



WIPO/GRTKF/IC/4/10 ORIGINAL:English DATE:October20,2002

WORLD INTELLECTUAL PROPERTY ORGANIZATION

GENEVA

INTERGOVERNMENTALCO MMITTEEON INTELLECTUALPROPERT YANDGENETICRESOUR CES, TRADITIONALKNOWLEDG EANDFOLKLORE

FourthSession Geneva,December9to17,2002

REPORTONELECTRONIC DATABASEOFCONTRAC TUALPRACTICESAND CLAUSESRELATINGTO INTELLECTUALPROPERT Y,ACCESSTOGENETIC RESOURCESANDBENEFI T-SHARING

Document prepared by the Secretariat

I.OVERVIEW

- 1. Atitsthird session,theIntergovernmentalCommitteeonIntellectualPropertyand GeneticResources,TraditionalKnowledgeandFolklore("theCommittee")decidedonthe establishmentofadatabaseofcontractualpracticesconcerningintellectualproperty,accessto geneticresourcesandbenefit -sharing.Followingthisdecision,theSecretariatcirculateda questionnairetoMemberStatesandawiderangeofstakeholderstosecureinformationabout relevantcontractsandlicenses.TheSecretariathascreatedapilotda tabase,incorporating responsestothequestionnaire.
- 2. Thisdocumentreportsonthequestionnaireandthecreationofthedatabase, and provides a preliminary discussion of some of the intellectual property aspects of the contracts covered by the database. It proposes that the process of collecting information for the database continue, with a view to developing a fully operational and more comprehensive version of the database for future consideration by the Committee.

II.INTRODUCTION

- 3. Atitsfirstsession,theCommitteeexpressedsupportforthedevelopmentof, "contractualpractices,guidelines,andmodelintellectualpropertyclausesforcontractual agreementsonaccesstogeneticresourcesandbenefit -sharing,takinginto accountthespecific natureandneedsofdifferentstakeholders,differentgeneticresources,anddifferenttransfers withindifferentsectorsofgeneticresourcepolicy."
- 4. Atitssecondsession,theCommitteeconsidereddocumentWIPO/GRTKF/I C/2/3, ("OperationalPrinciplesforIntellectualPropertyClausesofContractualAgreements ConcerningAccesstoGeneticResourcesandBenefit -Sharing").Thisdocumentwaslargely baseduponexistingcontractualagreementswhichhadbeenanalyzedorrefer redtoin previousWIPOdocuments.Itdidnotaimtopresentarepresentativesampleofrelevant agreementsandpractices.
- 5. Inordertoensureamorewide -rangingbasisfordiscussion,theSecretariatwas requestedtoundertakeasystematic surveyofactualcontractualagreements,includinga questionnairetobesenttoCommitteemembersandotherstakeholders.Italsosuggestedthat thissurveycouldserveasabasisforthesystematicandbalanceddevelopmentofcontractual practices,guid elinesandmodelintellectualproperty("IP")clauses,whichwouldreflectthe operationalprinciplesagreedandidentifiedbyCommitteemembers.
- 6. Inaddition,theCommitteeadoptedaproposalcirculatedbytheDelegationofAustralia for "Su mmaryChecklistofKeyContractualIntellectualPropertyTermsonAccesstoGenetic ResourcesandBenefitSharing." ³Thisproposalentailedcreatingasearchableelectronic database,tobepublishedontheWIPOwebsite,andhyper -linkedtothewebsiteo fthe ClearingHouseMechanism ("CHM") of the 1992Convention on Biological Diversity ("CBD"). TheCommitteedecided that the results of the proposed question naire would be compiled into an electronic database, and could serve as a resource on contractual practices, guidelines and model IP clauses for contracts concerning access to genetic resources and benefit-sharing.
- 7. Atitsthirdsession,theCommitteeconsideredasuggestedstructurefortheproposed database,andadraftquestionnaire. ⁴ Bothwereapproved,subjecttoseveralmodificationsto thescopeofthequestionnaire. ⁵TheCommitteefurthernotedthatthequestionnaireshouldbe disseminatedaswidelyaspossibletoarangeofrelevantstakeholders.

III.QUESTIONNAIREWIPO/GRTK F/IC/Q.2

8. CommentsmadebytheCommitteeatitsthirdsessionwerereflectedinarevised questionnaire,WIPO/GRTKF/IC/Q.2("QuestionnaireofContractualPracticesandClauses RelatingtoIntellectualProperty,AccesstoGeneticResourcesand Benefit-sharing").This documentwassubsequentlydisseminatedbytheSecretariattoCommitteeparticipants,andto

SeedocumentWIPO/GRTKF/IC/1/13,paragraph128.

SeedocumentWIPO/GRTKF/IC/2/3,paragraphs131to134.

DocumentWIPO/GRTKF/IC/2/12, ProposalfortheCompilationofC ontractualTermsfor AccesstoGeneticResourcesandBenefit -Sharing

⁴ DocumentWIPO/GRTKF/IC/3/4

SeeWIPO/GRTKF/IC/3/17,paragraphs31to61.

aconsiderablenumberofstakeholdersinthepublicandprivatesectorwithpractical experienceofcontractualpracticesandagreementsre latingtoIP,accesstogeneticresources andbenefit -sharing.Itwassent,forinstance,tomembersoftheExpertPanelonAccessand Benefit-SharingthathadbeenconvenedbyMemberStatestotheConventiononBiological Diversity("CBD")andthathadb eeninstrumentalindrawinguptherecentlyadopted "Bonn GuidelinesonAccesstoGeneticResourcesandFairandEquitableSharingoftheBenefits ArisingoutoftheirUtilization," ⁶andwasdisseminatedontheworldwidewebthrough BIOPLAN,anelectronic BiodiversityCommunicationNetworkmaintainedbyUNEP.

