agriculture exclude the use of IPRs. See for example Sample Clause 34:

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[101] Model Material Transfer Agreement (MTA) of the Biotechnology Industry Organization (BIO), Clause 4.3

[102] Uniform Biological Material Transfer Agreement, dated March 8, 1995 for the Transfer of Materials between Non-Profit Institutions and an Implementing Letter for the Transfer of Biological Material, Clause 8.3

[103] See UNEP/CBD/WG-ABS/7/2

Sample Clause 34: Agricultural research

"The Recipient shall own the progeny or germplasm which are not essentially derived from the Material. The Recipient agrees that it: …

'(d) shall not seek intellectual property rights over the Material or related information which could act to the detriment of the continuing availability of the Material for agricultural research and breeding purposes'".[104]

Other agricultural research MTA provide for such possibility at a later stage. See Sample Clause 35:

Sample Clause 35: Agricultural Research including IP

10.7 The Commissioned Organisation agrees that it will enter into equitable arrangements with the Collaborating Institution in relation to the following matters:

(a) the allocation of ownership of Intellectual Property in the Material between the Commissioned Organisation and the Collaborating Institution in countries other than Australia and the Collaborating Country;
(b) the terms of any licences between the Commissioned Organisation and the Collaborating Institution to use or exploit the Intellectual Property referred to in clause 10.3 and paragraph (a);
(c) the terms of any licences of other Intellectual Property owned or licensed by either the Commissioned Organisation or the Collaborating Institution which are necessary for the utilisation of the Material; and
(d) the allocation of costs relating to the application for and maintenance of the Intellectual Property rights between the Commissioned Organisation and the Collaborating Institution.[105]

[104] A Material Transfer Agreement (Germplasm and Unregistered Lines) between the Department of Agriculture and Agri-Foods, Canada (AAFC) and several public breeding institutions and see Model Transfer Agreement (MTA) on Plant Genetic Resources for Food and Agriculture (PGRFA), recommended model for institutions participating in the "National Programme on Plant Genetic Resources and Agro-biodiversity Conservation and Utilization" of the Czech Republic, Czech Gene Bank, Crop Research Institute (CRI) and providing PGR to users

[105] Standard Conditions for Project Agreements between the Australian Centre for International Agricultural Research (ACIAR) and the Commissioned Organisation

C. NON COMMERCIAL RESEARCH

73. IP Clauses in access and benefit-sharing in non-commercial share the common element that the material transfer agreements and mutually agreed terms are primarily not aiming at commercial use and therefore mostly exclude the use of IPRs or provide the opportunity to renegotiate later commercial use and the exploitation of the genetic resources by IPRs. The sector is mainly characterized by utilization of genetic resources by conservation, characterization and evaluation, production of naturally occurring compounds of live or dead organism. Recipients and providers use standard mutually agreed terms and benefit-sharing arrangement terms (both monetary and non-monetary).[106]

74. Normally, no economic utilization of genetic resources or research results is expected and, therefore, intellectual property protection is not primarily sought. However, the agreements may provide for some provisions concerning the change of intent from non-commercial to commercial research, eventually to seek new prior informed consent or to re-negotiate the material transfer agreement. Some agreement provide for a default benefit-sharing arrangement for unanticipated commercial benefits. If no commercial use is intended the agreement normally ends when the research is finished. In general, the material transfer or cooperation agreements base on an interest in providing training and technical assistance. For an example, see Sample Clause 36:

Sample Clause 36: Change of interest

"*If the recipient, as the results of the field trials, has interest to develop the material in the commercial market, the recipient agrees to negotiate in good faith with INIA, prior to marketing of such products, the compensation to be paid by the recipient to INIA. Such compensation may include royalties on the gross sales value of such products derived from the material*".[107]

D. EX SITU CONSERVATION

75. Similar as the sector of non-commercial research the sector of *ex situ* conservation including botanical gardens and microbial resources centers is primarily not aiming at commercial use and therefore mostly excludes the use of IPRs or provide the opportunity to renegotiate later commercial use and the exploitation of the genetic resources by IPRs. Concerning specifically ex situ collections and collection of Botanical Gardens, mostly genetic resources on Micro-organisms for collection, identification, preservation and distribution are used. The benefits are mainly in non-monetary benefits of sharing the microbes, conservation of microbes for sustainable use and consultation of treatment of microbes, such as cultivation and preservation. Microbes are mostly freely available for non-commercial research. Users have to negotiate mutually agreed terms if they want to use accessions commercially. In addition, it was observed that ABS arrangements range from highly standardized forms of transactions to customized arrangements to meet the

