WIPO/INV/MTY/02/15

ORIGINAL:English
DATE:April2002







INSTITUTEOFTECHNOLOGYAND SUPERIORSTUDIESOFMONTERREY

INTERNATIONALWORKSH OPON MANAGEMENTANDCOMME RCIALIZATIONOFINVENT IONS ANDTECHNOLOGY

organizedby the World Intellectual Property Organization (WIPO)

incooperationwith the Mexican Institute of Industrial Property (IMPI)

and

theInstituteofTechnologyandSuperiorStudiesofMonterrey(ITESM)

Monterrey(Mexico), April 17to 19,2002

LICENSINGAGREEMENTS FORTECHNOLOGYCREA TEDTHROUGH UNIVERSITY RESEARCH PROGRAMS

DocumentpreparedbyMr.WayneH.Watkins,AssociateVicePresidentforResearch,and IntellectualPropertyFellow,UniversityofAkron,Ak ron,Ohio,UnitedStatesofAmerica

I. INTRODUCTION¹

- 1. Technologylicenseagreementsandrelateduniversity -industryagreementsarebeing concludedwithincreasingfrequencyandforincreasingeconomicstakes. The growth is driven by amult itudeof factors including:
 - universityfundingneedsandopportunities
 - industrial competitiveness;
 - facultyexpectations;
 - communityeconomicdevelopment;
 - rapidtechnologicaladvancement; and
 - growthofscience -basedandtechnology -intensiveindustries.
- 2. Themajorpurposesofthispresentationaretoinformseminarparticipantsaboutthe nature, scopeandimportanceofuniversity -industrytechnology development and licensing relationships and toprovides ampleagreement references and suggestio nsfor the resolution of frequently disputed provisions. It reflects two keymessages: (1) university to business (U2B) relationships are in the stakeholders best interests; and (2) universities and industry have the tools with which to substantially esolve the times conflicting interests associated with license and related agreements.

II. HISTORICALCONTEXT

- 3. Industryanduniversitycooperationhasbeenshapedbyhistoricalandrecentevents. TheUnitedStatesMorrillActof1862create d "land-grantcolleges "directedto wardsthe applicationof newtechnologicaladvancesinagricultureandengineeringtoenhancethe economicgrowthandcompetitivenessoftheagriculturalindustry.Yearslater,WorldWarII andtheColdWarU.S.rivalry withtheSovietUnionspawnednewandmorediverse partnershipsbetweenindustryandacademia ,promptingtheinvestmentofbillionsofdollars inscientificresearchasanationalpriorityandgivingrisetotheresearchuniversity.
- 4. Anewand highlysuccessfuleraofcollaborationamongresearchuniversities, Governmentandindustrybeganin1980withpassageoftheBayh -DoleAct(P.L.96 -517), whichacceleratedthetransferofresearchresultsfromuniversitiestothecommercialsector . This statute clarified the roles and responsibilities among these three partners with respect to ownership and commercialization of Federally -funded university -developed inventions, and created powerful incentives for technology transfer . Explain the Bayh -Dolesuccess story include:
 - establishingauniformFederalinventionpolicy
 - permittinguniversitiestoretaintitletoinventionsdevelopedthrough Federally-fundedresearch;

¹ PresentationbasedinpartonpublicationsoftheCouncilonGovernmentalRelations –see <u>www.cogr.edu</u>

PublicLaw96 -517,PatentandTrademarkAmendment sof1980.ThisLawamendedTitle35 USC,addingChapter18,Section200 -212.

