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CONTRACTUAL PRACTICES AND CLAUSES RELATING TO INTELLECTUAL PROPERTY, ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

Document prepared by the Secretariat

I. OVERVIEW

1. This document provides updated input into the work of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the Committee") on intellectual property ("IP") aspects of contracts and licenses concerning genetic resources. At its fourth session, the Committee agreed on the further development of the pilot database of contractual practices and clauses relating to IP, access to genetic resources and benefit-sharing as a practical tool in the provision of information in this area ("the Contracts Database"). The Committee also agreed that Questionnaire WIPO/GRTKF/IC/Q2 should continue to be disseminated as a means of promoting a wider range of material in the database.

2. This document reports on the updating of the Contracts Database to a more fully operational and comprehensive version, including the translation of the Contract Checklist Pages into three languages, discusses the role of contractual arrangements in recently enacted legislation on access to genetic resources and associated traditional knowledge (TK), and provides an overview of the IP aspects of contracts relating to biological material and associated TK. It proposes that the process of collecting information for the Contracts Database continue, and that the database be maintained and updated so that it can continue to

be used as a permanent, freely available resource by all those with a practical or policy interest in the IP aspects of contractual practices and contracts concerning access to genetic resources and benefit-sharing. It also proposes that, on the basis of the empirical evidence provided in the Contracts Database, work should resume on the development of guidelines, best practices or other guidance, on the IP aspects of contracts and licenses concerning access to genetic resources and benefit-sharing.

II. INTRODUCTION

3. Against a background of growing international need for more practical tools and information in this area,[1] the Committee at its first session expressed support for the development of, "contractual practices, guidelines, and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing, taking into account the specific nature and needs of different stakeholders, different genetic resources, and different transfers within different sectors of genetic resource policy."[2]

4. Document WIPO/GRTKF/IC/2/3 considered operational principles for IP clauses of contractual agreements concerning access to genetic resources and benefit-sharing. Further study of IP and genetic resources licensing was based on a widely circulated survey (questionnaire WIPO/GRTKF/IC/Q.2)[3] 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 (based on a proposal set out in document WIPO/GRTKF/IC/3/4 and approved by the Committee at its third session).

5. At the fourth session of the Committee, the Secretariat gave an informal presentation of the pilot Contracts Database, which, at that time, contained nineteen actual or model contracts, licenses or questionnaire of contractual practices and clauses concerning IP, access

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1 As recently as September 2002, the World Summit on Sustainable Development (WSSD), held in Johannesburg, considered the issue of benefit-sharing. In its Plan of Implementation, it agreed to: "Promote the wide implementation of and continued work on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, as an input to assist Parties to the Convention (on Biological Diversity) when developing and drafting … contract and other arrangements under mutually agreed terms for access and benefit-sharing (42.N); and 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 (42.O)". The Bonn Guidelines, *inter alia*, encourage 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:" see Decision VI/24 of the sixth Conference of the Parties of the CBD.

2 See document WIPO/GRTKF/IC/1/13, paragraph 128.

3 For instance, WIPO/GRTKF/IC/Q.2 was disseminated to members of the Expert Panel on Access and Benefit-Sharing that had been convened by Member States to the Convention on Biological Diversity ("CBD") and that had been instrumental in drawing up the recently adopted "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization," and, on the world wide web, through BIOPLAN, an electronic Biodiversity Communication Network maintained by UNEP.

to genetic resources and benefit-sharing.[4] The Committee also considered a report on the background and development of the database (document WIPO/GRTKF/IC/4/10) and agreed that the process of collecting information continue, with a view to developing a fully operational and more comprehensive version of the Contracts Database for future consideration by the Committee.

III. DEVELOPMENT OF THE CONTRACTS DATABASE

6. Based on the experience gained and comments made during the presentation of the pilot database, the database has been modified in the following ways:

(a) The search tools and results pages have been further refined to ensure that a user may be more directly linked to the contractual clauses or information sought. In particular:

- The full text search option has been adapted to provide a more user-friendly results page;

- The search tool directed at retrieving information on a specific kind of contractual clause, or combination of contractual clauses, has been tailored to provide individual hyper-links which directly connect to the relevant clause in the contract itself, or the completed questionnaire (whichever has been provided). For instance, a user searching all contracts with clauses on licenses and confidentiality will be able to access those clauses directly, rather than via. the Contract Checklist Page (as had been the case in the pilot database); and

(b) The individual Contract Checklist Pages, which provide a summary of the background to the submitted contract or questionnaire, are in the process of being translated into English, French and Spanish. The actual contracts and licenses, or questionnaires, have been left in the language in which they were submitted to WIPO. The rationale behind this decision was a concern that, otherwise there would be a considerable risk that complex contractual provisions may be misconstrued, once translated, or simply mistranslated. Were extra resources allocated to the future development of this project, this decision could, of course, be revisited; alternatively, such extra resources could be used to translate the individual Contract Checklist Pages into additional WIPO official languages.

7. The updated version[5] of the Contracts Database, which incorporates these modifications, is publicly available on the WIPO web site at:

http://www.wipo.int/globalissues/databases/contracts/index.html

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[4] The Secretariat had received a further twelve replies were from Member States stating, in effect, that they had no information on this topic.

[5] This updated version includes the twelve additional model or actual contracts or licenses submitted to, or compiled by, the Secretariat between the end of the fourth session of the Committee and Friday, March 28, 2003.

8. The Contracts Database currently contains over thirty examples of contracts or licenses concerning IP, access to genetic resources, and associated TK, and benefit-sharing. Most of these agreements, and the greater part of the information submitted, were provided in the English language. Given, however, the extensive experiences of many non-anglophone regions and countries in the IP aspects of access to genetic resources and benefit-sharing,[6] it is hoped that the development of a more comprehensive version of the database, and the translation of the Contract Checklist Pages into English, French and Spanish will encourage responses from a wider linguistic pool.

IV. CONTRACTUAL ARRANGEMENTS FOR ACCESS TO GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE

9. Contracts or agreements have potential use in relation to a wide range of scenarios concerning access to and benefit-sharing from genetic resources and associated TK. For instance, under Article 15, paragraph 7, of the Convention on Biological Diversity, each Contracting Party shall "take legislative, administrative or policy measures, as appropriate... with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms." Thus the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization[7] were developed to serve as inputs for, among other measures, 'contracts and other arrangements under mutually agreed terms for access and benefit-sharing.' The Bonn Guidelines indicate that 'mutually agreed terms should be set out in a written agreement,'[8] set out 'guiding parameters in contractual agreements' and provide 'an indicative list of typical mutually agreed terms'[9] which may be applicable in contracts regarding access to genetic resources. This illustrates the potential application and elements of contracts relevant to the sharing of benefits.

National laws governing access to genetic resources

10. Many contracts regarding access to genetic resources are established under general contract law within national legal frameworks – for instance, material transfer agreements concluded between two parties. In a number of countries, specific requirements for contracts or licenses are established under national laws governing access to genetic resources. Some national laws also govern access to TK that is associated with genetic resources. For example, document WIPO/GRTKF/IC/5/INF/2 provides details of the three laws which regulate access to genetic resources and TK and rely on the use of contracts or license agreements to regulate and monitor such access. These provisions are outlined here in order

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6 For instance, Article 32 of Decision 391 of the Andean Community (Colombia, Venezuela, Peru, Ecuador and Bolivia), which established a "Common System on Access to Genetic Resources" states that an access contract must be signed between the Applicant and the State.. For detail of the access contracts signed to date, see Factsheet: Access to Genetic Resources in the Andean Community, 2002 by Patricia Molina - Foro Boliviano sobre Medio Ambiente y Desarrollo (FOBOMADE) at: http://www.biowatch.org.za/pmolina.htm. See also Section IV below which describes recent developments in access legislation in Brazil, Panama and Peru.