[106] See UNEP/CBD/WG-ABS/7/2

[107] Material Transfer Agreement (MTA): Restricted License for non-profit purposes of the National Agricultural Research Institute (INIA Uruguay), Clause 10

specific circumstances and interests of both provider and user. Use is also made of phased agreements, where, for instance, a research agreement is concluded for a first phase, and later on a second agreement might be concluded that will cover product development and commercialization. As access to resources for basic research normally precedes developing value chains, most requests for *in situ* access therefore are for research purposes.[108]

76. However, IPRs could be part of future uses of the genetic resources provided. The sector has developed a wide range of code of conducts, guidelines and model material transfer agreements. For a typical clause making IP subject to a separate written agreement, see Sample Clause 37 and for non-monetary benefits of an *ex situ* conservation agreement, see Sample Clause 38:

Sample Clause 37: *Ex situ* conservation
"*BG Kew will not commercialise any Genetic Resources transferred under this Agreement.*
Without prejudice to the above, any Commercialisation to which RBG Kew and LARI may agree will be subject to a separate written agreement.
"Commercialise" and "Commercialisation" shall include, but not be limited to, any of the following: sale, filing a patent application, obtaining, or transferring intellectual property rights or other tangible or intangible rights by sale or licence or in any other manner; commencement of product development; conducting market research and seeking pre-market approval".[109]

[108] See UNEP/CBD/WG-ABS/7/2

[109] Access and Benefit-Sharing Agreement between the Lebanese Agricultural Research Institute, Tal Amara, Rayak, Lebanon and The Board of Trustees of the Royal Botanic Gardens, Kew, Richmond, Surrey, TW9 3AE United Kingdom

Sample Clause 38: Non-monetary benefits in ex situ conservation

"*Benefits arising from the collection, study or conservation of Material transferred under this Agreement may include the following:*
- Accession of a representative, viable portion of the Material into the collections at the Seed Bank;
- Processing and viability testing of Material, its progeny or derivatives;
- Taxonomic identification of Material, its progeny or derivatives;
- Acknowledgement of LARI as the source of Material in research publications;
- Joint authorship of publications, as appropriate;
- Ensuring that the parties provide each other with copies of the results of all such scientific study, research and publications;
- Informing each other of any relevant opportunities for training and/or study by appropriate staff personnel at LARI or Kew;
- Encourage appropriate staff personnel at LARI or Kew take up any such opportunity for training and/or study". [110]

[Appendixes follow]

[110] Access and Benefit-Sharing Agreement between the Lebanese Agricultural Research Institute, Tal Amara, Rayak, Lebanon and The Board of Trustees of the Royal Botanic Gardens, Kew, Richmond, Surrey, TW9 3AE United Kingdom

APPENDIX I

MONETARY AND NON-MONETARY BENEFITS

The Bonn Guidelines list the following potential benefits from access and benefit-sharing:

1. Monetary benefits may include, but not be limited to:

(a) Access fees/fee per sample collected or otherwise acquired;
(b) Up-front payments;
(c) Milestone payments;
(d) Payment of royalties;
(e) Licence fees in case of commercialization;
(f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
(g) Salaries and preferential terms where mutually agreed;
(h) Research funding;
(i) Joint ventures;
(j) Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:

(a) Sharing of research and development results;
(b) Collaboration, cooperation and contribution in scientific research and development programs, particularly biotechnological research activities, where possible in the provider country;
(c) Participation in product development;
(d) Collaboration, cooperation and contribution in education and training;
(e) Admittance to ex situ facilities of genetic resources and to databases;
(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favorable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
(g) Strengthening capacities for technology transfer to user developing country Parties and to Parties that are countries with economies in transition and technology development in the country of origin that provides genetic resources. Also to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources;
(h) Institutional capacity-building;
(i) Human and Material resources to strengthen the capacities for the administration and enforcement of access regulations;
(j) Training related to genetic resources with the full participation of providing Parties, and where possible, in such Parties;
(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
(l) Contributions to the local economy;
(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in provider countries;
(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;

(o) Food and livelihood security benefits;
(p) Social recognition;
(q) Joint ownership of relevant intellectual property rights.