- encouraginguniversities to collaborate within dustry in promoting the commercialization of inventions;
- establishingpreferenceforlocalmanufacturing;
- retainingGovernmentmarch -inrightstoensurediligenceincommercializationby patentlicensees .³
- 5. TheresultsoftheBayh -DoleActhavebeenremarkable.Comme rcializationof university-developedtechnologiesundertheActspawnedthebiotechnologyindustryandled tosignificantcommercialadvancesinothertechnology -intensiveindustries.
- 6. Otherforceshavealsoprompted the creation and expansion of alliances between universities and industry. These include:
 - technological progressandthegrowthofscience -basedandtechnology -intensive industries:
 - increasedcompetitiveness offoreignfirmsinU.S.markets,combinedwithaloss ofinternational marketsharebyU.S.companies,hasforcedAmericancompanies toseekwayso fimprov ingtheircompetitivepositionsthroughallianceswith universities;
 - as lowing ofthegrowthrateofpublicandprivatesupportforindustrial R&D activities.⁴
- 7. The Technology Transfer Actof 1988 authorized Federal laboratories to enterinto cooperative research and development agreements (CRADAs) with third parties, including private firms and universities, to provide additional incentives for the development and commercialization of technology. A wide array of cooperative programs have been created by the statest opromote economic development through technology development and deployment.

III. BENEFITSOFUNIVERSITY -INDUSTRYCOLLABORATION

8. Cooperativeuniversity -industryresearchanddevelopmenteffortshave risento unprecedentedlevels. AlmosteverystateandFederalagencyfundscooperativetechnology programs. Directindustrysponsorshipofresearchatuniversitiesis also atunprecede nted

NationalScienceBoard.ScienceandEngineeringIndicators
 U.S.GovernmentPrintingOffice,1993),pp.116
 -117.

⁵ Coburn, Christopherand Dan Berglund. Partnerships: A Compendium of State and F cooperative Technology Programs. Columbus: Battelle Memorial Institute, 1995, p. 487.

⁶ Feller,Irwin."TheUniversityasanInstrumentofStateandRegionalEconomicDevelopment: TheRhetoricandRealityoftheU.S.Experience."Presentationat theConference"University Goals,InstitutionalMechanismsandIndustrialTransferabilityofResearch,"CenterforEconomic PolicyResearch(Stanford,California)March18 -20,1994.

Coburn, Partnerships, p.2.

The Councilor Governmental Relations (COGR) has produced a compendiument it led "The Bayh-Dole Act: A Guide to the Laward Implementing Regulations," November 1993 obtainable upon request from COGR.

levels. 8 This surely confirms that benefits accrue to both university and industry collaborators. Alliances are based on the perception that collaboration will result in more value to the participants than separate investments of resources. The ben efits takemany different forms, a few of which are described below.

- <u>BasicResearch</u> -Basicresearchisseenasamajorroleofuniversities, while appliedresearchanddevelopmentismorecommoninindustriallaboratories .
 Researchallianceswithuniver sitiesprovideagrowing proportionofindustry 's basicresearchascorporateR&Dbudgetsarereducedbyshort -termcompetitive pressures.
- <u>GraduateEducation</u> –Industry -fundeduniversityresearchandinternships enhancegraduateeducationbyprovidingfac ultyandstudentswithabetter understandingofindustrialproblems.
- <u>IncreasedAwareness</u> -Collaborationwithindustryenhancesacademia 's understandingofthechallengesfacingindustrybyexposinghe universityfaculty toindustrialconcernsandindus trialapproachestoresearch.Conversely, collaborationwithuniversitieshelpsindustrialscientiststo keepabreastof the latestdevelopmentsinbroadareasofbasicscience thatare ofstrategicinterestto thecompany.
- <u>Cost-effectiveness</u> -Collabora tion, whether singly or with several inconsortia, provides a cost effective means of doing research where by funds invested are leveraged by the contributions of other participants. All parties are able to stretch limited resources.
- <u>GovernmentFunding</u> Bydesign, alliances between university and industry partners are required for Federal funding to be obtained in certain competitive situations. These programs are generally aimed at expediting development of the nation's critical technologies.
- <u>Business Opportunities</u> -TheBayh -DoleActhasspawneda university technology-transferindustry inwhich universitiesprotecttheintellectualproperty resultingfromresearchandlicenseitforcommercialapplications. In biotechnologyandotherscience -basedin dustries, universities are recognized as primary source of new business opportunities .9

National Science Foundation, Academic Science and Engineering; R&D Expenditures, Fiscal Year 1992 (Washington, DC: National Science Foundation, 1994), p.23.

