

## **Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore**

**Seventeenth Session**  
**Geneva, December 6 to 10, 2010**

### **NOTE ON UPDATING OF WIPO'S ONLINE DATABASE OF BIODIVERSITY-RELATED ACCESS AND BENEFIT-SHARING AGREEMENTS**

*Document prepared by the Secretariat*

#### **I. INTRODUCTION**

1. At its sixteenth session, held from May 3 to 7, 2010, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the Committee") "requested the Secretariat to update the database of biodiversity-related access and benefit-sharing agreements currently online on the WIPO website and to report, in an information document, on such updating to the next session of the Committee".<sup>1</sup>
2. Following this decision and in order to facilitate the updating of the database concerned, the Secretariat circulated a questionnaire to Member States and observers contained in document WIPO/GRTKF/IC/Q.6 ("Questionnaire on Contractual Practices and Clauses relating to Intellectual Property, Access to Genetic Resources and Benefit-Sharing"). The present document reports on the updating of the database (the full title of which is the WIPO Database of Biodiversity-related Access and Benefit-sharing Agreements) and on information contained in the replies to WIPO/GRTKF/IC/Q.6, including model or actual contracts concerning IP, access to genetic resources and associated benefit-sharing.

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<sup>1</sup> Draft Report of the Sixteenth Session of the Committee (WIPO/GRTKF/IC/16/8 Prov. 2)

3. This document is related to another document prepared for this session, namely document WIP/GRTKF/IC/17/INF/12 (“Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing: Updated Version”).
  4. The database in question is accessible on the WIPO website at: <http://www.wipo.int/tk/en/databases/contracts/search/index.html>
- II. BACKGROUND: WORK ON QUESTIONNAIRE, DATABASE AND IP GUIDELINES FOR ACCESS AND BENEFIT-SHARING CONTRACTS
5. At its first session in April 2001, the Committee 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”.<sup>2</sup>
  6. At its second session in December 2001, the Committee considered operational principles for intellectual property (IP) clauses contained in document WIPO/GRTKF/IC/2/3 (“Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to Genetic Resources and Benefit-Sharing”) based upon existing contractual agreements.<sup>3</sup> In order to ensure a more wide-ranging basis for discussion, it was proposed by the Committee that the Secretariat undertake a systematic survey of actual contractual agreements, which might include a questionnaire to be sent to Committee members and other stakeholders.<sup>4</sup> Results of the questionnaire would be compiled into an electronic database and could serve as a resource on guide contractual practices, guidelines and model IP clauses for contracts concerning access to genetic resources and benefit-sharing.<sup>5</sup>
  7. At its third session in June 2002, Committee Members were invited to comment on the structure of the electronic database proposed by the Secretariat (documents WIPO/GRTKF/IC/3/3 and WIPO/GRTKF/IC/3/4). The Committee expressed broad support both for the structure of the proposed database and the dissemination of the questionnaire.<sup>6</sup> The Committee accordingly decided on the establishment of the database of contractual practices concerning intellectual property, access to genetic resources and benefit-sharing.
  8. Following this decision in July 2002, the Secretariat circulated a questionnaire to Member States and a wide range of stakeholders to secure information about relevant contracts and licenses, document WIPO/GRTKF/IC/Q.2, “Questionnaire of Contractual Practices and Clauses Relating to Intellectual Property, Access to Genetic Resources

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<sup>2</sup> See document WIPO/GRTKF/IC/1/13 (“Report”), para. 128; WIPO/GRTKF/IC/1/3 (“Matters Concerning Intellectual Property And Genetic Resources, Traditional Knowledge And Folklore – An Overview”) paras. 35 to 41, task A.1 under Agenda item 5.1

<sup>3</sup> See document WIPO/GRTKF/IC/2/3, Annex II list all 16 contractual agreements referred to in the document

<sup>4</sup> See document WIPO/GRTKF/IC/2/3, paras. 131 to 134

<sup>5</sup> See document WIPO/GRTKF/IC/3/3 para. 6

<sup>6</sup> See document WIPO/GRTKF/IC/3/3 (“Proposed Structure of Database”); and approval in document WIPO/GRTKG/IC/3/17, paras. 59 to 61

and Benefit-sharing”.<sup>7</sup> The responses received to the questionnaire were incorporated into a pilot, on-line database.<sup>8</sup>