- 9. ByFriday,October11,2002,theSecretariatofWIPOhadreceivedtwentyrepliesto QuestionnaireWIPO/GRTKF/IC/Q2, ⁷andhadcompiledelevenfurthermodeloractual contractsconcernin gIP,accesstogeneticresourcesandassociatedbenefit -sharingthathad beenpreviouslypublishedorprovidedtoWIPO,withtheunderstandingthattheycouldbe referredtoinfuturepublicationsordocuments.
- 10. Itisapparentthatrelevanta greementsdoexistinmanydifferentjurisdictionsandin manydifferentsectors. ⁸Moreover,itseemshighlylikelythatcontractualarrangements concerningIP,accesstogeneticresourcesandassociatedbenefit -sharingwillbecomemore commoninthefutu re.Inparticular,manycountrieseitherhavedeveloped,orareinthe processofdeveloping,nationallegislationonaccesstogeneticresourcesandbenefit -sharing. Severalnationallegislativeframeworks,whicharecurrentlyinforce,providefortheu seof contractualagreementsasatoolforimplementingtherequirementofmutuallyagreedterms indeterminingaccesstogeneticresourcesundertheirjurisdiction. ⁹Furthermore,reports proposingtheestablishmentofsuchnationalframeworksforeseethe useofcontractual agreements. ¹⁰Additionally,modellawswhichwouldgovernaccesstogeneticresourcesare

SeeDecisionVI/24ofthesixthConferenceofthePartiesoftheCBD.TheBonnGuidelines, *interalia*, en courageWIPOtomake, "rapidprogressinthedevelopmentofmodelintellectual propertyclauseswhichmaybeconsideredforinclusionincontractualagreementswhen mutuallyagreedtermsareundernegotiation".

TwelveofthesereplieswerefromMemberS tatesstating,ineffect,thattheyhadnoinformation onthistopic.

See, for example, "Elements of Commercial Biodiversity Prospecting Agreements," by Michael Gollinin, "BiodiversityandTraditionalKnowledge; EquitablePartnershipsinPractice," ed ited bySarahA.Laird,Earthscan(2002).Theclausescitedinthisarticleweredrawnfromthe followingagreements: ACooperativeResearchandDevelopmentAgreementforDrug DiscoveryandBiodiversityConservationinAfrica;AgreementbetweentheUnive ArizonaandAmericanCyanamid;AgreementbetweentheUniversityofArizonaandPontificia UniversidadCatolicadeChile;AgreementtoallowCollection,Transfer,Export,andUseof Biological Materials between the Smithsonian Institution and AutoridadNacionalDel Ambiente, Panama; International Cooperative Biodiversity Grant Collaborative Research Agreement between IN BIO and Cornell; International Cooperative Bio diversity GrantCollaborativeResearchAgreementbetweenVirginiaPolytechnicInsti tuteandMissouri BotanicalGardens; and an Agreement between Strathcly deand the University of South Pacific (Fiji). The Clauses are available electronically at: http://www.rbgkew.org.uk/peopleplants/manuals/biological/annexes2.htm.

See, for example, the access legislation of the Philippines: Philippines Executive Order 247 and its Implementing Rules and Regulations (IRR).

See,forexample,theReportofthe CommonwealthPublicInquiryonAccesstoBiological ResourcesinCommonwealthAreasoftheCommonwealthofAustralia(2000),whichproposes anaccessschemeunderwhich, "eithertheowner, orholderofresources intheparticular"

orhavebeendevelopedbyregionalintegrationorganizations, suchastheOrganizationof AfricanUnity(OAU), ¹¹andtheAndeanCommunity, which,i nDecision391, establisheda "CommonSystemonAccesstoGeneticResources." ¹²Suchmodellawstendtoenvisage, as animplementingtoolfornationalaccesslegislation, the use of contractual agreements between an ational authority, the applicant or collector and, where applicable, the concerned local community or communities.

- 11. Accordingly, since itseems likely that additional examples of relevant agreements do exist, or are in the process of being developed, Committee Participants may ne edmore time to disseminate Questionnaire WIPO/GRTKF/IC/Q2 more widely in order to access such agreements. In particular, Member States may need more time to liaise with other sactive in this area at an ational level, over and above those active in the first eldof IP alone; for instance:
- (a) appropriategovernmentauthorities, such as the CBDF ocal Point for each country, ministries or departments concerned with a griculture, environment, in digenous affairs, and justice, and any national commissions on gene ticresources;
- (b) relevantnationalassociationsofindustryorprofessionals, suchas associations of legal professionals, technology licensing professionals, and the pharmaceutical and biotechnology industries;
- (c) holdersoftraditionalknowledgean daccessproviderstogeneticresources, such as associations of healers, in digenous peoples or local communities, peoples 'organizations, traditional farming communities; and
- $(d) \quad \textit{exsitu} \ \text{collections} \\ \text{of genetic resources, such a suniversities, botanical} \\ \text{microbial collections} \\ \text{and} \\ \text{microbial collections} \\ \text{micr$
- 12. Forthisreason, it is suggested that the Committee approve an extension of time for Questionnaire WIPO/GRTKF/IC/Q.2 to be further disseminated, and followed up, by Committee Participants and by the Secretaria tof WIPO, and for receipt of answers, to Friday,

Commonweal tharea, is empo were dtone gotiate abene fit -sharing contract with the proponent (bioprospector). The contract will be based on a model contract to be developed and agreed by industry, Indigenous organizations and other stakeholders. The model contract will include provisions for benefits haring through non -monetary and monetary benefits, such as fees, milest one payments and royal ties, from sources including... in tellectual property rights." (p.1).