AssociationofUniversityTechnologyManagers,Inc.(AUTM),TheAUTMLicensingSurvey: ExecutiveSummaryandSelectedData,FiscalYe ars1993,1992,and1991(Norwalk,CT:AUTM, 1994),p.2.Seealso,Henderson,Rebecca,AdamJaffeandManualTrajtenberg,"NumbersUp, QualityDown?TrendsinUniversityPatenting,1965 -1992."PresentationattheConference "UniversityGoals,Institut ionalMechanismsandIndustrialTransferabilityofResearch,"Centerfor EconomicPolicyResearch(Stanford,California)March18 -20,1994.

IV. CHALLENGESOFUNIVERSITY -INDUSTRYCOLLABORATION

- 9. Twoverydifferentculturesinteractinthecollaborationbetweenuniversities and industry. Un iversities have societal missions of education, research and service based on the free exchange of ideas and providing the public with access to an impartial source of information. This academic freedom allows the university research er to pursue research agendas with open -ended goals, interact with colleagues and freely publish the results. In contrast, the focus of industry is no meeting customer needs in a way that maximizes profit to stockholders. So industry research and development agendast end to be driven by profit objectives and limited publication to protect competitive positions.
- 10. Itisinevitablethatjoiningthesedifferentculturescreateschallengesforindustryand universitycollaborators,especiallyinseveralkeyareas:
 - <u>IntellectualProperty</u> -UndertheBayh -DoleAct, theintellectualpropertyr ights derivingfromGovernment -sponsoredresearchhas accrueto theuniversity conductingit .Universitiesalso retaintherights inresearchresultsto ensurethata facultyorlabo ratoryisnotblockedfromcontinuedresearchinthatarea.In researchrelationshipswithindustry,universities haveto guard carefullytheir abilitytodisseminateknowledgetostudentsandthepublic.Nevertheless, corporatesponsorsneedtobeassur edthattheresultsoftheresearchtheyfundat universitieswillbeavailabletothemforcommercialexploitation.

Compromises onintellectualpropertyhavebeenreachedtosatisfythe requirementsofbothparties andrelease themillionsofdollars annually invested byindustryinuniversityresearch. Ingeneral, universities retain the rights in intellectual property resulting from industry -sponsored research, with some of them being licensed to the industry sponsor. The scope of the license may rang e from an on -exclusive, royalty -free right to use results for internal purposes to an exclusive, royalty -bearing license for commercial applications. No one "solution" fits all circumstances, so terms are negotiated on a case -by case basis.

- 11. TheIndustrialResearchInstituteandtheGovernment -University-IndustryRoundtable haveproducedapublicationentitledIntellectualPropertyRightsinIndustry -Sponsored UniversityResearch: AGuidetoAlternativesforResearchAgreements ,which address es theseissuesindepthandprovid essampletermsasabasisfor the negotiationofintellectual propertyrights .¹⁰
 - ConfidentialityandPublication -Universitiespreferopenresearcheffortswith unrestrictedpublicationofresearchresults.Incontras t,industrysponsorsoften desirelimitedpublicationofresearchresultstoprotectthecompany 'sproprietary position.Again,compromiseshavebeenworkedoutthatenableuniversitiesto upholdtheirmissiontodisseminateknowledgewhilesatisfyingthe corporate sponsor'sneedsforprotection againstcompetition .Acommonlynegotiated compromiseregardingpublication givestheindustrysponsortheopportunityto reviewandcommentonaproposedarticleinadvanceofpublication.This

-

IndustrialResearchInstituteandGovernment -University-IndustryRoundtable,Intellectual PropertyRightsinIndu stry-SponsoredUniversityResearch:AGuidetoAlternativesforResearch Agreements(Washington:NationalAcademyPress,1993).

permitsthesponsortoidentifyproprietaryinformation thathearticlewill discloseand/ortodelaypublicationforaspecifiedperiod,e.g.60days, forthe filingof patentapplicationsbeforepublicationtoavoidlossofU.S.orforeign patentrights.