7 http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp#

8 Bonn Guidelines, paragraph 42(g)

9 Bonn Guidelines, paragraph 44

to illustrate the potential implications for contractual provisions on genetic resources and associated TK.

(a) Brazilian Provisional Measure No. 2.186-16, of August 23, 2001;

(b) Panamanian Law No. 20 of June 26, 2000, on the Special Intellectual Property Regime Governing the Collective Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and their Traditional Knowledge; and Executive Degree No. 12 of March 20, 2001; and

(c) Peruvian Law No. 27811 ("A Law introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources"), published on August 10, 2002.

Brazilian Provisional Measure No. 2.186-16, of August 23, 2001[10]

11. Under the recently enacted Brazilian Provisional Measure No. 2.186-16, of August 23, 2001, whenever there is a prospect of subsequent commercial use, *in situ* access to samples of components of genetic heritage and associated TK may only be granted after a Contract for Use of the Genetic Heritage and Benefit-Sharing has been signed.[11] The purpose of the Contract is to give "the particulars of the parties, the purpose and the conditions of access to and dispatch of components of the genetic heritage and associated TK, and also the conditions for the sharing of benefits".[12]

12. The Brazilian Provisional Measure contains considerable detail regarding the development and practical operation of such a contract. For example, it creates a Council for the Management of Genetic Resources within the Ministry of the Environment. With respect to contractual arrangements, the Council will:

(a) Establish directives for drafting the Contract for Use of the Genetic Heritage and Benefit-Sharing;[13] and

(b) Approve Contracts for the Use of the Genetic Heritage and Benefit-Sharing as complying with the requirements of this Provisional Measure and the regulations under it.[14]

13. Furthermore, the Chairman of the Management Council shall be competent to sign the Contract for the Use of the Genetic Heritage and Benefit-Sharing. This power may, however, be delegated to a Federal public research and development institution or Federal public management institution, depending on the area of activity with which the Contract is concerned (although should such an institution have an interest in the contract, the Contract shall be signed by the Chairman of the Management Council).[15] The Management Council may also accredit a national public research and development institution or Federal public management institution for authorizing another national institution, whether public or private, which carries on research and development activities in the biological and related fields to:

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10 See Annex III to WIPO/GRTKF/IC/5/INF/2 for the full text of this legislation.
11 Brazilian Provisional Measure No. 2.186-16, of August 23, 2001, Chapter V, Article 16.
12 Ibid., Chapter II, Article 7 (Definitions).
13 Ibid., Chapter IV, Article II 2 (c).
14 Ibid., Chapter IV, Article V.
15 Ibid., Chapter IV, Article 13.

(a) Create and maintain a database of Authorizations of Access and Dispatch, Terms of Transfer of Material and Contracts for the Use of Genetic Heritage and Benefit-Sharing;

(b) Disclose periodically a list of Authorizations of Access and Dispatch, Terms of Transfer of Material and Contracts for the Use of the Genetic Heritage and Benefit-Sharing;

(c) Take part in the implementation of Terms of Transfer of Material and Contracts for the Use of the Genetic Heritage and Benefit-Sharing in the case of processes that it has itself authorized; and

(d) Register Contracts for Use of the Genetic Heritage and Benefit-Sharing, following their approval by the Management Council.[16]

14. Chapter VII on Benefit-Sharing sets out the proposed detail of the Contract itself. The Contract shall mention and clearly identify the contracting parties, being on the one hand the owner of the public or private area or the representative of the indigenous community and the official indigenous body, or the representative of the local community and, on the other hand, the national institution authorized to have access and the receiving institution.[17] Contracts that are signed in a manner not conforming to the terms of the Provisional Measure and the regulations shall be null and devoid of legal effect.[18]

15. Essential clauses in the Contract are those that relate to:

(a) Purpose, elements, quantification of samples and intended use;

(b) Duration;

(c) Method of fair and equitable sharing of benefits and, where applicable, access to and transfer of technology;

(d) Rights and responsibilities of the parties;

(e) Intellectual property rights;

(f) Cancellation;

(g) Penalties; and

(h) Jurisdiction in Brazil.[19]

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16 Ibid., Chapter IV, Articles 14 – 15.
17 Ibid., Chapter VII, Article 27.
18 Ibid., Chapter VII, Article 29.
19 Ibid., Chapter VII, Article 28.

Panamanian Law No. 20 of June 26, 2000; and Executive Degree No. 12, of March 20, 2001[20]

16. Contractual arrangements form a central aspect of recently enacted access legislation in Panama (although in this case, access to TK and expressions of folklore, rather than to genetic resources *per se*). Under Panamanian Executive Degree No. 12, of March 20, 2001,[21] the term "license contract" is defined as meaning " the right of the indigenous people or peoples to grant third parties, by written contract, a registered collective right[22] to the use of knowledge." Industrial reproduction, either totalor partial, of registered collective rights shall be permitted once the Registries authorized by law have studied and analyzed the submissions by the owners of the registration. In addition to the express consent and the application itself, the owners of the registration shall submit the following documentation:

(a) A record of the agreement or express authorization of the congress, indigenous authority or, failing that, the indigenous council that is holding the registered traditional indigenous knowledge, which shall specify that the use of the collective rights shall be licensed to third parties by contract;

(b) A copy of the license contract for use of the registered collective rights;

(c) The identity of the representative(s) of the congress(es) or indigenous authority (authorities) of the indigenous community (communities) holding the registered TK or expression of folklore, who have signed the contract;

(d) The identity of the other parties to the contract and of their representatives; and

(e) The use that is to be made of the TK or expression of folklore.

17. Under Article 18 of Executive Degree No. 12, a license contract for the use of collective rights shall be registered only where the following requirements have been met:

(a) Identification of the parties;

(b) Description of the registered collective rights to which the contract relates;

(c) Specification of the royalties that the indigenous peoples will receive for the use of the collective rights; those royalties shall include an initial payment or some form of immediate, direct compensation to the indigenous peoples, and a percentage of the value of

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20 Copies of both Law No. 20 of June 26, 2000, and of Executive Degree No. 12 of March 20, 2001, can be found at Annex III to WIPO/GRTKF/IC/5/INF/2.

21 This Executive Degree regulates Law No. 20 of June 26, 2000, on the Special Intellectual Property Regime Governing the Collective Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and their Traditional Knowledge.

22 The collective rights of the indigenous communities are recognized in their musical instruments, music, dances or form of performance, oral and written expressions contained in their traditions that constitutes their historical, cosmological and cultural expression: Panamanian Executive Degree No. 12, of March 20, 2001, Article 4.

the sales resulting from the marketing of products developed on the basis of the said collective rights;

(d) Provision of sufficient information on the purposes, risks and implications of the activity concerned, the periods of use, including possible uses of the collective rights, and the value thereof where applicable; and

(e) The obligation on the licensee to give a periodical account to the licensor, in general terms, on the progress made in research and industrialization and the marketing of the goods developed on the basis of the licensed collective rights. Where the contract contains a reserved rights obligation, that fact shall be expressly stated.

18. The Panamanian Executive Degree continues by stating that a license for the use of the collective rights of an indigenous people shall not prevent the indigenous communities that possess the TK from continuing to use it, neither shall it affect the right of present and future generations to continue to use it and develop it on the basis of the collective knowledge. Likewise, the license shall not prevent other peoples that hold the same registered collective rights from licensing those rights, even where they are not parties to the contract in question. Sub-licensing may only take place with the authorization of the Ministry of Commerce and Industries and the express prior consent of the owner or owners of the registered collective rights (who meet the requirements prescribed in Article 1 of the Regulations). The license can be cancelled at the request of one of the parties to the contract, and after the parties concerned have been heard, where:

(a) It has been granted in violation of any of the provisions of this enactment;

(b) It has been granted on the basis of false or inaccurate data contained in the application, which are essential.[23]

Peruvian Law No. 27811- A Law introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resource[24]

19. Licensing agreements also play a central role in Peruvian Law No. 27811, which seeks to protect and promote the collective knowledge[25] of Indigenous peoples derived from biological resources.[26] 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.[27] The minimum clauses that should be included in such an agreement include:[28]

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23 Ibid., Articles 21 to 23.