SeetheOAUAfricanModelLegislationfortheProtectionoftheRight sofLocalCommunities, FarmersandBreeders,andfortheRegulationofAccesstoBiologicalResources.

- FormerlyknownastheCartagenaAccordandpreviouslycommonlyreferredtoastheAndean Pact.ThefollowingcountriesmakeuptheAndeanCommunity: Colombia,Venezuela,Peru, EcuadorandBolivia.
- 13 Forinstance, Article 32 of Decision 391 states that an access contract must be signed between the Applicant and the State. For indigenous organizations, this contract should also include thoseorgani zationsinwhoseterritoriestheresourcesarelocated, and who are the guardians of associatedknowledge.OfthefivecountriesthatmakesuptheAndeanCommunity, "Ecuador and Peruhavenotap proved contracts, because they do not have regulations to imp Decision. Venezuelahasnot promulgated this regulation either, but due to the Decision and to theirrecentlyapprovedBiodiversityConservationLaw,ithasapproved15accesscontracts, fourofthem[with]foreigners.Colombiaalsohasseveral approvedcontracts and Bolivia, which approved the Regulation in 1996, has approved one of three applications": see Factsheet: AccesstoGeneticResourcesintheAndeanCommunitybyPatriciaMolina -ForoBoliviano sobreMedioAmbienteyDesarrollo(FOBOM ADE)at: http://www.biowatch.org.za/pmolina.htm

March28,2003. This would enable the Committee, at its fifths ession, to consider a more broadly-based version of the draft database, and to consider a longer term approach to its development, use and management.

IV.AMENDMENTSTOTHEPROPOSEDDRAFTSTRUCTUREOFTHEDATABASE

- 13. Asaresultoftheresponsesreceived,theproposedstructureoftheelectronicContracts
 Databasewasfurtheramendedtoreflectthetechnicalandpractical realitiesofincorporating
 theseresponsesintoanelectronicformatinasuser -friendlyamanneraspossible.For
 instance:
- (a) Thesearchtoolshavebeenconsiderablysimplified and made more relevant to the type of information that an end -user may is htoretrieve. It is now possible to search by:
 - Browsingorscrollingthroughalistofallresponsescontainedinthedatabase;
 - Carryingoutatextsearchofallcontractinformationcontainedinthedatabase; and
 - Selectingthespecifickindcontr actualclause,orcombinationofcontractualclauses, toberetrievedbythesearch;forinstance,ausercouldelecttosearchallcontracts thathaveclausesonpatents,orallcontractsthathaveclausesonpatents, confidentialityanddisputeresolutio n,etc.
- (b) Thelayoutoftheso -calledContractChecklistPagehasbeenclarifiedby inserting,asstandardinformationatthetopofeachpage,thefollowinginformationforeach contractinthedatabase:
 - ContractTitle:
 - SubjectMatter;
 - SummaryofU se(s);
 - PurposeorBackground;
 - ContractLanguage; and
 - ContactDetails.
- (c) TheContractChecklistPage,asagreedatthethirdsessionoftheCommittee,also includedalistofrelevantspecificcontractclausesandinformationrelatingto:Intellectual Property;OtherClauses(suchasownership,confidentiality,transfertothirdparties,etc.); ApplicableLaw;andPracticalAdvice.Thispagehasnowbeenmodifiedtoinclude individualhyper -linkswhichdirectlyconnecttotherelevantclauseinthec ontractitself,or thecompletedquestionnaire,(whicheverhasbeenprovided),ratherthanbytransposingeach specificanswer,oreachspecificclauseinacontract,intoaseparatetextbox,ashadbeen suggestedindocumentWIPO/GRTKF/IC/3/4;
- 14. AnoutlineoftherevisedlayoutisprovidedastheAnnextothisdocument. This revisedContractChecklistPage,togetherwithasampleoftheContractsDatabaseitself,will shortlybeavailableforviewontheWIPOwebsiteat:

http://www.wipo.int/globalissues/

15. Alivedemonstration of the pilot version of the Contracts Database will be given at the fourthsession of the Committee, beheld in Geneva from December 9 to 17,2002.