[Appendix II follows]

APPENDIX II

LIST OF ACTUAL AND MODEL CONTRACTUAL AGREEMENTS FOR ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING, REFERRED TO IN THE PRESENT DOCUMENT

1. Access and Benefit-Sharing Agreement between the Lebanese Agricultural Research Institute, Tal Amara, Rayak, Lebanon and The Board of Trustees of the Royal Botanic Gardens, Kew, Richmond, Surrey, TW9 3AE United Kingdom
2. Confidentiality Agreement NIH
3. Exclusive License Agreement (sample) - Harvard College, United States of America
4. Exclusive Variety License Agreement between her Majesty the Queen in Right of Canada, as represented by the Ministry of Agriculture and Agri-Food (AAFC), and the Company
5. Know How Licencing Agreement between The Tropical Botanic Garden and Research Institute, Kerala, India (TBGRI) and The Arya Vaidya Pharmacy (Coimbatore) Ltd, Coimbatore, India (the PARTY), dated November 10th, 1995
6. Material Transfer Agreement (Germplasm and Unregistered Lines) between the Department of Agriculture and Agri-Foods, Canada (AAFC)
7. Material Transfer Agreement: Restricted License for non-profit purposes of the National Agricultural Research Institute (INIA Uruguay)
8. Material Transfer Agreement, American Type Culture Collection (ATCC)
9. Memorandum of Understanding between [Source Country Organization] and the Developmental Therapeutics Program
10. Model Access and Benefit Sharing (ABS) agreement between Australian Government and access party
11. Model Biodiscovery Benefit-Sharing Agreement prepared by the State of Queensland, Australia to facilitate the development of the Queensland Biodiscovery Industry
12. Model Letter of Collaboration between the Developmental Therapeutics Program Division of Cancer Treatment/Diagnosis National Cancer Institute, United States of America (DTP/NCI) and a Source Country Government (SCG)/Source Country Organization(s) (SCO)
13. Model Material Transfer Agreement of Korean Research Institute of Bioscience and Biotechnology
14. Model Material Transfer Agreement of the Biotechnology Industry Organization (BIO)
15. Model Material Transfer Agreements for Equitable Biodiversity Prospecting (Version One: For Transfer of Biological Resources to Non-Commercial or Non-Profit Organizations)
16. Model Material Transfer Agreement, MOSAICC 2009, the “Micro-Organisms Sustainable use and Access regulation International Code of Conduct”
17. Model project on “Genetic Modification of hyaluronidase inhibitor glycoprotein (WSG) in the roots of Withania Somnifera (Hania plant) for Anti Vanum Treatment” between the Astra Zeneca (Medicine Company), UK, the National Institute of Health (NIH),Islamabad and the Local Government, Karimabad (Hunza Valley, Pakistan)
18. Model Transfer Agreement (MTA) on Plant Genetic Resources for Food and Agriculture (PGRFA), recommended model for institutions participating in the “National Programme on Plant Genetic Resources and Agro-biodiversity

Conservation and Utilization" of the Czech Republic, Czech Gene Bank, Crop Research Institute (CRI) and providing PGR to users

19. Model Transfer Agreement (MTA): Terms and Conditions of limited non-exclusive license model agreement to use genetic material of the Culture Collection of Dairy Microorganisms (CCDM) of the Czech Republic, Crop Research Institute (CRI)
20. National Science Foundation draft letter Uniform Biological Material Transfer Agreement, Non-profit to Non-profit, Quoted in Barton, John and Siebeck, Wolfgang. *Material transfer agreements in genetic resources exchange – the case of the International Agricultural Research Centres*. International Plant Genetic Resources Institute, May 1994
21. Non-disclosure agreement between National Innovation Fund (NIF) and recipient
22. Non-exclusive License Agreement (sample) - Harvard College, United States of America
23. Recommended WIPO Contract Clauses and Submission Agreements
24. Standard Conditions for Project Agreements between the Australian Centre for International Agricultural Research (ACIAR) and the Commissioned Organisation
25. Uniform Biological Material Transfer Agreement, dated March 8, 1995 for the Transfer of Materials between Non-Profit Institutions and an Implementing Letter for the Transfer of Biological Material

[End of Annex and of document]