9. In the fourth session in December 2002, the Secretariat reported on the questionnaire and the creation of the database in document WIPO/GRTKF/IC/4/10. The Committee agreed that Questionnaire WIPO/GRTKF/IC/Q.2 continue to be disseminated and approved “*the further development of the Contracts Databases as a permanent, freely available resource for contracts concerning IP, access to genetic resources and benefit-sharing*”.<sup>9</sup>
10. At its fifth session in July 2003, the Secretariat reported on the updating of the contracts database to a more fully operational and comprehensive version (document WIPO/GRTKF/IC/5/9). It proposed 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.<sup>10</sup> Member States were invited 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 from a broader base of practical experience<sup>11</sup>. The Committee noted document WIPO/GRTKF/IC/5/9 and postponed discussion of it to a later date.<sup>12</sup>
11. In this line of work, document WIPO/GRTKF/IC/6/5 (“Draft Intellectual Property Guidelines for Access and Benefit-Sharing Contracts”) prepared by the Secretariat for the sixth session of the Committee in March 2004, built on information gathered and principles agreed or identified in the first five sessions of the Committee, in order to advance the task of developing guide contractual practices. It applied those principles in the form of draft Guide Contractual Practices.
12. At the seventh session of the Committee in November 2004, the Annex of document WIPO/GRTKF/IC/7/9 (“Draft Intellectual Property Guidelines for Access and Benefit-Sharing Contracts”) provided updated guidelines, which incorporated various responses and comments received at the sixth session of the Committee and subsequently provided by Member States. The Committee’s work on these guidelines has been based on an empirical survey of experience in this field, and the database collecting actual terms of agreements, as described above.<sup>13</sup> These guidelines have also been updated for this session of the Committee (document WIPO/GRTKF/IC/17/INF/12) as describe above.
13. At its eleventh session in July 2007, document WIPO/GRTKF/IC/11/8(a) proposed further options for continuing work on IP and genetic resources. In option VIII of the cover document it proposed “considering options for the expanded use, scope and accessibility of the Online Database of IP clauses in mutually agreed terms for access and equitable

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<sup>7</sup> See document WIPO/GRTKF/IC/4/10

<sup>8</sup> See document WIPO/GRTKF/IC/7/9 para. 22

<sup>9</sup> See document WIPO/GRTKF/IC/4/15, para. 166

<sup>10</sup> See document WIPO/GRTKF/IC/5/9 para. 2 and Annex making reference to 16 model agreements and 13 actual agreements

<sup>11</sup> See document WIPO/GRTKF/IC/5/9 para. 57 (ii)

<sup>12</sup> See document WIPO/GRTKF/IC/5/15, para. 121

<sup>13</sup> See documents WIPO/GRTKF/IC/2/12; WIPO/GRTKF/IC/2/16

benefit sharing” and in its Annex under “options for possible activities on IP and mutually agreed terms for fair and equitable benefit-sharing” in option C.1.: “The contents of the Online Database could be published in additional, more easily accessible forms, such as on CD-ROM, for wider accessibility and easier use by all relevant stakeholders.<sup>14</sup> The Committee decided at this session that document WIPO/GRTKF/IC/11/8 (a) should remain on the table.<sup>15</sup> The document was reissued for subsequent sessions as WIPO/GRTKF/IC/12/8(a) and WIPO/GRTKF/IC/13/8(a). Documents WIPO/GRTKF/IC/16/6 and WIPO/GRTKF/IC/17/6 are revised versions of WIPO/GRTKF/IC/13/8(a), including proposed amendments to and comments made during the fifteenth and sixteenth sessions of the Committee, as well as the written comments received during the intersessional written commenting processes, and also including a factual update on relevant developments in the CBD, FAO and the WTO.

### III. FOLLOWING UP AND QUESTIONNAIRE WIPO/GRTKF/IC/Q.6

14. Pursuant to the decision of the Committee at its sixteenth session to update the database of biodiversity-related access and benefit-sharing agreements currently online on the WIPO website, the Secretariat prepared questionnaire WIPO/GRTKF/IC/Q.6 (“Questionnaire on Contractual Practices and Clauses relating to Intellectual Property, Access to Genetic Resources and Benefit-Sharing”). It was meant to facilitate the updating exercise. No substantial amendments were made to the structure and content of the original questionnaire WIPO/GRTKF/IC/Q.2. It concentrated especially on the clauses and provisions in those contracts that have a bearing on IP.<sup>16</sup>
15. The Secretariat received the following replies to questionnaire WIPO/GRTKF/IC/Q.6: It received eleven completed questionnaires including two actual agreements and seven model agreements. Beyond that, eight Member States replied that they had no or not yet relevant information available or they were still in the process of drafting or implementing framework legislation on biodiversity and access and benefit-sharing.
16. Completed questionnaires were received from the following Member States: Czech Republic (Crop Research Institute: two questionnaires), Pakistan (Intellectual Property Office), Thailand (Pathumthani Rice Research Centre, Medicinal Plant Research Institute, Flower and Ornamental Plant Group, Forest and Plant Conservation Research Office, in total four questionnaires), Uruguay (Agricultural Research Institute, INIA), the Republic of Korea (Korean Research Institute of Bioscience and Biotechnology) Australia (Department of Environment, Water, Heritage and the Arts) and Myanmar (Ministry of Science and Technology).
17. Two actual agreements were received from the following Member States: Pakistan and Thailand. Seven model agreements were received from the following Member States and an observer: Czech Republic (Crop Research Institute: two model agreements), Uruguay (Agricultural Research Institute, INIA), the Republic of Korea (Korean Research Institute of Bioscience and Biotechnology), Australia (Department of Environment, Water, Heritage and the Arts, two model agreements) and the Biotechnology Industry Organization (BIO).