24 See Annex III to WIPO/GRTKF/IC/5/INF/2 for the full text of this legislation.

25 "Collective knowledge" means the accumulated, trans-generational knowledge evolved by indigenous peoples and communities concerning the properties, uses and characteristics of biological diversity. The intangible components referred to in Decision 391 of the Commission of the Cartagena Agreement include this type of collective knowledge. Ibid., Article 2.

26 The protection regime established by Law No. 27811 does not affect the traditional exchange between indigenous peoples of the collective knowledge protected under this regime. Ibid., Article 4.

27 Ibid., Article 7.

28 Ibid., Article 27.

(a) Identification of the parties;

(b) A description of the collective knowledge to which the contract relates;

(c) A statement of the compensation that the indigenous peoples shall receive for the use of their collective knowledge; such compensation shall include an initial monetary or other equivalent payment for its sustainable development, and a percentage of not less than five per cent of the value, before tax, of the gross sales resulting from the marketing of the goods developed directly and indirectly on the basis of the said collective knowledge, as the case may be;

(d) The provision of sufficient information on the purposes, risks and implications of the said activity, including any uses of the collective knowledge, and its value, where applicable;

(e) The obligation on the licensee to inform the licensor periodically, in general terms, of progress in the research on and industrialization and marketing of the goods developed from the collective knowledge to which the license relates; and

(f) The obligation on the licensee to contribute to the improvement of the ability of the indigenous peoples to make use of the collective knowledge relating to its biological resources.

20. All licenses shall be in writing, in the native language and in Spanish, for a renewable period of not less than one year or more than three years. They shall be entered in a register kept for the purpose by The National Institute for the Defense of Competition and Intellectual Property (INDECOPI). Contracts that do not conform to the provisions of the law will not be registered.[29] Furthermore, the licensing of the use of the collective knowledge of an indigenous people shall not prevent others from using or licensing the same knowledge, nor shall it affect the right of present and future generations to continue to use and develop collective knowledge. Sub-licensing shall be allowed only with the express permission of the representative organization of the indigenous peoples that granted the license.[30]

21. Finally, and in light of the Committee's work on patent disclosure requirements relating to genetic resources and TK,[31] it is notable that one of the closing articles in Peruvian Law No. 27811, which provides a clear link between license agreements, and the interface between the IP system (in particular the patent system) and the regulation and management of genetic resources and TK:[32]

> "Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge, the applicant shall be obliged to submit a copy of the license contract as a prior requirement for the grant of the rights concerned, except

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29 The Office of Inventions and New Technology of INDECOPI will also maintain a Register of Licenses for the Use of Collective Knowledge and keep it up to date; and assess the validity of contracts for the licensing of collective knowledge of indigenous peoples, taking due account of the opinion of the Indigenous Knowledge Protection Board. Ibid., Article 64.

30 Ibid., Article 25 to 33.

31 See in particular documents WIPO/GRTKF/IC/4/11 and WIPO/GRTKF/IC/5/10.

32 Ibid., Title IX.

where the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned."

22. These three examples of recently enacted access legislation all confer a central role on contracts and license agreements in the successful management and utilization of biological material and TK, including express recognition of the role that IP can play in such agreements. In the future, it therefore seems likely that many more contractual arrangements which address IP related issues, such as benefit-sharing clauses, and patent or know-how licenses, will be developed (often in languages other than the English language). The maintenance, and continued development of, the Contracts Database, should serve as a valuable resource with which to build capacity in this important, and growing, area.[33]

V. INTELLECTUAL PROPERTY ASPECTS OF CONTRACTS CONCERNING BIOLOGICAL MATERIAL AND ASSOCIATED TRADITIONAL KNOWLEDGE

23. A consideration of the list of contracts, licenses and questionnaires currently included in the Contracts Database (see Annex), reveals the very broad range of model and actual agreements[34] so far included in the database. This range reflects the many difference types of scenario involving the use of biological material and associated TK, in particular, the diversity of:

(a) *Providers and recipients of biological materials:* 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.*)

(b) *Biological material:* this may include plant, animal or microbial biological material, and derivatives;

(c) *Licensed uses of the biological 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 commercialisation (including realizing the market potential of the biological 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.

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[33] The Discussion Paper presented by Brazil at the Ministerial Meeting of Countries with Mega Biodiversity held in Cancun, Mexico, between February 18 to 20, 2002 stated as follows: "Benefit-sharing Arrangements: this is one of the most difficult and controversial issues related to access to genetic resources. Mega Biodiverse (MBD) countries need to advance in these discussions especially with regards to the terms of Transfer Contracts and of Material Transfer Agreements (MTAs)."

[34] See paragraphs 27 to 29 of WIPO/GRTKF/IC/4/10 for an explanation of the distinction between model and actual agreements.

(d) *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 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 commercialisation); and

(e) *Legal jurisdictions* which may govern the contractual relationship between the parties.

24. All of the above factors will define and shape the way in which any IP aspects are incorporated into a contractual relationship. For instance, in some scenarios, there may be no role for IP rights in the early stages of a research relationship. An initial agreement may concentrate on non-IP related benefit-sharing, such as training and education and technology transfer, and the parties may agree to negotiate a separate commercialization package (including consideration of ownership of IP, right to license the IP, benefit-sharing arising out of any licensing agreement etc.) at a later date, should the need arise. 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.

25. Hence, while the Contracts Database may be useful in illustrating various approaches that have been taken, the information it contains should only be viewed as a general starting point, to be interpreted according to the individual circumstances of a particular transaction and collaboration. No single set of contracts can illustrate the full set of options that are available between two parties in a licensing negotiation, nor can it indicate what the optimal approach is in any actual negotiation. In any event, in any potentially legally binding relationship, it is generally speaking advisable for all parties to seek independent advice, with experience in the relevant national legal system (or systems), which can:

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

(b) Clarify whether the rights and obligations are reasonable, fair and legal.

Such individual advice cannot be obtained from a consideration of the model or actual agreements of other institutions or organizations; the more that 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.

26. A review of contracts and licenses should shed light on the different roles that IP can, and does, play as a practical tool for sharing benefits across a range of possible contractual agreements relating to biological materials and associated TK, and to establish some preliminary insights into possible IP guidelines and best practices. For the sake of analysis, the contractual scenarios can be considered under four the broad categories set out below for illustrative purposes. Many agreements are, in fact, a combination of all, or some, of these categories, depending upon the individual circumstances of the collaboration. Negotiators are normally advised to think first about the nature of the practical arrangement that you want to enter into, and then to think about how that arrangement should be expressed in legal terms,

rather than limiting the co-operative mechanism to a pre-existing legal precedent; actual agreements therefore may incorporate elements from several of these general categories:

(a) Letters of Intent or Heads of Agreement;

(b) Confidentiality or Non-Disclosure Agreements (as part of a research collaboration, or as a condition of employment);

(c) Material Transfer Agreements (MTAs) (used when obtaining biological material for research.); and

(d) Licensing Agreements (such as agreements to license the use of research tools and other technology).

27. As research on biological material increases, MTAs are increasingly combined with broader access and research agreements, such as Co-operative Research and Development Agreements (CRADAs) and Access and Benefit-Sharing Agreements. A CRADA is increasingly common 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. A CRADA will normally establish clear goals and milestones (these can be used as specific decision points for planning future joint research or the commitment of additional funds), and will usually address key IP issues, such as ownership of IP rights on any research outcomes.