- <u>ConflictofIn terest</u> -Allianceswithindustryhavethepotentialforcreating conflictsofinterest,bothforindividualuniversityresearchersandforthe universityitself.Conflictsarisewhentheresearchersortheirinstitutionshave opportunitiesforfinancialg ainthroughprivateutilizationofresearchresultsor throughprivaterelationshipswithcompaniesresponsibleforexploitingthe researchresults.Theseopportunitiesmayerodetheobjectivityofresearchersor universityadministrators.TheGovernment hasissuedrulesto ensurethattheir granteeshaveappropriatepoliciesandprocedures attheirdisposal foridentifying andmanagingconflicts .¹¹
- The Public Interest Apart from the education of students, the most significant roles of universities are the creation and the dissemination of new knowledge. Those roles are so fundamental and crucial to the public interest that universities and industry have worked out mutually satisfactory terms and models of interaction that protect and facilitate these roles. Most universities that have significant research collaborations within dustry enjoy substantial levels of Federal funding for their research programs. Thus it is common for the results of Federally-funded research to flow into the seuniversity industry relationships. This creates a situation in which both the university and industrial researchers need to protect the public interest stemming from the Federal funding.

V. MODELSOFUNIVERSITY –INDUSTRYRELATIONSHIPS

- 12. Universitiesandind ustryhaveverydifferentmissionsandcultures ,leadingtoavariety ofchallengestomanageintheirrelationships. Adiversearrayofrelationships between the two parties exists, each "model" having a different goal and offering different benefits to the participants as determined on a case specific basis. Six major models are described below.
 - <u>SponsoredResearch</u> -Directsponsorshipofuniversityresearchbyindustryisthe mostfrequentformofresearchrelationship. Typically, the corporatesponso r provides funding for aspecified piece of work during a limited period of time. Deliverables such as reports, test data, software or materials may also be specified for the sponsored project. While most universities have standard agreement stoinit iate these projects, certain terms, such as those on intellectual property rights are usually negotiable. The sponsor expects a license to use and exploit the intellectual property resulting from the funded research. The nature and scope of the license is generally defined in the research agreement.
 - <u>CollaborativeResearch</u> -Federalsponsorshipofuniversity -industrycollaborative researchisatanunprecedentedlevel.CertainFederally -fundedpartnership programsrequireuniversity -industrycollaboratio nasaconditionofobtainingthe

¹¹ FederalRegister:60FR35810,HHSruleand60FR35820,NSFrule(July11,1995).

Federalfunding. University -industryresearchcenters, which mayor may not have Federalfunding, are likewise founded on the premise of collaborative research 12. Collaborative research enables participants to leverage i mited resources in the achievement of mutually beneficial research objectives. Terms of collaborative research agreements may be stipulated by Federal program guidelines, or may be negotiated between the parties to specify research performance, joint tech no logy developments, ownership of intellectual property, future commercial development of intellectual property and so on.