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<sup>14</sup> See document WIPO/GRTKF/IC/7/9 para. 1

<sup>15</sup> See document WIPO/GRTKF/IC/11/15 para. 542

<sup>16</sup> See document WIPO/GRTKF/IC/Q.2 para. 3

18. Further replies were received from the following Member States: Spain (Permanent Mission), Kyrgyzstan (Intellectual Property Office, Kyrgyzpatent), Latvia (Latvian Patent Office), Georgia (National Intellectual Property Center Sakpatenti), Mexico (National Commission for Development of Indigenous People, CDI), Republic of Moldova (Agency of Intellectual Property, AGEPI), Peru (INDECOPI) and Denmark (Danish Patent and Trademark Office).
19. The information received is being used to update the existing WIPO Database.<sup>17</sup> This database is currently online on the WIPO website and hyper-linked to the web site of the Clearing House Mechanism (“CHM”) of the CBD. The information received also contributed to providing practical experience and additional sample clauses to document WIPO/GRTKF/IC/17/INF/12 (“Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing: Updated Version”) as also requested by the Committee at its sixteenth session. The questionnaire stays available for further responses at: <http://www.wipo.int/tk/en/databases/contracts/index.html>.

#### IV. PURPOSE OF THE DATABASE

20. The purpose of the database is two-fold. As a capacity building tool, it aims to provide information resources for those seeking assistance on current practices relating to IP, access and benefit sharing and genetic resources and, as an empirical basis, it aims to contribute to the development of the WIPO Intellectual Property Guidelines for Access and Equitable Benefit-sharing (see document WIPO/GRTKF/IC/17/INF/12).
21. As indicated in document WIPO/GRTKF/IC/4/10, with regards to the first function, the contract database is not intended as a normative exercise, but rather to illustrate current practices relating to contracts or licenses concerning IP and genetic resources. This should facilitate the understanding of the process of negotiating and concluding contracts in this area, potentially for the benefit of a wide range of institutions and communities with an interest in the IP aspects of access to genetic resources. The database could also help in the future to illustrate emerging trends or patterns. The WIPO Database could continue to be developed and maintained as a permanent, freely available WIPO resource. Such a resource is meant to help to build capacity in this important area, particularly in the development of contractual expertise in those sectors and parts of the world with otherwise limited exposure to such know-how, and yet with increasing exposure to negotiated contractual arrangements concerning IP, access to genetic resources and benefit-sharing.<sup>18</sup>
22. Regarding the second function, the database is also meant to provide an empirical basis for the development of guide contractual practices, guidelines, and model IP clauses for contractual agreements on access to genetic resources and benefit-sharing and work on policy issues related to IP aspects of contracts and licenses concerning access to genetic resources and benefit-sharing.<sup>19</sup> The information contained in the database has been used for updating the Draft Intellectual Property Guidelines for Access and Equitable Benefit-sharing as contained in document WIPO/GRTKF/IC/17/INF/12.<sup>20</sup> The database

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<sup>17</sup> See below, Section VI: Contractual Information received

<sup>18</sup> See document WIPO/GRTKF/IC/4/10 paras. 30 to 31

<sup>19</sup> See document WIPO/GRTKF/IC/5/9 para. 22

<sup>20</sup> See as well document WIPO/GRTKF/IC/7/9 para. 7

could potentially further assist in the systematic and balanced development of the Draft Guidelines.<sup>21</sup>

23. The revised list of options on work on IP and genetic resources as contained in document WIPO/GRTKF/IC/17/6 reflects these two purposes of the database in its proposals for further work of the Committee, as contained in options C.1 and C.2:

*“C.1 [Online Database of IP clauses in mutually agreed terms on ABS]  
Considering options for the expanded use, scope and accessibility of the online database of IP clauses in mutually agreed terms for access and equitable benefit-sharing. The contents of the Online Database could be published in additional, more easily accessible forms, such as on CD-ROM, for wider accessibility and easier use by all relevant stakeholders.*

*C.2 [Draft guidelines for contractual practices]  
Considering options for stakeholder consultations on and further elaboration of the draft guidelines for contractual practices contained in the Annex of document WIPO/GRTKF/IC/7/9, updated in information document WIPO/GRTKF/IC/17/INF/12, based on the additional information available and included in the online database”.*

24. The Committee might identify additional aspects of the development, updating and use of the database in the course of its ongoing negotiations.

## V. UPDATING OF THE STRUCTURE OF THE DATABASE

25. At the time of the sixteenth session of the Committee, the database contained sixteen model agreements and eleven actual agreements. The completed questionnaires had been reproduced under the categories of model agreement or actual agreement either together with an agreement or as a stand-alone item. The structure of the database was described in document WIPO/GRTKF/IC/5/9 as follows: The search tool had been directed at retrieving information on a specific kind of contractual clause, or combination of contractual clauses. It has been tailored to provide individual hyper-links which directly connect to the relevant clause in the contract itself, or the completed questionnaire.<sup>22</sup>

26. The Secretariat is in the process of further improving the user-friendliness and updating the structure of the database. As a first step, the stability and user-friendliness of the database's search engine will be improved and its search will be effectively based on a full text search. The IP related key terms and questions will be kept as an indicator of useful search terms. The updated version of the WIPO Database of Biodiversity-related Access and Benefit-sharing Agreements will be available before this session of the Committee in December 2010 at:

<http://www.wipo.int/tk/en/databases/contracts/index.html>

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<sup>21</sup> The systematic and balanced development of IP guidelines is part of two-step approach was described as follows: first, “a complete and systematic survey of IP clauses could be undertaken ... [Second,] once existing access and benefit-sharing agreements have been compiled through the survey, the variables and principles identified [by the Committee members] may be applied for the development of guide practices and model IP clauses, based on the existing practices and clauses.” (WIPO/GRTKF/IC/2/3, para. 134)

<sup>22</sup> See document WIPO/GRTKF/IC/5/9, para. 6

27. As a second step, it is intended to improve the performance and visual presentation of the full text search in the contractual terms of the agreements contained in the database by moving the database in due course to another more effective platform and server. Further, the WIPO Database may be constantly improved and adapted to its purpose and needs as identified by the Committee.

#### VI. CONTRACTUAL INFORMATION RECEIVED

28. A very broad range of model and actual agreements was submitted in response to WIPO/GRTKF/IC/Q.6 updating the WIPO Database on Biodiversity-related Access and Benefit-Sharing Agreements. Most respondents enclosed the actual or model text of a contract, either instead of, or in addition to, completing the questionnaire. While confidential information has been removed, some agreements have disclosed very specific commercial information, such as agreed royalty percentage rates and model schemes on such royalty rates. The model and actual agreements are quoted in this document. In order to increase the accessibility and user-friendliness of the database and documents, the Secretariat corrected obvious type errors, edited the formatting of the agreements, and, where appropriate, summarized passages which have been taken from the questionnaire.
29. All recent contracts submitted had been drafted in the English language only. In any event, it is proposed that the contractual text should remain in the language in which it was received by WIPO and, where applicable, only be translated into English, since otherwise there is a considerable risk that complex contractual provisions may be misconstrued, once translated, or simply mistranslated.
30. The following questionnaires and model and actual agreements received, which will be entered in the database, illustrate the information concerning Intellectual Property, Access to Genetic resources and Benefit-sharing that has been collected by the Secretariat:
- (a) Model Transfer Agreement (MTA) on Plant Genetic Resources for Food and Agriculture (PGRFA), recommended model for institutions participating in the “National Programme on Plant Genetic Resources and Agro-biodiversity Conservation and Utilization” of the Czech Republic, Czech Gene Bank, Crop Research Institute (CRI) and providing PGR to users;
  - (b) Model Transfer Agreement (MTA): Terms and Conditions of limited non-exclusive license model agreement to use genetic material of the Culture Collection of Dairy Microorganisms (CCDM) of the Czech Republic, Crop Research Institute (CRI);
  - (c) Model project on “Genetic Modification of hyaluronidase inhibitor glycoprotein (WSG) in the roots of *Withania Somnifera* (Hania plant) for Anti Venom Treatment” between the Astra Zeneca (Medicine Company), UK, the National Institute of Health (NIH), Islamabad and the Local Government, Karimabad (Hunza Valley, Pakistan);
  - (d) Access Regulation to Plant Genetic Resources (PGR) of the Pathumthani Rice Research Centre of Thailand;
  - (e) Model Material Transfer Agreement (MTA) of the Korean Research Institute of Bioscience and Biotechnology;

- (f) Material Transfer Agreement (MTA): Restricted License for non-profit purposes of the National Agricultural Research Institute (INIA Uruguay);
- (g) Model Access and Benefit Sharing (ABS) Agreement between Australian Government and access party;
- (h) Model Access and Benefit Sharing (ABS) Agreement between access provider and access party, proposed by the Australian Government; and
- (i) Model Material Transfer Agreement (MTA) of the Biotechnology Industry Organization (BIO).

31. Even within this short list, the contracts submitted relate to a wide variety of contract parties (government, private sector, public research institutions) and contract objectives (commercial, non-commercial research, research and development). As to their IP aspects, although the majority of contracts relate to research on either plant or microbial genetic resources (as opposed to animal genetic resources, or research associated with traditional knowledge or know-how), the IP aspects of even this small sample of agreements are largely distinct. The following common issues arising from the contracts may be of particular interest:

#### A. TYPES OF AGREEMENTS

32. Several different types of biodiversity-related access and benefit-sharing agreements have been received. These types of agreements have different purposes either commercial or non-commercial:

##### (1) Material Transfer Agreements (MTAs)

33. MTAs are common tools in commercial and academic research partnerships involving the transfer of biological materials, such as germplasm, microorganisms and cell cultures. MTAs are agreements setting the conditions for the transfer of biological material including the mutual obligations of the parties, irrespectively of the term used, sometimes being called licensing agreements of biological materials. With a look at the purpose of the agreement, it can be differentiated among the agreements received between MTAs for commercial use, research agreements and combined uses as research, breeding and education.

##### (a) *MTAs for commercial use*

34. Several MTAs on biological materials received were concluded for commercial purposes. The Model Project on Hania Plant between Astra Zeneca, NIH and Karimabad clearly defines the contract purpose of taking and cultivating plants for commercial use (questions 4 and 12). Further, the Model ABS Agreements by the Australian Government and the Model MTA of BIO are for commercial uses of genetic resources (questions 4 and 12).