28. An example of an access and benefit-sharing agreement contained in the Contract Database is the agreement between the Lebanese Agricultural Research Institute, Tal Amara, Rayak, Lebanon and The Board of Trustees of the Royal Botanic Gardens,[35] which addresses, *inter alia*: prior informed consent, agreed project activities, including the transfer of material (seeds and associated, duplicate herbarium specimens) and agreed areas of research on the material; the fair and equitable sharing of benefits; the transfer of material to third parties; termination; and dispute resolution.

A. Letters of Intent or Heads of Agreement

29. Prior to entering into any detailed contract or license negotiations, and at an early stage in any collaboration, it can be a useful exercise for prospective partners to draw up either a short Letter of Intent or a Heads of Agreement (also known as a “memorandum of understanding” or “agreement in principle”). The purpose of such a document is to provide a 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 (which may be expensive and time consuming) have a solid basis of understanding.[36] The legal consequences of such an arrangement depend upon the legal system in the country in question. Some national laws view them as legally binding, whereas others take the view that, whilst they may establish the seriousness of intention of the

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35 http://www.wipo.int/globalissues/databases/contracts/summaries/larikew.html

36 See, for example, the Model Letter of Collaboration between the Developmental Therapeutics Program Division of Cancer Treatment/Diagnosis National Cancer Institute, United States of America and a Source Country Government/Source Country Organization(s) at: http://www.wipo.int/globalissues/databases/contracts/summaries/nciloc.html

parties, they fall short of a binding contract. However, even if non-binding, such documents can represent a significant step forward in a collaboration, without legal formalities.

30. In relation to IP, such documents can permit the prospective partners to carry out, in effect, an IP audit of their potential collaboration. This should ensure that, right from the start, the IP implications of their relationship are identified and that subsequently, any IP rights can be properly managed. In particular, consideration of IP in the context of a Letter of Intent or a Heads of Agreement can help prospective partners to consider key issues such as ownership of subsequent IP, whether ownership covers future developments, and how benefits will be shared arising from the exploitation of that IP. For instance:

(a) Who will own a patent in any invention arising out of the collaboration? Will it be dependent solely upon scientific contribution and inventorship?[37] Or will the patent be jointly owned[38] by the partners, regardless of contribution to the invention?[39] If so, what responsibilities will arise out of such joint ownership? For instance, who will pay for the cost of making, and maintaining, any patent application(s)? Who will be responsible for enforcing the patent in the event of infringement? Do the partners need to consider who is funding the project, and whether there are any terms and conditions relating to ownership of IP rights, or subsequent licensing decisions, attached to the funding itself?

(b) Will the planned research activities result in the creation of progeny and derivatives? How will these be defined? Who will own them, or any IP flowing from them?

(c) Who will negotiate and agree the terms of any subsequent licensing arrangement (for instance, the parties could bid for licenses to commercialize the research outcomes, or a separate commercial or industrial partner could be brought in once the research outcomes were proven)? How will the appropriate rates of royalties and other financial arrangements be set?[40] Will the license be sole, exclusive or non-exclusive? Who will own, maintain and

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37 If each party separately retains the rights to the IP that it creates, one way of sharing the uses and benefits of that IP would be to enter into cross-licensing agreements with the other party(ies).

38 Joint ownership of IP tends to be a legal possibility (depending upon the legal system in the country in question), although it can lead to practical problems. It can mean that neither party has complete control. For instance, one party may be able to use the invention protected by the patent without the other co-owner's permission. However, the agreement of all co-owners may be needed for the patent to be licensed, sold or mortgaged. In cases of joint ownership, it is often more practical for one co-owner (or more) to license or sell their interest in the patent to another of the co-owners. There is an exception to these rules for joint ownership in the United States, where, unless the joint owners have agreed differently, each one is free to use the patented invention without being accountable to the others.

39 In the Research Agreement between Syngenta Crop Protection AG, Basel, Switzerland (Recipient) and HUBEI Academy of Agricultural Sciences, Wuhan, China (Provider), patent rights on metabolites are granted to the Recipient, except in the territory of the Provider, where the patents will be jointly owned. See: http://www.wipo.int/globalissues/databases/contracts/summaries/syngenta.html

40 The African International Cooperative Biodiversity Group (ICBG) decided to entrust the Walter Reed Army Institute of Research (WRAIR) with the responsibility of protecting and perfecting any IP rights flowing from the ICBG research, “because WRIAR is the only non-commercial member of the ICBG with both the financial ability and the administrative structure to negotiate the best licensing agreement with potential licensees. The patents generated from the ICBG will be in the name of all the individual investigators who participated in the discovery of a particular drug, including of course the African scientists and traditional healers who

manage the IP rights relating to improvements and adaptations to the licensed technology, arising from the licensed use of the technology?

(d) How will benefits arising from the creation and exploitation of IP rights be shared? For instance, in addition to sharing royalties between the licensor(s) and licensee(s), will licensing royalties be shared with the original holders or owners of the biological material and/or traditional knowledge?[41] Or would the owner prefer to receive immediate short term benefits (most probably non-IP related), rather than waiting to receive longer term IP related benefits? Do any specific structures or procedures need to be established to ensure that benefits do indeed flow back down the line; for instance, a benefit-sharing trust fund?

31. These are just a small sample of some of the IP issues that may need to be considered as part of entering into collaboration involving biological material and TK. Early identification of the IP implications of a relationship, including consideration of the type of contractual arrangement that might best flow from those implications, is a key aspect in establishing a workable and mutually beneficial, long-term partnership. Furthermore, given the potential complexities of such IP implications, it is generally speaking advisable, prior to entering into any potentially legally binding relationship, for all parties to seek independent advice with experience in the relevant national legal system (or systems), and type of transaction, under consideration.

32. Many of the concerns surrounding the role of IP in benefit-sharing may be avoided if an IP strategy is developed, and agreed, as an integral part of any initial project or research planning. The WIPO Toolkit on Intellectual Property Management when Documenting Traditional Knowledge and Associated Genetic Resources, currently under development (see documents WIPO/GRTKF/IC/4/5 and WIPO/GRTKF/IC/5/5), will provide some useful insights into the advantages of proper identification and management of possible IP from an early stage in any collaboration concerning traditional knowledge.

B. Confidentiality or Non-Disclosure Agreements

33. In order to decide whether or not to enter into a legally binding contract or license, it is reasonable to assume that prospective partners will wish to exchange information relevant to the proposed agreement. Some of this information may have commercial, cultural or spiritual value. For instance, a potential licensee may begin by seeking from a licensor a non-confidential summary of a technology. In order to evaluate a technology properly, access to additional confidential information may be required. This information will be regarded as a

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contributed to the process leading to the new product. … The implication is that WRAIR is holding the IPR on trust for the ICBG. … Although it may appear more elegant and would serve public relations to have the IPR vested and retained within the other non-profit, non-governmental ICBG partners, it is unlikely that multinational pharmaceutical companies would respect the IPR knowing that poor developing country institutions lack the financial resources to prosecute a violation." Extract from Case Study Six, The International Cooperative Biodiversity Group: *Drug Development and Biodiversity Conservation in Africa*: Case Study of a Benefit-Sharing Plan by M. Iwu and Sarah A. Laird in "Case Studies on Benefit Sharing Arrangements" published by the Secretariat of the CBD for the fourth Conference of the Parties (1998).

[41] See, for example, Clause 9 of Model Material Transfer Agreement between the American National Cancer Institute (NCI) and Applicant Investigators at: http://www.wipo.int/globalissues/databases/contracts/summaries/ncimta.html

trade secret if it can be characterized as information which attracts the obligation of confidence. A confidentiality or non-disclosure agreement can be a vital tool for ensuring that the obligation of confidence is established. Similarly, information provided by a traditional healer may be viewed as a trade secret, in appropriate circumstances. Parties may also need to consider the role of customary laws and practices when accessing such information, and seeking to entering into formal agreements, with traditional healers, or their associations. Furthermore, 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.