- <u>Consortia</u> -Inauniversity -basedresearchconsortium,participatingcompanies joinforcesandcontributeresources,ofteninthefo rmofanannualfee,tosupport researchinatechnicalareaofcommoninteresttothegroup.Consortiaenablethe memberstoleveragefinancialinvestmentsandprovidecost -effectiveaccessto generic,pre -competitiveresearchprojects.
- TechnologyLicen sing -TheBayh -DoleActgaveriseto adramaticincreasein technologylicensing byuniversities .Universitytechnologylicensing of impetus forindustrialgrowth ,hasbeenespeciallysignificantinscience industriessuchasbiotechno logy. Auniversitylicenseagreement differs from a sponsoredresearchagreementinthatconsiderationisofferedbythelicenseeto secure commercialization rights in intellectual property owned by the university. Theconsiderationmayincludelicensef eesand/orreimbursementofpatentcosts, aswellasroyaltiesonproductsales. Thelicensetypically grants the company the righttomake, use and sell commercial products under the university propertyrights; thescopeofthelicense(e xclusivevs.non -exclusive,term,field ofuse, etc.) is defined in the agreement. Finally, license agreements usually include "duediligence "orperformancemilestonesforthelicensee ; ifthe milestonesarenotmet, the university may terminate the lic enseagreementand recoverthe rightsinthetechnology.
- <u>Start-upCompanies</u> -Theembryonicstateofmanyuniversitytechnologies, coupledwiththechallengeofredirectingestablishedcompaniestofocusonnew high-riskopportunities,hasledtoaprolif erationof "start-up"or "spin-off" companiesaroundmajorresearchuniversities.Thenewcompaniesare establishedtocommercializeauniversitytechnology, the rightstowhichare obtainedthroughalicenseagreement.Inconsiderationforthelicense, the universitymaytakeasmallequitypositioninthestart -upcompanyinlieuoforin additiontootherconsideration(fees,royalties,etc.).Mostuniversityspin -off companiesincludetheuniversityinventor(s)intheenterpriseinsomefashion,and thecompanymayrelyontheacademicresearchgroupforthetechnologybase essentialtocompanyformationandgrowth.

Cohen, Wesley, Richard Florida and W. Richard Goe. "University - Industry Research Centers in the United States: Final Report to the Ford Foundation." Pittsburgh: Carnegie Mellon University, 1993, cited in National Science Board, Science and Engineering Indicators - 1993, p. 121.

• <u>ExchangeofResearchMaterials</u> -Theexchangeofresearchmaterialsbetween universityscientistsandindustriallaboratorieshasbec omeacommonpractice. Materialtransferagreementsareutilizedt ofacilitatetheseexchanges. These agreementsgenerallystipulatethatthematerialsareprovidedforresearch purposesonly, and not for commercialization.

VI. LICENSEAGREEMENTISSUES

13. AnnexB isasamplelicenseagreementforinstructional purposes only. All provisions should be closely examined, but the following merit a special mention:

Definitions

- <u>LicensedField</u> –Limitsthelicensetospecificuses.Needstobe exceptionallyclearinthedefinition.Oftenbecomesproblematicwhenuses aremarginalasrelatedtothedefinition.Frequentlydifficulttoanticipate futureuses.
- <u>LicensedTerritory</u> –Usuallylimitstheabilitytomake,useandsell the productortechno logyinaparticulargeographic alarea.Becomes problematic owingotheincreasing lyglobaleconomy ,withcompanies functioninginmarketsthatarenotnecessarilywelldefinedbygeographic al boundaries.
- <u>NetSales</u> itis recommendedthat the royaltyibasedonadefinitionofnet sales,thatis ,totalrelatedrevenueslessshipping,taxesandperhaps the cost ofselling. Usually should notbebasedonanetincomeoranumberthatis reducedbyoperatingexpensesoreven the costofgoodssold.
- <u>PatentRightsandLicensedTechnology</u> –Needscleardefinition ;needsto takeaccount of technologicalprogress .
- LicenseGrant –Usuallyexclusive, limitedto certainfieldsofuseandcertain territories, with reservation of the licensor 'sright to pursue aca demicuses of the technology.
- Payments –usuallyinclude:
 - licenseissuefee ;
 - licensemaintenancefeestoencourageactiveexploitation
 - minimumroyaltiesalsoto ensureactive exploitation .
- Reports –licensormusthaveaccesstoinformationto ensureco mpliancewiththe licenseandtodemonstrateadequateexploitationefforts.
- Equity –licenseeconsiderationmayalsoincludeequityinthecompany.Needto consultwithtaxadvis ersregardingtaxissues. Needtoaddressvotingrightsand therighttovo teshares.Shouldalsoconsideruniversityofficeranddirector liabilityiftheshareholderselectauniversitylicensorrepresentativeasaboard member.