V.CON TRACTUALINFORMATIONRECEIVED

- 16. Averybroadrangeofmodelandactualagreementshasbeensubmittedforinclusionin the Contracts Database. Mostrespondents en closed the actual textofacontract, either instead of, or in addition to, comple ting the question naire. While confidential information has been removed, some agreements have disclosed very specific commercial information, such as agreed royal typercentage rates.
- 17. MostcontractssubmittedhavebeendraftedintheEnglish languageonly.Inanyevent, itisproposedthat,atthecurrentpilotstage,thecontractualtextshouldremaininthelanguage inwhichitwasreceivedbyWIPO,sinceotherwisethereisaconsiderableriskthatcomplex contractualprovisionsmaybemisc onstrued,oncetranslated,orsimplymistranslated.In furtherversionsofthedatabase,onceitsgeneraloperationhasbeenassessedandapproved, thecontractinformationmaybetranslatedintosomeorallofWIPO'sofficiallanguages, dependingonthe allocationofresourcesforthefuturedevelopmentofthisproject.
- 18. Thefollowingsampleofcontractsreceivedillustratesthebreadthofinformation concerningIP,accessandbenefit -sharingthathasbeencollectedbyWIPO,andthatwillb containedintheContractsDatabase:

e

- (a) ACornInbredReleaseandLicensingAgreementbetweenAgricultureand Agri-Foods,Canada(AAFC)andcommercialcorncompanies;
- (b) AModelAgreementbetweentheNationalInstituteforPharmaceuticalResearch andDevelopment,NigeriaandaConsultantHerbalist;
- (c) Standard Conditions for Project Agreements between the Australian Center for International Agricultural Research (ACIAR) and the Commissioned Organization;
- (d) AnAccessandBenefit -SharingAgree mentbetweentheLebaneseAgricultural ResearchInstitute,TalAmara,Rayak,LebanonandTheBoardofTrusteesoftheRoyal BotanicGardens,Kew,Richmond,Surrey,TW93AEUnitedKingdom;
- (e) An Agreement pertaining to the testing of plant extracts between the Company and the University (SriLanka), dated January 1,2000;
- (f) ASampleLicensingAgreementsubmittedby MichaelA.Gollin,VENABLE AttorneysatLaw,1201NewYorkAvenue,N.W.,Suite1000,Washington,DC20005- 3917 UnitedStatesofAmerica:
- (g) AResearchAgreementbetweenSyngentaCropProtectionAG,Basel, SwitzerlandandHUBEIAcademyofAgriculturalSciences,Wuhan,China;and
- (h) AKnowHowLicencingAgreementbetweenTheTropicalBotanicGardenand ResearchInstitute,Kerala,India (TBGRI)andTheAryaVaidyaPharmacy(Coimbatore)Ltd, Coimbatore,India.

19. Evenwithinthisshortlist,thecontractssubmittedrelatetoawidevarietyofcontract parties(government,privatesector,publicresearchinstitutionsand/orindiv idualhealersetc) andcontractobjective. Astotheir IP aspects, although the majority of contracts relateto research oneither plantor microbial genetic resources (asopposed to an imalgenetic resources, or research associated with traditional knowle dge or know-how), the IP aspects of even this small sample of agreements are largely distinct, and may often be truly explicable only with a fuller understanding of the underlying project and the negotiating history between the parties to the agreement. The forthis reason, it is not proposed to try to analyze each response received in this present interimd ocument. To Nonetheless, the following common is suesarising from the contracts may be of particular interest.

A. <u>IntellectualProperty</u>

- 20. Intellectual property elements of the contracts cover a range of issues, for instance:
- (a) RequirementsorlimitationsconcerningtheobtainingandmanagementofIP rights,(suchaslimitationsonIPrightsclaimedoverthelicensedmaterial,requirements seekandmaintainIPrights,approachesfordeterminingtheownershipofanyIPrightson technologicaldevelopmentsbasedonthelicensedmaterial,etc.);and
- (b) LicensingofIPrights(suchasmechanismstoensurelicensestousetechnologies basedonthematerialsprovided,licensestouseIP -protectedtechnologyforspecificpurposes suchasnon -commercialresearch,andlicensingofimprovementstotechnology).
- 21. TheIPaspectsofthecontractstendtobediverse,andsomeclausesma yonlybetruly explicablewithafullerunderstandingoftheunderlyingprojectandtheprojectpartiesetc. ThemajorityofcontractstendtofocusonIPinageneralsense,ormorespecificallyonpatent rights(asopposedtootherspecificareasofIP suchascopyright,tradesecretsandIP protectionoftraditionalknowledge). AccesstoIP -protectedtechnologiesmayformpartof thesharingofbenefitsunderacontract. Thefollowingclausesmayillustratethediversityof contractprovisions:

The Contracts Database include contact details (E -mail, telephone and facsimile) of the individual or institution which submitted the contractinf or mation, thereby enablinged -users to address specific queries directly to the originators of the information.

Foracomprehensivereviewofintellectualproperty -related clauses incertain contractual arrangements, seeworking document WIPO/GRTKF/IC/2 /3 entitled, "Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to Genetic Resources and Benefit -Sharing."

IntellectualProperty(general)

- (a) A MaterialTransferAgreement(GermplasmandUnregisteredLines)betweenthe DepartmentofAgricultureandAgri -Foods,Canada(AAFC)andseveralpublicbreeding institutions:
 - "TheRecipientshallowntheprogenyorgermp lasmwhicharenotessentially derivedfromtheMaterial.TheRecipientagreesthatit:...
 - '(d) shallnotseekintellectualpropertyrightsovertheMaterialorrelated informationwhichcouldacttothedetrimentofthecontinuingavailabilityofthe Materialforagriculturalresearchandbreedingpurposes'."
- (b) StandardConditionsforProjectAgreementsbetweentheAustralianCentrefor InternationalAgriculturalResearch(ACIAR)andtheCommissionedOrganisation(extracts fromClause10whichfocuses onIntellectualProperty):
 - "10.6Recognisingthatitwillbedesirabletouseorexploitadvancesor discoveriesthatmaybemadeinthecourseoftheProject,thePartiesagree thatownershipofallIntellectualPropertyintheMaterialwillinAustrali vestintheCommissionedOrganisation,andwillintheCollaborating Country,vesteitherintheCollaboratingInstitutionoranauthority designatedbytheCollaboratingInstitution.