34. As part of the process of developing a project and/or negotiating a more complex legal agreement, short stand-alone confidentiality agreements are often entered into. In many countries, it is not absolutely necessary to have a written agreement for confidentiality obligations to apply. However, a written agreement provides greater certainty and protection against legal challenges. The role of such agreements is to provide legal certainty by making clear that information, or sample material, provided by either party is considered by that party to be: confidential; provided for a specific purposes (such as in order to evaluate a potential future collaboration, rather than other commercial or industrial uses); not to be used for any other purpose; and not to be disclosed to others.

35. The issue of confidentiality will, of course, be addressed differently depending upon the IP policies, and strategies, of a particular party. For instance:

> "e (i). Agreements and research plans should anticipate the tension between the traditional scientific ethic of public access to information, including publication of results, and the understandable desire of indigenous or commercial partners for confidentiality of information with potential commercial value, pending protection through patenting or other means."[42]

Scientific institutions, such as universities and *ex situ* collections may, however, allow limited time restrictions on publications to allow an industrial partners to review research results and to arrange for protection of any resulting IP rights. Such a time restriction would need to be clearly stated in the accompanying confidentiality agreement.

36. There are no specific examples of stand-alone confidentiality agreements in the Contracts Database. However, in providing the Secretariat of WIPO with an Academic Research Agreement, the Government of the Republic of the Philippines noted that where biological materials are being supplied for research, both a confidentiality agreement and a material transfer agreement should be agreed or, alternatively, the two types of agreement can be combined, so that, in effect, the material transfer agreement includes express provisions on confidentiality.

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[42] See the "Principles for the Treatment of Intellectual Property and the Sharing of Benefits associated with International Cooperative Biodiversity Group (ICBG) Sponsored Research" (modified by second request for applications – August 15, 1997): Appendix 1 to Case Study Eleven, "*The International Cooperative Biodiversity Groups (ICBG) Program*", by Joshua P. Rosenthal in "Case Studies on Benefit Sharing Arrangements" published by the Secretariat of the CBD for the fourth Conference of the Parties (1998).

37. A consideration of the agreements contained in the Contracts Database demonstrates that the various categories of potential agreement overlap considerably and that, in fact, the majority of material transfer agreements, research agreements and licenses concerning biological material contain express provisions on confidentiality.[43] For example:

(a) Clause 12 of a Licensing Agreement (sample) submitted by Michael A. Gollin, Venable Attorneys at Law, states as follows:

> "12. CONFIDENTIALITY.
>
> The Parties agree to treat as confidential any and all Confidential Information obtained from each other and to that end further agree that information disclosed pursuant to this Agreement relating to the Formulations, including efforts to commercialize the Formulations, shall be deemed Confidential Information.
>
> Notwithstanding the foregoing, Confidential Information may be disclosed to the extent required by any law or regulation of any governmental authority having jurisdiction over any of the Parties, with appropriate efforts made to maintain confidentiality.
>
> Both Parties shall maintain Confidential Information in confidence as set forth herein, for a period of five (5) years beyond termination or expiration of this Agreement. Upon request from either Party, the confidentiality of specific Confidential Information may be maintained for a longer time as the Parties may subsequently agree.
>
> There are no obligations of confidentiality as to specific information (a) which is publicly known at the time of disclosure under this Agreement or becomes publicly known at any time other than through disclosure by the recipient of the information; (b) which is demonstrably known to the recipient of the information prior to its receipt from the disclosure; (c) which is disclosed to the recipient by a third party not under an obligation of confidentiality and independently of the studies contemplated by this Agreement; or (d) for which disclosure has been approved by the mutual written consent of the Parties; or (e) independently developed without access to Confidential Information from the discloser."

(b) Clause 14 of the San Diego State University (SDSU), Graduate and Research Affairs Model Proprietary Material Transfer Agreement states as follows:

> "RECIPIENT agrees to use reasonable efforts (which shall be at least as great as the efforts to maintain the confidentiality of its own confidential information) to maintain the MATERIAL technology in confidence, and to use the same only in accordance with this Agreement. Such obligation of confidentiality shall not apply to information, which RECIPIENT can demonstrate:
>
> (i) Was at the time of disclosure in the public domain;

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[43] As stated earlier, the key is, of course, to think first about the nature of the practical arrangement or partnership that is intended by the two parties, and only then to think about how that arrangement should be expressed in legal terms, rather than limiting the co-operative mechanism to a pre-existing legal precedent that may reflect a completely different approach to a cooperative partnership.

(ii) Has come into the public domain after disclosure through no fault of RECIPIENT or its employees;

(iii) Was known to RECIPIENT or its employees prior to disclosure thereof by PROVIDER; or

(iv) Was lawfully disclosed to RECIPIENT without prior obligation of confidence by a third party who was not under an obligation of confidence to RECIPIENT with respect thereto. The foregoing obligations of confidentiality shall survive termination of this Agreement."

(c) Clause 11 of the Model Agreement between the National Institute for Pharmaceutical Research and Development, Nigeria and a Consultant Herbalist, 1997 states that:

"11. Any information acquired by the "CONSULTANT HERBALIST" in the course of his services, transactions and operations under this Agreement regarding the sample preparation process, research and development work and details of the formulae of the products shall be treated by him as secret and confidential and shall not be disclosed by him without consent and authority in writing of the "INSTITUTE" provided that, and it is hereby agreed that, the "INSTITUTE" shall not unreasonably withhold such consent."

38. This small sample of clauses shows an awareness across a range of sectors of the interface between research on biological material, confidentiality provisions, and the exploitation of IP. By considering additional examples contained in the Contracts Database, it is possible to establish some elements that may be considered for inclusion in a contractual arrangement when considering the issues of IP and confidentiality; namely:

(a) A description of the information covered by the agreement;

(b) The nature of the protection required;

(c) 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);

(d) The scope of permitted use (for technical or commercial evaluation; for non-commercial research; or for the development of a particular commercial product);

(e) 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;

(f) Time limitations on the permitted use of the confidential information; and

(g) Monitoring and reporting on the use of the confidential information.[44]

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[44] For a fuller discussion on the role of confidentiality agreements, and possible elements to be included in such agreements, see "*Module Eight – Researching and IPRs*" in "Intellectual Property and Biotechnology, a Training Handbook" published by the Australian Foreign Affairs and Trade and AusAID, the Australian Government's overseas aid program, 2002, cited in paragraph 38, document WIPO/GRTKF/IC/3/17, and available at: http://www.apecipeg.org/library/resources/biotech.asp, and http://www.dfat.gov.au/publications/biotech/index.html

39. It does not matter whether these elements are incorporated in a short, stand-alone confidentiality agreement, or as part of the wider negotiations on the access, transfer and use of biological material and any associated TK. As with all contracts and licenses concerning biological material and TK, what is important is that the resulting document accurately reflects the individual circumstances surrounding the project and partnership in question.

C. Material Transfer Agreements (MTAs)

40. MTAs are standard tools in commercial and academic research partnerships involving the transfer of biological materials, such as germplasm, microorganisms, cell cultures, proteins etc. They tend to be used in a range of contexts, including:

(a) The exchange of materials between research institutions;

(b) Access to public germplasm collections (seed banks); and

(c) Access by a researcher to *in situ* genetic resources (where the agreement will be between the research institution and the access provider). In essence, in a standard MTA, 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. A standard MTA often includes both the terms on which the original access was granted (which may include restrictions as to future use) and a list of benefit-sharing provisions linked to the uses that may be made of that material.