*(b) Research agreements*

35. On the other hand, several MTAs had research purposes excluding commercial uses of the materials transferred. Other agreements contained as well specific clauses opening the possibility of commercial use under the condition that additional prior written authorization by the provider was given.
36. The Model Licensing Agreement for non-profit purposes of INIA, Uruguay, the Access Regulation to PGRs of the Pathumthani Rice Research Centre, the Model MTA of the Korean Research Institute, the Access Regulation to PGR of the Pathumthani Rice Research Centre of Thailand and the MTA on PGRFA by the CRI, Czech Republic were agreements for research purposes (question 4). The Model Licensing Agreement for non-profit purposes of INIA, Uruguay, expressly restricts the permitted use further in clause 3 on the “*only purpose of evaluation of different cultivars. No one is permitted any cloning or molecular manipulation of the proteins and/or specific genes contained in the material.*” However, the limited non-exclusive license of CRI provides the possibility for commercial use subject to prior written authorization in clause 10.

*(c) MTAs for research, breeding and education*

37. The MTA on PGRFA by the CRI, Czech Republic enables access to PGR for their conservation and utilisation in research, breeding and education. The purpose of the agreement is the use of the material for research in the sector of food and agriculture.

(2) Licensing Agreements

38. Licensing agreements are important for the commercialization of an invention and contain specific provisions on the exploitation of IP rights resulting from research and development on the biological material received. The Model project on Hania Plant between Astra Zeneca, NIH and Karimabad indicates that licensing agreements for a better commercialization of the patented invention will be part of a separate agreement (question 12).

## B. INTELLECTUAL PROPERTY CLAUSES IN GENERAL

39. IP clauses are designed to reflect the different options chosen on the use of IP in the agreement. IP clauses might exclude the use of IP rights, require prior authorization, set conditions for the development and managements of IP rights or regulate ownership of IP rights.

(1) Exclusion of IP rights

40. Some agreements explicitly exclude the use of IP rights on the transferred resources, in particular research agreements or agreements on food and agriculture: The Model MTA on PGRFA of CRI partly excludes the use of IP rights by the recipients if they could restrict the access to plant genetic resources:

*“He will not apply on provided plant genetic resources any form of intellectual property rights or other rights that could restrict an easy availability of plant genetic resources for food and agriculture or their genetic segments or components that he obtained on the basis of this agreement”.*

41. Within the same agreement, it is indicated that when legal protection is applied, the recipient shall inform the provider on the use of legal protection:

*“In case, that the result of use of provided PGR samples in research or breeding is a material (e.g. cultivar) on which legal protection is applied, the recipient of PGR samples undertakes to inform the provider and send him copies of documents constituting such legal protection”.*

(2) Authorization needed to use IP rights

42. Other agreements make the use of IP rights dependent on further prior written authorizations by the provider. The Model MTA of the Korean Research Institute states in clause 8 that *“patent applications on such invention shall not be filed without a prior written consent of provider concerning to the disclosure and claim of the said application”.*

(3) IP rights as purpose of agreement

43. In other agreements, the application for IP rights and their exploitation has been their purpose, in particular if the agreement has been made for commercial purposes. Therefore, in some agreements, exploitation of IP rights is the purpose of the project and it is explicitly provided for the use of IP rights. On the model project on the Hania Plant between Astra Zeneca, NIH and Karimabad, it is reported in question 12 as follows:

*“(1) The development of anti-venom drug will be based on research carried out at NIH, Islamabad. Therefore a special clause for filing patent application in Pakistan, UK and other target countries/regions has been included. The patent application will be filed at the end of the second year of research and it is expected that Patent for genetically modified hyaluronidase inhibitor glycoprotein (WSG) will be awarded from all relevant countries/regions up to the end of fifth year of the Contract.*

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

(4) Ownership of IP rights defined

44. In some of the agreements received, specific terms on ownership of IP rights are contained, as for example in clause 5.2.1. of the Model ABS Agreements by the Australian Government. It states as follows:

*“As between the Access Provider and the Access Party (but without affecting the position between the Access Party and a third party) Intellectual Property arising from R&D Activity is vested or will vest in the Access Party”.*

C. SPECIFIC INTELLECTUAL PROPERTY RIGHTS (IPRS)

(1) Overview

45. Agreements received either contained a general list of different IP rights which could result from the use of the genetic materials or a reference to specific IP rights. The Model ABS agreements by the Australian Government includes in Clause 1.1. several forms of different IP rights. It reads as follows:

*“Intellectual Property Includes:*

- (a) copyright*
- (b) all rights in relation to inventions (including patent rights)*
- (c) all rights in relation to plant varieties (including plant breeders rights);*
- (d) registered and unregistered trademarks (including service marks), designs, and circuit layouts, and*
- (e) all other rights resulting from intellectual activity;*
- (f) know-how (whether patentable or not) ...”.*