a,

- 10.7 TheCommissionedOrganisationagreesthatitwillenterintoeq uitable arrangementswiththeCollaboratingInstitutioninrelationtothefollowing matters:
- (a) the allocation of ownership of Intellectual Property in the Material between the Commissioned Organisation and the Collaborating Institution in countries oth erthan Australia and the Collaborating Country;
- (b) the terms of anylicence sbetween the Commissioned Organisation and the Collaborating Institution to use or exploit the Intellectual Property referred to inclause 10.3 and paragraph (a);
- (c) the terms of anylicences 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 or 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) theintellectualcontributionsoftheCommissionedOrganisationandthe CollaboratingInstitution;
- (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) suchot herrelevantconsiderationsastheCommissionedOrganisationand theCollaboratingInstitutionmaymutuallydetermine."

Patents

(c) A Model Memoran dum of Understanding (MoU) between the Development al 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).

"Both[SCO]andDTP/NCIrecognizethatinventorshipwillbedeterminedunder patentlaw.DTP/NCIand[SCO]will,asapp ropriate,jointlyseekpatent protectiononallinventionsdevelopedjointlyunderthisMOUbyDTP/NCIand [SCO]employees,andwillseekappropriateprotectionabroad,includingin [SourceCountry],ifappropriate.Applicationforpatentprotectiononin ventions madeby[SCO]employeesalonewillbetheresponsibilityof[SCO].Application forpatentprotectiononinventionsmadebyDTP/NCIemployeesalonewillbethe responsibilityofDTP/NCI.

Withrespectonlytothosecompoundsthathavebeendetermi nedtopossesssuch significantanti -cancerpotentialastobescheduledforclinicaltrialsbyDCTD,the U.S.Governmentshallhavearoyalty -free,irrevocable,nonexclusivelicenseto manufactureand/orusebyorfortheU.S.Governmenttheinvention(s) claimedin anypatentsthat[SCO]mayhaveormayobtainonsuchcompoundsorona processforuseofsuchcompounds.However,thislicensewillapplyonlyto [SCO]patentsthatrelyupondatageneratedbyDTP/NCIorDTP/NCItesting laboratories.Thisli censeshallbeonlyformedicalresearchpurposesrelatedtoor connectedwiththetherapyofcancer.Theterm"medicalresearchpurposes"as usedhereinshallnotincludetreatmentofpatientsoutsideofclinicaltrialsor commercialdistributionofthe compounds."

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

"Should a patentable invention result from the Company's or the University's testing and analytical activ ity, the Company is free to apply for patents with regard to such invention in its name and at its expense as it wishes. Any such patents will be filed by the Company indicating the name (s) of the University, its collaborator(s) and the representative(s) of the company, as the case may be, as inventor(s). To this end, the University agrees to execute such documents and signatures as may be all ybe required."

Licensing

(e) AKnowHowLicencingAgreementbetweenTheTropicalBotanicGardenand ResearchIn stitute,Kerala,India(TBGRI)andTheAryaVaidyaPharmacy(Coimbatore)Ltd, Coimbatore,India.

"A.4. GRANTOFLICENCE

- A.4.1 InconsiderationofthepaymentasprovidedforinClause5.1and performancebyPARTYofthecovenantshereincontained,TBGRI herebygrantstothePARTYthelicencetoutilisetheKNOWHOWto makeandsellthePRODUCTdirectlyorthroughanymarketingagency authorisedbyTheAryaVaidyaPharmacy(Coimbatore)Ltd.
- A.4.2 ThelicenseherebygrantedtothePARTYbyTBGRIisforutil isationof KNOWHOWforaperiodofsevenyearsonexclusivebasiscommencing fromthedateoftransferofKNOWHOWprovidedthattheKNOWHOW iseffectivelyutilisedwithin4yearsfromthedateoftransferof KNOWHOW.
- A.4.3 Thelicenseshallcomeintoforce fromTenthdayofNovemberOne ThousandNineHundredandNinetyFive(hereinaftercalledthe EFFECTIVEDATE)andshallremainvalidforaperiodofsevenyears thereafter.
- A.4.4 The PARTY will produce and market the PRODUCT within 4 years from the date of transfer of KNOWHOW. If PARTY fails to do so TBGRI will have the right to cancel the licence granted to PARTY and the PARTY in turnshould surrender the KNOWHOW. In such a circumstance the PARTY will not have any right to claim licence fee already paid to TBGRI."
- (f) The UniformBiologicalMaterialTransferAgreement(UBMTA)fortheTransfer ofMaterialsbetweenNon -ProfitInstitutions:
 - "5.(c)WithoutwrittenconsentfromthePROVIDER,theRECIPIENTand/orthe RECIPIENTSCIENTISTmayNOTprovideMOD IFICATIONSfor COMMERCIALPURPOSES.ItisrecognizedbytheRECIPIENTthatsuch COMMERCIALPURPOSESmayrequireacommerciallicensefromthe PROVIDERandthePROVIDERhasnoobligationtogranta commerciallicensetoitsownershipinterestintheMATERIA Lincorporatedin theMODIFICATIONS.Nothinginthisparagraph,however,shallpreventthe RECIPIENTfromgrantingcommerciallicensesundertheRECIPIENT's intellectualpropertyrightsclaimingsuchMODIFICATIONS,ormethodsoftheir manufactureortheir use.
 - 6.TheRECIPIENTacknowledgesthattheMATERIALisormaybethesubject of apatentapplication. Except as provided in this Agreement, no expressor implied licenses or other rights are provided to the RECIPIENT under any patents, patent application s, tradesecrets or other proprietary rights of the

PROVIDER,includinganyalteredformsoftheMATERIALmadebythe PROVIDER.Inparticular,noexpressorimpliedlicensesorotherrightsare providedtousetheMATERIAL,MODIFICATIONS,oranyrelatedpa tentsof thePROVIDERforCOMMERCIALPURPOSES.