41. It may not, however, necessarily address IP rights directly (instead reflecting the fact that the person giving access to the biological material has control over it as physical property).[45] However, as transfers in biological materials increase, in practice, many MTAs have become integrated into broader research and access agreements, such as a Co-operative Research and Development Agreements (CRADAs), or Access and Benefit-Sharing Agreements.[46] Such agreements are often dependent, at some stage, upon the physical transfer of biological material; however, they often be more complicated than a standard MTA since the rights of the provider of the material go beyond property rights and will probably include terms on prior informed consent (including terms of original access and benefit-sharing); ownership of the material transferred, including of any progeny or derivatives; transfer to third parties (whether or not this is permitted, and if so, the terms of such transfer); ownership of any resulting IP (whether dependant upon inventorship etc.), including agreement as to how any IP rights may be exploited (by licensing, assignment etc.); and benefit-sharing provisions to ensure the fair and equitable sharing of benefits arising from the agreed activities, and any resulting IP.

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[45] See, for example, the standardized MTA used by the Consultative Group on International Agricultural Research (CGIAR) centers for material covered under the Food and Agricultural Organization (FAO) Trust Agreement at: http://www.wipo.int/globalissues/databases/contracts/summaries/cgiar.html.

[46] For a more detailed consideration of the terms and conditions that may be included in an MTA, which does not solely address the transfer of proprietary material, see Appendix I to the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, "Suggested Terms for Material Transfer Agreements" at: http://www.biodiv.org/decisions/default.asp?m=cop-06&d=24.

42. For example, the United States National Parks ("NPS") Access Policy requires any party submitting an application for a Scientific Research and Collecting Permit, and proposing to use the results of research for commercial or revenue-generating purposes, to enter into a CRADA, or other approved benefit-sharing agreement, with the NPS:[47]

> "The CRADA, or other benefit-sharing agreement, would identify the allocation of ownership in any inventions made, and the other rights and obligations of the parties, including reporting requirements and the manner in which any disputes will be handled. Some contracts might provide for express damages in the event of a breach of any of the provisions of the agreement by the party seeking to collect research specimens or other materials. Reporting requirements might include notification of the development of any invention based upon research using research specimens collected in the parks and identification of the contract in any patent application claiming an invention developed as a result of the research on collected specimens or other materials."

43. An example of an IP provision that is increasingly used in MTAs is that of the "reach through" licensing term. In this case, the biological material transferred is not useful in itself, but may be used as a research tool for discovering another compound or method that may lead to a commercial product. Since the immediate value of the original material is unknown, the recipient agrees to share with the provider any royalties on the proceeds of any commercial product that is discovered using the original material:

> "The recipient is willing to provide such a royalty in order to get access to the material at a low initial cost. The benefit-sharing language of the CBD encourages source-country providers to ask for such a 'reach through'. The value of the biological resources is speculative and recipients tend to be willing to share the potentially large up side of a commercially successful product. It is crucial to remember, though, that a reach-through clause covers a highly unlikely event."[48]

44. There is a wide range of examples of standard MTAs, or agreements incorporating the transfer of biological material into a broader agreement, contained in the Contracts Database. For instance, the San Diego State University (SDSU), Division of Research Administration, Graduate and Research Affairs distinguishes between a Simple Agreement for the Transfer of Non-Proprietary Biological Materials, and a Proprietary Material Transfer Agreement:

> "Transfers involving proprietary materials and/or commercial entities may require greater levels of protection. … For non-proprietary materials or transfers to non-profit entities, it may be simpler to use a Simple Agreement which is shorter and contains fewer restrictions and reporting requirements."

In relation to IP, Clause 4 of the SDSU Simple Agreement for the Transfer of Non-Proprietary Biological Materials states that: "Nothing in this Agreement grants any rights under any patents or in any know-how of SDSU nor any rights to use the (Biological) Materials or any product or process related thereto or derived therefrom for profit-making or

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47 Paragraphs 32 to 34 of WIPO/GRTKF/IC/4/13 (Access to Genetic Resources Regime of the United States National Parks).

48 See "Elements of commercial biodiversity prospecting agreements" by Michael A. Gollin in "The Commercial use of Biodiversity and Traditional Knowledge", edited by Sarah A. Laird. Earthscan Publications Limited, 2002.

commercial purposes such as, but not limited to, production, sale, drug screening or drug design."[49] In contrast, Clause 5 of the SDSU Proprietary Transfer Agreement addresses a variety of IP issues such as: disclosure; the filing of patents; the licensing of any IP derived from research carried out on the "material or modifications"; and the sharing of any consequential royalties.[50]

45. The Uniform Biological Material Transfer Agreement[51] addresses IP in the following ways:

> "5(c) Without written consent from the PROVIDER, the RECIPIENT and/or the RECIPIENT, SCIENTIST may NOT provide MODIFICATIONS for COMMERCIAL PURPOSES. It is recognized by the RECIPIENT that such COMMERCIAL PURPOSES may require a commercial license from the PROVIDER and the PROVIDER has no obligation to grant a commercial license to its ownership interest in the MATERIAL incorporated in the MODIFICATIONS. Nothing in this paragraph, however, shall prevent the RECIPIENT from granting commercial licenses under the RECIPIENT's intellectual property rights claiming such MODIFICATIONS, or methods of their manufacture or their use.
>
> 6. The RECIPIENT acknowledges that the MATERIAL is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights of the PROVIDER, including any altered forms of the MATERIAL made by the PROVIDER. In particular, no express or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS, or any related patents of the PROVIDER for COMMERCIAL PURPOSES.
>
> 7. If the RECIPIENT desires to use or license the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES, the RECIPIENT agrees, in advance of such use, to negotiate in good faith with the PROVIDER to establish the terms of a commercial license. It is understood by the RECIPIENT that the PROVIDER shall have no obligation to grant such a license to the RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the MATERIAL to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government.
>
> 8. The RECIPIENT is free to file patent application(s) claiming inventions made by the RECIPIENT through the use of the MATERIAL but agrees to notify the PROVIDER upon filing a patent application claiming MODIFICATIONS or method(s) of manufacture or use(s) of the MATERIAL.
>
> 11. This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL or the MODIFICATIONS. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgement of the source of the MATERIAL in all publications."

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49 See: http://www.wipo.int/globalissues/databases/contracts/summaries/sdsusimplemta.html.

50 See: http://www.wipo.int/globalissues/databases/contracts/summaries/sdsupropmta.html.

51 See: http://www.wipo.int/globalissues/databases/contracts/summaries/ubmta.html.

46. Finally, an extract from the IP provisions in the Standard Conditions for Project Agreements between the Australian Center for International Agricultural Research (ACIAR) and Commissioned Organization(s) (which involve the exchange of genetic resources and/or biotechnology applications) notes as follows:[52]

> "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.
>
> 10.8 The Commissioned Organisation agrees that the arrangements referred to in clause 10.7 will be made taking into account the following factors:
>
> (a) The intellectual contributions of the Commissioned Organisation and the Collaborating Institution;
> (b) The financial contributions of the Commissioned Organisation and the Collaborating Institution;
> (c) The contribution of pre-existing Intellectual Property, materials, research effort and preparatory work of the Commissioned Organisation and the Collaborating Institution;
> (d) The facilities provided by the Commissioned Organisation and the Collaborating Institution; and
> (e) Such other relevant considerations as the Commissioned Organisation and the Collaborating Institution may mutually determine."

47. As can be seen from this small sample, the Contracts Database contains a range of both standard MTAs, and of more complex agreements that combine the physical transfer of material with broader agreement as to research and access and benefit-sharing. Each contractual arrangement is, of course, unique, and therefore each contract demonstrates a particular approach to IP. Nonetheless, the MTAs in the Contracts Database do provide examples of common features, and the principal IP options, that may be of interest to source countries, collectors or ultimate transferees, and that may help to build capacity in this growing area by facilitating the development of IP guidelines, or best practices, in such contractual arrangements.

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[52] See: http://www.wipo.int/globalissues/databases/contracts/summaries/aciar.html.