(2) Patents

46. The Model Project on Hania Plant between Astra Zeneca, NIH and Karimabad defines the joint exploitation of a patent based on the material transferred as the purpose of the contract. It states in question 12 as follows: *“The development of anti-venom drug will be based on research carried out at NIH, Islamabad. Therefore a special clause for filing patent application in Pakistan, UK and other target countries/regions has been included. The patent application will be filed at the end of the second year of research and it is expected that Patent for genetically modified hyaluronidase inhibitor glycoprotein (WSG) will be awarded from all relevant countries/regions up to the end of fifth year of the Contract”.*

The Bio Model MTA states in clause 4.3. that *“the [Transferee] shall not seek patents ... in the Materials as such as they are listed in Article 2 (i.e., materials in the form they are transferred to the [Transferee]). The [Transferee] may apply for the grant of patents claiming inventions developed using samples of the transferred Materials, including inventions embodied in modified forms of the materials ...”.*

(3) Trademarks

47. Trademark protection has been chosen as an additional mechanism. The Model Project on Hania Plant between Astra Zeneca, NIH and Karimabad states in question 12 that *“the medicine will be given a special commercial name "Astra-Hania" or "Hanio-Zeneca" and trade mark registration will be applied in Pakistan, UK and other target countries/regions at the end of the 2nd year of Contract”.*

(4) Copyright

48. The Model Project on Hania Plant between Astra Zeneca, NIH and Karimabad includes copyright in the IPRs related to the project. It states in question 12 as follows: *“The artistic design of "Astra-Hania" or "Hanio-Zeneca" on the packing of medicine will be copyrighted. The manual of treatment for patient's guide will also be copyrighted at the time of commercialization”.*

(5) Plant Variety Protection

49. The Bio Model MTA states in clause 4.3. that *“the [Transferee] shall not seek ... plant variety protection rights in the Materials as such as they are listed in Article 2 (i.e., materials in the form they are transferred to the [Transferee]). The [Transferee] may apply ...for the grant of plant variety protection claiming varieties developed using samples of the transferred Materials”.* The Access Regulation to PGR of the Pathumthani Rice Research Centre of Thailand also includes Plant Variety Protection.

#### D. PRIOR INFORMED CONSENT

50. Prior informed consent forms an important part of agreements on access to genetic resources and traditional knowledge. Some agreements received contain explicit information on prior informed consent.
51. The Model Project on Hania Plant between Astra Zeneca, NIH and Karimabad indicated in question 21 that *“the Local Government of Karimabad with the technical support of IPO-Pakistan, WTO wing of Ministry of Industries and Production, SMEDA and CBD focal point Ministry of Environment took steps to obtain prior informed consent of local community and seek advice of abovementioned institutes for negotiations on the Contract”*.
52. The Model MTA of the Korean Research Institute provides in clause 8 that *“patent applications on such invention shall not be filed without a prior written consent of provider concerning to the disclosure and claim of the said application”*.

#### E. LICENSING OF IP RIGHTS

53. Licensing of IP rights is part of the different strategies on how to commercialize IP. Some agreements received, in particular the ones with commercial purposes, allow third party licensing to exploit IPRs on the material provided. The Model ABS agreement between the Australian Government and access party provides for third party licensing in clause 5.3.1: *“Without limiting clause 5.2.1, the Access Party may grant third parties the right to exploit the Intellectual Property arising from R&D Activity”*.

#### F. BENEFIT-SHARING

54. Benefit-sharing is a central aspect of IP clauses in biodiversity-related agreements. For instance, the Model MTA of BIO sets in clause 5.1. a general obligation to share benefits. It states that *“the [Transferee] [and the entity for which the Transferee is any agent] shall provide, at a mutually agreed time, benefits arising from use of the transferred materials”*. The definition of the benefits is left open to parties to the agreement. In other agreements received, it is expressly distinguished between monetary and non-monetary benefits.

##### (1) Monetary Benefits

55. A range of agreements disclosed the exact rates for benefit-sharing, other indicated that monetary benefits were shared through trust funds. Some contracts contained detailed rules on sharing of monetary benefits. Other agreements provide for arrangements that benefits were administered by a trust fund for local communities.
56. The Model Project between Astra, NIH and Local Government in Karimabad states in question 12 that *“a separate chapter for Benefit Sharing has been included in the contract. Following are the main points of this chapter regarding monetary benefit-sharing:- (1) A special Trust Fund for the local community of Karimabad will be established with initial amount of Rs. 100 million with in 6 months of signing the contract. Astra Zeneca will share 80%, NIH 15% and Local Government of Karimabad 5% in the initial amount of Trust Fund. A three member committee (one from each partner) will administer this Fund. The initial amount of Trust will be consumed within first 5 years of*

*the Contract. During next 20 years 5% of total annual profits will be designated for Trust Fund as royalty. The Fund will be consumed for three purposes; (i) Increase in literacy rate and upgrading of education standard in Karimabad; (ii) Fully funded scholarships for higher education on competitive basis for residents of Karimabad; and (iii) Improvement of public health facilities in Karimabad”.*

57. The Access Regulation to PGR of the Pathumthani Rice Research Centre of Thailand provides for a “*Plant Variety Protection trust funds*” as indicated in question 12.
58. The Model ABS agreement between the Australian Government and access party provides detailed rules on threshold payments in schedule 3 as follows:

*”Where the gross exploitation revenue received by the access party in a calendar year falls within the relevant threshold range specified in column 1 of the table below the access party will pay to the access provider the corresponding percentage of gross exploitation revenue specified in column 2 of the table (Threshold Payments)”.*

<i>Purpose of the Product</i>	<i>Gross Exploitation Revenue received in one calendar year (\$ Australian Dollars)</i>	<i>Threshold Payment (% of gross Exploitation Revenue)</i>
<i>Pharmaceutical, Nutraceutical or Agricultural</i>	<i>&lt; 500 000</i>	<i>0</i>
	<i>500 000 – 5 000 000</i>	<i>2.5</i>
	<i>&gt; 5 000 000</i>	<i>5.0</i>
<i>Research</i>	<i>&gt; 200 000</i>	<i>2.5</i>
	<i>or</i>	
	<i>&lt; 100 000</i>	<i>0</i>
	<i>100 000 – 3 000 000</i>	<i>1.0</i>
<i>Industrial, Chemical, Diagnostic or Other</i>	<i>&gt; 3 000 000</i>	<i>3.0</i>
	<i>&gt; 200 000</i>	<i>1.5</i>
	<i>or</i>	
	<i>&lt; 100 000</i>	<i>0</i>
	<i>100 000 – 3 000 000</i>	<i>1.0</i>
	<i>&gt; 3 000 000</i>	<i>2.0</i>

(2) Non-Monetary Benefits

59. There is a wide range of different possibilities for non-monetary benefit sharing. A schedule on non-monetary benefits is provided by the Model Project between Astra, NIH and Local Government in Karimabad in question 12:

*“As mentioned earlier a separate chapter for benefit-sharing has been included in the Contract. Following are the main points of this chapter regarding non-monetary benefit-sharing:*

- (1) *The technical expertise of local people and farmer community will be preferred for development of 50 hectare Botanical Garden in Karimabad.*
- (2) *The agricultural graduates and botanical experts of local area will be preferred for research work on Hania plant in the said Botanical Garden and they will be trained by experts of NIH and Astra Zeneca to develop their Negotiation capacity.*

- (3) *Special IP training courses will be conducted for officials of Local Government to develop their capacities for royalty and other arrangements.*
- (4) *The technology should be transferred automatically to the Local Government after the expiration of 25 years of the contract”.*

60. The Access Regulation to PGR of the Pathumthani Rice Research Centre of Thailand specifies in question 12 “*IP training*” as non-monetary benefit sharing. The Model ABS agreements by the Australian government provide in schedule 3 and 4 for “*offers of specimens*”, “*knowledge transfer*” and “*publications*” as non-monetary benefits. In addition, parties may include “*ad hoc research*”, “*research funding*”, “*joint ventures*”, “*capacity building*”, “*technology transfer*”, “*scientific research*” and “*development programmes*” as non-monetary additional benefits.

## G. OTHER IP ISSUES

### (1) Confidentiality Clauses

61. Confidentiality clauses are common tools in IP agreements to ensure legal protection of materials and knowledge transferred. The Model project on Hania Plant between Astra Zeneca, NIH and Karimabad contains the following clause on confidentiality as indicated in question 14:

*“All the researchers and technical workers of Local Government, NIH and Astra Zeneca are bound to maintain secrecy until research work is going on and patent applications are not accepted by the relevant offices of target countries. The people involved in research work are not allowed to leave without strong valid reason up to the end of fifth year of the contract”.*

62. Further the two different types of Model ABS agreements proposed by the Australian Government define “*confidential information*” in clause 1.1.1. as “*any information described as confidential in Schedule 1 to this deed; and any information that is agreed between the parties after the date of this deed as constituting confidential information for the purposes of this deed*”.

63. The INIA Uruguay MTA assures that the recipient “*agrees that this material will not be released to any other person than the signatories of this agreement, except co-workers working directly under a signatory supervision who have agree to bide by the terms and conditions for this agreement*”.

### (2) Clause of acknowledgement of contribution of the provider

64. Several biodiversity-related IP clauses contain terms on the acknowledgement of the contributions of the provider. They provide for an obligation to acknowledge the providers’ contribution to research and development in any publication, as well as an obligation to inform about any publication. The Model MTA on PGRFA of CRI obliges the recipient to acknowledge the contribution and information of the provider:

*“If the results of the use of provided samples of PGR or their segments or components are published, the recipient (user) undertakes to recognise and quote provider of used genetic resources in the publication and send a copy of such publication to the provider”.*

65. Similar clauses are contained in the Limited non-exclusive license of CRI and in the INIA Uruguay MTA. Further, the Model MTA of the Korean Research Institute states in clause 5:

*“In all oral presentation or written publications concerning the research project, recipient will acknowledge provider’s contribution of this research material unless requested otherwise”*

(3) Dispute Settlement

66. Different options have been chosen in the agreements received for clauses on dispute settlement. The Model Project on Hania Plant between Astra Zeneca, NIH and Karimabad refers to mutual conciliation among the parties and in case of further dispute national jurisdiction in question 19. The Access Regulation to PGR of the Pathumthani Rice Research Centre of Thailand designates the national jurisdiction in question 19. The Model Law on International Commercial Arbitration by the United Nations Commission on International Trade Law (UNCITRAL), 1995 has been opted by the INIA Uruguay Model MTA. The two Model ABS Agreements proposed by the Australian Government provide for detailed rules on the procedure of the dispute settlement in clause 14, but did not specify the applicable law. The BIO Model MTA refers to the principles of conflict of law for dispute settlement in clause 7.7.