7.IftheRECIPIENTdesirestouseorlicensetheMATERIALor MODIFICATIONSforCOMMERCIALPURPOSES, theRECIPIENTagrees, in advanceofsuchuse, tonegotiateingoodfaithwiththePROVIDERtoestablish thetermsofacommerciallicense. It is understood by the RECIPIENT that the PROVIDER shall have no obligation to grant such alicense to the RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others, or sellor assignal lorpart of the rights in the MATERIAL to anythird party (ies), subject to any pre-existing rights held by others and obligations to the Federal Government."

22. Thisoverviewshouldillustratehowsuchclausestendtobedistinctiveand context-dependent. Takenoutoftheircontextwithintheoverallcontract, and the underlying transaction or cooperative partnership as awhole, these clauses may be difficult to appreciate fully. For this reason, the Contracts Database gives direct access to other clauses within the contracts that would provide the necessary context for the specific IP elements of each contract (for instance, Definitions; Ownership; Confidentiality, etc.). Contact details of the provider of the contractual information are also available the related information.

B. Benefit-Sharing

- Thedatabasedistinguishesbetweenmonetaryandnon 23. -monetarybenefits.The contractspr ovidedsofargivesomeevidenceofatrendawayfrombenefit -sharingperceived inexclusivelyfinancialterms, and towards agreater appreciation of the role of non--monetary benefits, such a stransfer of technology, access to IP -protectedtechnology,trai ningof researcherslocally, sponsoring of researchers to undertake post -graduateresearchlocally and/orabroad,transferofequipment,andexchangeofinformation.Indeed,insome contracts, greater emphasis appears to be placed on non -monetarybenefit -sharing, possibly reflectingtheneedtobalancebenefitslinkedtouncertain,longer -termcommercial success, as againstthenon -monetarybenefitsthatmaybeavailableimmediatelyandonamoresecure basis.Forinstance:
- (a) MrWalterSmoldersofthe SyngentaIntellectualPropertyDepartment,submitting informationrelatingtoSyngentaCropProtectionAG,Basel,SwitzerlandandHUBEI AcademyofAgriculturalSciences,WuhannotesthattheagreementaddressbothMonetary Benefit-Sharing(royalties)and NonmonetaryBenefit -Sharing(fundingofstraincollection, fermentationandprescreeningactivitiesinChina,transferofassaytechnologiesand know-howtoChina,trainingofChinesescientistsandtechniciansinSwitzerland);

- (b) AModelAgreementb etweentheNationalInstituteforPharmaceuticalResearch andDevelopment,Nigeria,andaConsultantHerbalist,addressesbenefit -sharinginthe followingway:
 - "16. INCONSIDERATION of the foregoing provisions, the "INSTITUTE" shall at the point of commer cialization of products derived from the "CONSULTANTHER BALIST'S" input negotiate on behalf of the "CONSULTANTHER BALIST" for some royal ty of at least 10% of the net profit to accrue to the "CONSULTANTHER BALIST".
 - 17. INFURTHERCONSIDERATIONoftheser vicesrendered by the "CONSULTANTHERBALIST", the "INSTITUTE" shall make payment to him as follows:
 - (a) The cost of collection, travelling, shipping of samples, identification, curating and processing, literatures earch as may be applicable.
 - (b) The "CO NSULTANTHERBALIST'S" costofworkalready carried out on the samples.
 - (c) The "CONSULTANTHERBALIST" S" costof specified quantities of samples delivered to the Institute upon request and such sum outstanding due before the formal execution of this agreem ent.
 - (d) [......]quarterlysubventiontofacilitatethe"CONSULTANT HERBALIST'S"herbalplantcollectiondrive,overallproductivity,research andfurtherdevelopment."
- (c) AModelBiodiscoveryBenefit -SharingAgreementpreparedbytheStateof Queensland,AustraliatofacilitatethedevelopmentoftheQueenslandbiodiscoveryindustry illustratesthatbothmonetaryandnon -monetarybenefitshavearoleinbiodiscovery.The followingisasampleofsomeofthebenefit -sharingclausesfoundinthisModelA greement:

"7.2 MaximisingBenefits

InconductingBiodiscoveryResearch,theOrganisationmustuseitsbest endeavourstomaximisebenefits(includingNon -MonetaryBenefits)for Oueensland.

7.3Non - Monetary Benefits

The Organisation agrees to providet he Non-Monetary Benefits (if any) specified in item 10 of schedule 1 on the terms and conditions specified (if any).

8.3ApprovalofCommercialisationPlan

. . .

(c)IndecidingwhethertoapproveadraftCommercialisationPlan,the
Departmentwillhave regardtothebenefits(includingNon -MonetaryBenefits)
forQueenslandoftheCommercialisationproposedtobeauthorisedunderthe
CommercialisationPlan."