D. Licensing Agreements.

48. The Contracts Database contains many examples of actual or model agreements where IP rights in biological material and TK, in particular patents, have been licensed to others to develop and use commercially. IP Rights are not direct rewards in themselves. They simply create an opportunity for an inventor, or originator of creative work, to seek rewards for their invention or returns from their investment in the research. A patent can be expensive to obtain, and even more expensive to enforce. Moreover, the existence of a patent does not, *per se*, mean that an invention has an economic value and will be commercially viable. The same applies to other IP rights, such as plant breeder's rights, trade marks and industrial designs (although these normally cost less overall than patents), and even for unregistered rights such as trade secrets and copyright (which may involve preparation of confidentiality documents, other forms of documentation, and monitoring and enforcement costs). Furthermore, commercialization of an invention 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 companies and institutions choose not to commercialize their IP rights themselves, but elect between a number of different options to manage those rights so as to get the commercial benefits of their research. These options tend to include licensing, assignment and joint ventures.[53] Which is the most appropriate commercial model for the exploitation of IP rights will depend on the value of those rights, and how much money and time is available to exploit them. In the case of assignment, ownership of the IP in question will be transferred to another, usually in exchange for a financial payment or other valuable consideration, such as shares in the company. Once the IP rights have been assigned, the original inventor or owner of the IP rights could be in infringement of the IP rights if they continue to use it, and will have normally lost any possibility of further licensing or commercializing those IP rights. Assignment may therefore be condition on licensing back the entitlement to use the technology covered by the IP rights.

49. Licensing agreements are, however, a particularly common way to exploit IP rights related to biological material and TK. They can be structured in many different ways and take many different forms, (although for the purposes of the commercial use of biological material and TK, technology licenses enabling the use of patents and associated know-how are probably the most common model). For example, the development of a licensing agreement can involve several different contractual stages: a letter of intent; a standstill agreement (by which a potential licensor agrees to grant a potential licensee a certain period of time to consider entering into a licensing agreements, within which period the licensor will not consider other potential partners); an agreement to negotiate a license (in which the potential licensor agrees not to license out for a certain period of time and agrees to negotiate towards the conclusion of a licensing agreement); and stand-alone confidentiality agreements.

50. In essence, 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 (although a license may, of course, be free of charge). Licenses are often limited to specific rights, territories and time periods. Depending upon the terms of the license agreement, the owner of the IP right will usually

[53] For example, IP rights can be pooled with a partner to form a joint venture to develop and exploit a new technology.

need to monitor the licensed use and will need to maintain and enforce the underlying IP right.

51. All licenses should ultimately be drafted and negotiated on a case by case basis, according to the underlying relationship, overall aims and legal context in which the proposed partnership will develop. The licenses contained in the Contracts Database reflect this diversity. The following agreements may, however, be of particular interest to the Committee, since they specifically demonstrate how the principles of the CBD may be incorporated into a contract concerning the commercial exploitation of biological material and associated TK:

(a) Clause 13 of a Licensing Agreement (sample) submitted by Michael A. Gollin, VENABLE Attorneys at Law, 1201 New York Avenue, N.W., Suite 1000, Washington, DC 20005-3917, United States of America refers specifically to the CBD:

> "13. Adherence to Regional and National Laws. The Parties shall adhere to the 1993 Convention on Biological Diversity (CBD), the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), and other regional and national laws and policies concerning biodiversity, and will endeavor to minimize environmental impacts of collecting Biological Materials. Relevant provisions of the CBD include: the sovereign rights of states over their biological resources; the concern that biological diversity is being significantly reduced by certain human activities; the need to provide additional scientific information about biological diversity that may contribute to its conservation and sustainable use of biological diversity; the need to promote fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including benefits that arise from TK; and the need to respect and maintain the knowledge and practices of indigenous communities that are relevant for the conservation and sustainable use of biological diversity."

(b) Clause 9 of Model Material Transfer Agreement between the American National Cancer Institute (NCI) and Applicant Investigators addresses the conditions under which an invention derived from research material may be commercially licensed:

> "Recipient acknowledges that NCI may have obtained the Research Materials from the Source Country Organization ("SCO") under a Letter of Collection ("LOC") agreement stipulating that NIH will require any commercial licensee of an invention by NCI personnel derived from the Research Material (whether the invention is directed to a direct isolate from the Research Material, a product structurally based upon an isolate from the Research Material, a synthetic material for which the Research Material provided a key development lead, or a method of synthesis or use of any aforementioned isolate, product or material) to enter into an agreement that addresses the mutual concerns of NIH's licensee and SCO, respectively.
>
> Even if the Research Materials were not obtained under such an LOC agreement, as an agency of the U.S. Government, NCI complies with the U.S. Government's policy to follow the principles articulated in the United Nations Convention on Biological Diversity ("U.N. CBD"). The U.N. CBD calls for "sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the [source country] providing such resources." (U.N. CBD; Article 15.7)

In order to abide by these principles and address the interests of SCO, Recipient further agrees that, should an invention derived from the Research Material eventually be developed and marketed by the Recipient, or licensed by Recipient to a company or other institution for development and commercialization (whether the invention is directed to a direct isolate from the Research Material, a product structurally based upon an isolate from the Research Material, a synthetic material for which the Research Material provided a key development lead, or a method of synthesis or use of any aforementioned isolate, product or material), Recipient or Recipient's Licensee(s) will negotiate and enter into an agreement with the appropriate SCO. This agreement between the Recipient and/or Recipient's Licensee(s) and SCO will address the mutual concerns of both parties. Recipient agrees that negotiations between either Recipient or Recipient's Licensee(s) and the SCO must commence prior to the start of clinical development studies that are conducted, directed or sponsored by either Recipient or Recipient's Licensee(s). Negotiations must be completed and an agreement executed prior to the commercial sale of an agent structurally based or isolated from the Research Material. This agreement relating to the agent must be binding upon SCO, Recipient and any Licensee(s) or assignees of Recipient with respect to any intellectual property rights relating to the agent.

Recipient will seek to utilize the Source Country as its first source of supply and/or cultivation for raw (natural product) materials required for the manufacture of an agent (regardless of whether the agent is an isolated natural product or is structurally based thereon) if such material can be made available in quantities and quality sufficient for use by the Recipient at a mutually agreeable fair price. If such material must be cultivated, recipient agrees to seek to utilize Source Country as its first source of such cultivation efforts."

52. Both of these examples show how contractual arrangements can be used to manage the interface between the principles of the CBD, IP, and fair and equitable benefit-sharing. Furthermore, the many additional examples of licensing agreements, or clauses, in the Contracts Database can be used to establish an initial checklist of some of the IP-related terms that a licensing agreement relating to biological material and TK may address:[54]

(a) Definitions and Scope (i.e. define the IP rights being licensed, such as patents or know how, and the purpose of the license);[55]

(b) Ownership of the IP rights that are being licensed (who retains ownership?);[56]

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[54] For a comprehensive explanation of technology licensing agreements, including an explanation of the type of terms that may be included in such an agreement, see Module Nine – Licensing & Enforcing IPRs in "Intellectual Property and Biotechnology, A Training Manual" published by the Australian Foreign Affairs and Trade and AusAID, 2002; and The WIPO Guide on the Licensing of Biotechnology produced by WIPO with the assistance of the Licensing Executives Society International (LESI), 1992.

[55] See, for example, the 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 at: http://www.wipo.int/globalissues/databases/contracts/summaries/varietylicence.html.

[56] See, for example, the Germplasm License Agreement for "Line Ten" between Her Majesty the Queen in Right of Canada and Company Canada Inc. at: http://www.wipo.int/globalissues/databases/contracts/summaries/lineten.html.