(4) Associated Traditional Knowledge (TK)

67. On associated TK, the response received by Australia stated in answer to question 9 the following: Under Australian legislation benefit-sharing agreements must provide for reasonable benefit-sharing arrangements with Indigenous peoples, including the protection for and valuing of any Indigenous people’s knowledge. Prior informed consent of the Indigenous owner or native title holder must be obtained for access to genetic resources on Indigenous people’s land. A general principle accepted by the Australian Government is that access and benefit-sharing must ensure the use of TK is undertaken with the cooperation and approval of the holders of that knowledge and on mutually agreed terms.

H. PRACTICAL GUIDANCE AND LESSONS LEARNED

68. Previous documents have drawn on lessons learned. In this respect reference is made to documents WIPO/GRTKF/IC/2/3, WIPO/GRTKF/IC/4/10, WIPO/GRTKF/IC/5/9. In summary, practical difficulties to obtain PIC according to different rules on a national level, the lack of clear regulations and information and the need for capacity building in provider countries were experienced and reported.<sup>23</sup>

Replies to Questionnaire WIPO/GRTKF/IC/Q.6 mention the following lessons learned:

69. Several model projects draw on lessons learned from the contractual practices. The Model Project on Hania Plant between Astra Zeneca, NIH and Karimabad states in response to question 22 as follows:

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<sup>23</sup> See document WIPO/GRTKF/IC/4/10 paras. 24 to 26

*“The important point of the contract is welfare of local community in the areas of basic education and public health. Although the alternative purpose of the project is development of anti-venom medicine, its commercialization and profit gain but the main objectives are social welfare of local community in Karimabad (Hunza valley) and R&D facilitation in NIH, Islamabad. If this project is successfully completed and the contract is acted upon according to its letter and spirit it will be win-win situation for all the contracting parties. The medicine company Astra Zeneca will strengthen its roots for further investment in the field of plant genetic resources, the research institute, NIH will be able to conduct more and more R&D activities for development of life saving drugs and indigenous communities like Karmiabad will be encouraged to share their knowledge for benefit of human beings”.*

70. The experiences on issuing model clauses on ABS were very positively described by the Australian Government. It stated in question 22 as follows:

*“Publication of an easily accessible model benefit-sharing agreement including a suggested monetary and non-monetary benefits has been a useful tool to facilitate negotiation of agreements. All agreements negotiated to date (September 2010) have followed the model agreement closely”.*

The Australian Government reported that since 2005 the Commonwealth Government has entered into seven access and benefit-sharing agreement contracts with organizations engaged in commercial or potentially commercial research. Four of the contracts are with Australian public institutions and three are with foreign research organizations. A further contract with an Australian research institution is under consideration. The mutually agreed terms for benefit-sharing closely followed the model contracts provided by the Commonwealth Department for the Environment, Water, Heritage and the Arts - the contracts do not have a specified duration.

71. The Korean Research Institute highlighted in particular the importance of IP ownership and national IP policies as lessons learned. It stated in questions 21 and 22 as follows:

*“It is recommended that the Recipient should retain IP ownership to the results obtained from the use of the genetic resources or material, if possible, and should share the benefits from commercializing the IP with the Provider. ... It is important to establish the own IP policy for genetic resources and benefit-sharing”.*

72. The State Agency on Intellectual Property of the Republic of Moldova (AGEPI) stated that the genetic resources were available free of charge and no particular agreements were concluded:

*“Much to our regret, there are no practices of setting a contract concerning access to and use of the plant genetic resources and non-pathogenic organisms from national collections of these resources. The samples included in the collections under discussion, are used free of charge, by the researches of the Republic of Moldova for research purposes. There were no requests from foreigner researches”.*

## VII. CONCLUSION

73. The WIPO Database of Biodiversity-related Access and Benefit-sharing agreements is not intended as a normative exercise, but to augment the information available on current



practices relating to contracts or licenses relating to IP and genetic resources. This resource might further facilitate the understanding of the process of negotiating and concluding contracts in this area. The responses received to the most recent questionnaire will further help to enrich and update not only the database but also the WIPO Draft Intellectual Property Guidelines for Access and Equitable Benefit-sharing in document WIPO/GRTK/IC/17/INF/12. Committee participants and others are encouraged to continue to respond to the Questionnaire WIPO/GRTKF/IC/Q.6, available at: <http://www.wipo.int/tk/en/databases/contracts/index.html>. The WIPO Database of Biodiversity-related Access and Benefit-sharing Agreements (available at: <http://www.wipo.int/tk/en/databases/contracts/search/index.html>) will continue to be updated and its structure and accessibility improved as indicated in this document.

*74. The Committee is invited to take note of the contents of the present document.*

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