C. PracticalGuidanceandLessonsLearned

- 24. Relativelyfewreplieshavebeenre ceivedtoPartIIIofthequestionnaire,on"Practical GuidanceandLessonsLearned". Theresponsesthathavesofarbeensubmitteddohowever illustratethebreadthofapproachestothepracticalitiesofworkingintheareaofIP, access andbenefit -sharing, perhapsreflectingthetendencytodevelopandadapteachcontractual arrangementoncase -by case, accordingto, *interalia*, applicablenationallegislationand policies, therespective interests and rolesofthe contract parties, and the contract objective.
- 25. Someexamplesoftherepliesreceivedtotheissueofwhether, and how, priorinformed consent (PIC) has been obtained are as follows:
- (a) Dr.V.Kumar,SeniorProfessoroftheUniversityofPeradeniya,SriLanka, submittingacontr actbetweentheUniversityandaCompanysettingupanarrangementtotest plantextractsprovidedbytheUniversity,notedthat"Nogovernmentbodyhasplayedarole. However,guidelines[are]beingfollowedtoobtainPIC";
- (b) Dr.BeatMoser,theDire ctor-GeneraloftheSwissSocietyofChemicalIndustries, stated:
 - "Weagreethatcompaniesshouldobtainpriorinformedconsentinapro -active mannerbeforegainingaccesstoacountry'sbiodiversity, e.g. eitherthroughlocal operators (middlemen) doi ngtheactual screening or directly innegotiation with the local government. Since the adoption of the CBD, this is a "best practice" that the Swiss companies consider to be of utmost importance. However, knowing what government a lagency is competent of give priorinformed consent, and the extent to which organizations of indigenous peoples (of tenin conflict with their own governments) should be involved is extremely difficult. It is a serious problem that no matter how hard companies try to actine on formity with the CBD, they almost always end up being accused of 'biopiracy'..."
- (c) MrWalter Smolders of the Syngenta Intellectual Property Department, submitting information relating to Syngenta Crop Protection AG, Basel, Switzerland and HUBEI Academy of Agricultural Sciences, Wuhan (Provider) noted that prior informed consent was the responsibility of the providing party; and
- (d) Dr.HassanMachlab,Head,oftheDepartmentofPlantbreedingattheLebanese AgriculturalResearchInstitute(LARI),in relationtoanoncommercialAccessandBenefit SharingAgreementbetweenLARIandtheBoardofTrusteesoftheRoyalBotanicGardens, Kew(RBGKew),UnitedKingdomrepliedasfollows:

"The Lebanese Government, represented by the Ministry of Agriculture, has signed as eparateletter in which it approves of the collaboration between LARI and RBGK ewand authorizes LARI to take all necessary action regarding the Access and Benefit - Sharing Agreement 'providing the regulations of the international conventions are adhered to.'

"Inaddition,intheAccessandBenefit -SharingAgreementitself, LARI undertakestohelpRBGKewtosecurethepriorinformedconsentofany competentnationalandlocalLebaneseauthoritiesandofanyotherappropriate

stakeholderst oenable(a)accesstotheplantmaterial;(b)entryuponthelandin theLebanononwhichtheprojectactivitieswilltakeplace;and(c)thecarrying outoftheaforesaidactivities."

- 26. Inrelationto "Lessons Learned", the following replies clearly illustrate the perceived limitation stothecurrent status quo, as viewed by two very different sectors. They also highlight the need for capacity building in this area, particularly in so -called 'Provider Countries' (i.e. biodiveristy rich count ries), as a matter of priority:
- (a) Dr. V. Kumar, Senior Professor of the University of Peradeniya, Sri Lanka, commented as follows:

"Negotiationsbetweendevelopingcountryinstitutionsandmultinational corporationsarenotnegotiationsbetweenequals. Thereforeafaircontractcannot beaccepted. The multinational corporation has teams of lawyers well experienced in similar contracts and negotiations. The developing country institution can rarely afford to pay for good legal adviceand, even if consulted, developing country lawyers do not have much experience in such contracts."

- (b) Dr.BeatMoser,theDirector -GeneraloftheSwissSocietyofChemicalIndustries, pointedoutintheSociety's replytoWIPOthat:
 - "...wewouldliketodrawyourattention tothefactthatalotofsuccessful chemicalandpharmaceuticalscreeningsaretakingplacewithinEuropeandinthe developedworld,baseduponsyntheticcompoundsproducedinlargenumbersby combinatorialchemistry. The R&D based chemical and pharmac eutical sectorin Switzerland...does not relyheavily upon biodiversity resources from developing countries. However, to the extent that local governments in the developing world create fast-trackeasy, reliable, access to the irnational resourcese.g.th rough local focal points, it is clear that the remay be an incentive for some companies to explore this option for screening further. On the other hand, the absence of clear regulations and lack of information about proper contact points in a provider country tends to render research with plant genetic resources unattractive."