(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;

(d) Sole, exclusive or non-exclusive license. It is important to clarify which one of these options applies to the IP right in question. The kind of license granted will influences the scale of royalties, or other payments, made by the licensee;

(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?; [57]

(g) Diligence and Milestones. 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;

(h) Payments and Pricing. There are many potential models for payment.[58] 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.[59] 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) Confidentiality. There may be a distinct confidentiality agreement, or obligations as to secrecy may be incorporated into the license agreement itself. [60] It may be important to agree the rights of the inventor(s) to publish their research;

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57 See, for example, the Model Biodiscovery Benefit-Sharing Agreement prepared by the State of Queensland, Australia to facilitate the development of the Queensland Biodiscovery Industry at: http://www.wipo.int/globalissues/databases/contracts/summaries/queensland.html

58 See, for example, the Know How Licencing Agreement between The Tropical Botanic Garden and Research Institute, Kerala, India (TBGRI) and The Arya Vaidya Pharmacy (Coimbatore) Ltd, Coimbatore, India at: http://www.wipo.int/globalissues/databases/contracts/summaries/tbgri.html; and the Licensing Agreement (sample) submitted by Michael A. Gollin, VENABLE Attorneys at Law, 1201 New York Avenue, N.W., Suite 1000, Washington, DC 20005-3917, United States of America at: http://www.wipo.int/globalissues/databases/contracts/summaries/licencegollin.html.

59 See, for example , the Corn Inbred Release and Licensing Agreement between Agriculture and Agri-Foods, Canada (AAFC) and commercial corn companies at: http://www.wipo.int/globalissues/databases/contracts/summaries/cornlicence.html.

60 See, for example, the Corn Inbred Release and Licensing Agreement between Agriculture and Agri-Foods, Canada (AAFC) and commercial corn companies at:

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

(k) Improvements and grant-back rights. 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;

(l) 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. This is often the basis of a joint venture.

(m) 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);

(n) 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;

(o) Maintaining and enforcing 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;

(p) Duration of license; Termination; Dispute resolution;[61] and Choice of law. A license will typically include provisions addressing all of these points.

53. This initial checklist of some of the IP-related terms that a licensing agreement relating to biological material and TK may address could be expanded to build capacity in this important area by the drafting IP guidelines, or IP best practices, in licensing agreements concerning access to genetic resources and benefit-sharing.

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http://www.wipo.int/globalissues/databases/contracts/summaries/cornlicence.html.

[61] See, for example, the Experimental Licensing Contract between the All-Russian Scientific Research Institute for Selections of Fruit Cultures and the Foreign Fruit Selection Organization, France at: http://www.wipo.int/globalissues/databases/contracts/summaries/russianfruit.html.

VI. CONCLUSION

54. The Contracts Database may help illustrate the different roles that IP can, and does, play in agreements for the access, research and use of genetic resources and associated TK. Even so, a wider range of options is possible than is already illustrated by the current range of materials in the Database. There is accordingly a continuing need for input from a broader base of experience. In addition, most contracts and licenses submitted for the database have been in the English language. Given the extensive experiences of many non-anglophone regions and countries in this area (and recently enacted access legislation in non-anglophone countries that relies heavily upon the negotiation of contracts or licenses to determine the terms of access and benefit-sharing), the Committee may wish to encourage the continuing development and of a more comprehensive version of the database. The translation of the Contract Checklist Pages into the Committee's working languages will encourage responses from a wider linguistic pool. The Committee may wish to confirm that the Contracts Database should be maintained, and regularly updated.

55. As noted in paragraph 3 above, the Committee approved at its first session[62] the development of guide contractual practices, guidelines, and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing.[63] Document WIPO/GRTKF/IC/2/3[64] proposed a number of general principles for comment and further elaboration, and invited Members of the Committee 'to propose principles and specify objectives for the development of guide contractual practices and model IP clauses for access to genetic resources and benefit-sharing' and 'to comment on the possible principles' identified in the document. The Committee approved the further development of this material.[65]

56. The Contracts Database provides a solid empirical basis for this continued work on policy issues related to IP aspects of contracts and licenses concerning access to genetic resources and benefit-sharing. This may assist the development of the proposed IP guidelines or best practice models. The Committee may therefore wish to renew the invitation for comments on possible IP principles for contractual practices for the development of a further draft document on these principles.

57. The Members of the Intergovernmental Committee are invited:

(i) to take note of the contents of the present document;

(ii) to approve the maintenance, and updating, of the Contracts Database as a permanent, freely available resource for contracts concerning intellectual property, aspects of access to genetic resources and benefit-sharing, and to encourage contributions of contracts for the Database

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62 Document WIPO/GRTKF/IC/1/13, paragraph 128

63 Document WIPO/GRTKF/IC/1/3, paragraph 41.

64 Paragraph 130

65 Document WIPO/GRTKF/IC/2/16, paragraphs 96 to 110.

from a broader base of practical experience; and

(iii) to comment further on the suggested principles set out in document WIPO/GRTKF/IC/2/3 as the basis for the development of draft IP guidelines or best practice models, on the IP aspects of licensing agreements concerning access to genetic resources and associated TK and benefit-sharing.

[Annex follows]

ANNEX

INDEX OF CONTRACTS IN THE DATABASE RELATING TO INTELLECTUAL PROPERTY, ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

MODEL AGREEMENTS

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

Corn Inbred Release and Licensing Agreement between Agriculture and Agri- Foods, Canada (AAFC) and commercial corn companies;

Exclusive License Agreement (sample) - Harvard College, United States of America

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;

Licensing Agreement (sample) submitted by Michael A. Gollin, Venable Attorneys at Law, 1201 New York Avenue, N.W., Suite 1000, Washington, DC 20005-3917 United States of America;

Model Agreement between the National Institute for Pharmaceutical Research and Development, Nigeria and a Consultant Herbalist drafted in1997;

Model Biodiscovery Benefit-Sharing Agreement prepared by the State of Queensland, Australia, to facilitate the development of the Queensland biodiscovery industry;

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

Model Material Transfer Agreement between the American National Cancer Institute (NCI) and Applicant Investigators;

Model Material Transfer Agreement: Consultative Group on International Agricultural Research (CGIAR);

Model Memorandum of Understanding between the Developmental Therapeutics Program Division of Cancer Treatment and Diagnosis National Cancer Institute, United States of America (DTP/NCI) and a Source Country and Source Country Organization (SCO);'

Non-exclusive License Agreement (sample) - Harvard College, United States of America;

San Diego State University (SDSU), Graduate and Research Affairs, Proprietary Material Transfer Agreement;

San Diego State University (SDSU), Graduate and Research Affairs, Simple Agreement for Transfer of Non-Proprietary Biological Materials;

Standard Conditions for Project Agreements between the Australian Center for International Agricultural Research (ACIAR) and the Commissioned Organization(s);

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.

ACTUAL AGREEMENTS

Academic Research Agreement submitted by the Government of the Republic of the Philippines;

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;

Agreement between Montreal Botanic Garden and private companies;

Agreement pertaining to the testing of plant extracts between the Company and the University (Sri Lanka), dated 1st January, 2000;

Commercial Research Agreement submitted by the Government of the Republic of the Philippines;

Contract for the Production of Hybrid Sorgum Seeds between INSORMIL, WINROCK and INRAN, represented by the Minisitry of Rural Development, National Institute of Agronomic Research, Niger and Mr Abdou Garba, Producer, 2000;

Experimental Licensing Contract between the All-Russian Scientific Research Institute for Selections of Fruit Cultures (Licensor) and the Foreign Fruit Selection Organization, France (Licensee);

Germplasm License Agreement for “Line Ten” between Her Majesty the Queen in Right of Canada (Licensor) and Company Canada Inc. (Licensee);

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

International Rice Genome Sequencing Project. Member Institution Registration Agreement between Genoscope (“Principal Investigator”) and Pharmacia Corporation (Extract of contract provided);

Material Transfer Agreement between the Government of Kenya, represented by The Ministry of Environment and Natural Resources, and the Board of Trustees of the Royal Botanic Gardens, Kew, United Kingdom;

Material Transfer Agreement (MTA) Germplasm and Unregistered Lines between the Department of Agriculture and Agri-Foods, Canada (AAFC) and several public breeding institutions;

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

[End of Annex and of document]