D. ModelAgreements

27. Whencollectingandinterpretingdatainthisarea,itisnecessarytodistinguishbetween modelagreements,andtheactualagreementsthathaveb eensettledandappliedinpractice. Anumberofthecontractssubmittedaremodelagreements. Theseareveryusefulin illustratingtherangeofpossibilitiesforlicensing,andthegeneralapproachesandprinciples thatapply,forexample,totheowner shipandexerciseofIPrights,andtobenefit -sharing. However,forthepurposesofstudyandanalysis,itmaybenecessarytodistinguishsuch standarddocumentsfromtheclausesinthefinal,negotiatedcontracts,evenwheretheseare basedonmodelte xts.AsDr.BeatMoser,theDirector -GeneraloftheSwissSocietyof ChemicalIndustries,pointedoutintheSociety'sreplytoWIPO:

"TheNovartisexampleshouldnotbeunderstoodtoserveasa' model' contractas weareoftheopinion, that, in principle, model contracts can only serve as guidelines and would never in reality replace the need for specially designed case by-case solutions. However, this does not mean that the Swisschemical and pharmaceutical industry would be opposed to asset of carefully prepared guidelines of best practices which could be developed in an international context."

- 28. Dr.HassanMachlab,Head,oftheDepartmentofPlantbreedingattheLebanese AgriculturalResearchInstitute(LARI)describedthedevelopmentofanon -commercial AccessandBenefit -SharingAgreementbetweenLARIandtheBoardofTrusteesoftheRoyal BotanicGardens,Kew(RBGKew),UnitedKingdom:
 - "AdraftcontractwasinitiallyproposedbyRBGKew,basedonamodel agreementusedbyRBGKew inotherinternationalpartnerships,butmodifiedto reflectthespecificsoftheproposedrelationshipbetweenLARIandRBGKew. ThisdraftwasthenstudiedbyLARI.Modificationsweresubsequentlyproposed byLARI,andacceptedbyRBGKew."
- 29. Forthisreason,theSecretariathasclassedagreementsinthedatabaseaseither'model' or 'actual,' sothatthey can be browsed or examined separately, with a clear understanding of whether they are illustrative models, or whether they correspond to the terms of contracts that have been actually implemented in practice.

VI.CONCLUSION

- 30. Thecontractdatabaseisnotintendedasanormativeexercise, butrathertoillustrate currentpracticesrelatingtocontractsorlicensesrelating toIPandgeneticresources. This should facilitate understanding of the process of negotiating and concluding contracts in this area, potentially for the benefit of a widerange of institutions and communities with an interest in IPaspects of access to genetic resources. In future, the database could also help illustrate emerging trends or patterns, but it would be premature at this stage to attempt to draw any conclusions. The responses already received help to illustrate the widerange of possibilities for contract provisions concerning IPaspects of genetic resources and benefit sharing. Future versions of the database may develop a saricher, more comprehensive and diverse source of information about practical approaches in this area.
- 31. Inparticular, should the Committee approve of an extension of time for dissemination and receipt of Questionnaire WIPO/GRTKF/IC/Q2, it is hoped that there ceipt of further responses would facilitate the development of the Contracts Database into aperma nent, freely available WIPO resource. Such are source could 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.

32.TheMembersoftheIntergovernmental Committeeareinvitedtotakenoteofthe contentsofthepresent document;toapprove anextensionoftimeinwhichthe Questionnaire(WIPO/GRTKF/IC/Q2)maybe disseminatedandansweredtoFriday, March28,2003;andtoapprovethefurther developmentoftheContractsDatabasesasa permanent,freelyavailableresourc efor contractsconcerningintellectualproperty, accesstogeneticresourcesand benefit-sharing.

[Annexfollows]

WIPO/GRTKF/IC/4/10

ANNEX

CONTRACTDATABASELAYOUT

CONTRACTITLE	CONTRACTTITI	E:
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SubjectMatter	Indicationofthemateriallicensedunderthecontrac t
SummaryofUse(s)	Indicationofthepermitteduseunderthecontract
PurposeorBackground	Descriptionofthegeneralcontextorobjectiveofthecontract, e.g. throughitspreambleorrecitals
ContractLanguage	Languageinwhichthecontractis availableinthedatabase
ContactDetails	Detailsofthepersonorinstitutionsubmittingthecontract

GOTOCONTRACTCLAUSES

(click on the following to go to the relevant provision in the contract)

INTELLECTUALPROPERTYRELATEDCLAUSES

IntellectualProperty(general)	LinkstoprovisionrelatingtoIPingeneral terms,ortoparticularformsofIPwhere specified
Patents	
DistinctiveSigns	
PlantBreeders'Rights	
TradeSecrets	
CopyrightandRelatedRights	
OngoingTraditionalandCust omaryUse	
Suigeneris ProtectionofTraditional Knowledge	

Licensing	Anyprovisionsconcerninglicensingof intellectualpropertyrights
Assignment	Anyprovisionsconcerninglicensingof
	intellectualpropertyrights

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OTHERCLAUSES

Definitions	
Ownership	Linkstoprovisionsoneachofthesematters, whentheyaredealtwithinthecontract
Confidentiality	
TransfertoThirdParties	
MonetaryBenefit -Sharing	
Non-monetaryBenefit -Sharing	
DisputeResolution	
GoverningLawoftheContract	
ContractVerification	
Termination	
Other	

APPLICABLELAW

National	
Regional	Linktoanyprovisiondeterminingwhich
International	jurisdictionappliestothecontract
Other(e.g.customarylaw)	

PRACTICALADVICE

Priorinformedconsent	
Benefit-Sharing	Linktoanypracticaladviceorexperience,
LocalorIndigenousCommunity	providedthroughthequestionnaire,onanyof
involvement	thesetopics
LegalAdvice	
ModelContracts/Clauses	
LessonsLearned	
Other	

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DownloadFullContractText(PDFonly)

[EndofAnnexandofdocument]