- DueDiligence –Needto ensureactive effortto exploitthetechnology.Minimum royalties,mini mumexpenditures,businessplandevelopmentrequirementmaybe usedtodemonstratereasonableexploitation.Need toe nsurethatlicenseeisnot tryingto "tieup" thetechnologytoexploitacompetingtechnology.
- UseofLicensorName –Universitiesneed toprotecttheirnamesandreputation andthereforeshouldcontrolanyuseofthenamebythelicensee .
- Confidentiality –eachpartyneedstoprotectitsconfidentialinformation. Usually subjecttostandardconfidentialityexceptionsofpriorknowledge ,independently developedknowledge, disclosure requiredbylawandinformationobtainedfrom anindependentsource.

VII. CONCLUSION

Academiaandindustryrepresenttwoverydifferentenvironments ,withcontrasting valuesandcultures,but bothcollaborat einresearchandcommercializationfor thebenefitof themselves and their stakeholders. Various structures or "models" areutilized to ac hieve collaborationinresearch, generally chosen on the basis of case -specificconsiderations. University -industryresearch collaboration has contributed and will continue to contribute significantlytoeconomiccompetitiveness, and also to the intellectual vitality of universities. Licensetermsthatreasonablyprotecttheinterestsofthecontrasting culturesareavailable ,but $need to be drafted so as to balance the competing and diverse cultures represented by the {\it the competing and the com$ universities and industrial licensees. There are many indications that university licenseagreementswillbeevenmorenumerous ,diverseandproductiveinthefuture.

[Annexesfollow]

WIPO/INV/MTY/02/15

ANNEXI

SAMPLETITLESOFUNI VERSITY-INDUSTRYAGR EEMENTS ANDRELATEDDOCUMENT S

(see http://www.utsystem.edu/ogc/IntellectualProperty/dbmock.htm)

(alphabeticalorder)

- AgreementtoNegotiate
- BetaTestSiteAgreement
- BiologicalsSupplyandLicenseAgreement
- CeaseandDesistLetter(CopyrightInfringement)
- ClinicalStudyAgreement(Non -Governmental)
- ConfidentialDisclosureandLi mitedUseAgreement
 - o UniversityDisclosing
 - o MutualConfidentiality
- ConfidentialityAgreement
 - o UniversityDisclosing
 - o UniversityReceiving
 - o Mutual
- ConsortiumAgreement
- ConsultingAgreement
- ContractforServices
- ContractResearchOrganizationAgreement
- ContributiontoPublication
- CopyrightAssignment
- CopyrightLicenseAgreement
- Federal Agency Services Subcontract
- EducationalMaterialsDevelopmentAgreement
- EducationalResearchAgreement
- ElectronicPublicationAgreement(forElectronicJournals)
- IndustrialR esearchAssistantAgreement
- Internet -ParentalConsentForm
- LaboratoryStudyAgreement
- MaterialTransferAgreement(UniformBiologicalMTA)
- MaterialsTransferAgreement(UniversityMaterials)
- Non-DisclosureAgreement
 - o UniversityDisclosing
 - o UniversityRe ceiving
 - o Mutual
- Non-GovernmentalClinicalStudyAgreement
- OptionAgreement
- PatentLicenseAgreement
- Publishing:UniversityPressAgreements
 - o StandardAuthorPublishingContractandVariations
 - Translator'sAgreement
 - DistributionAgreement
 - Proprietor's Ag reement
 - TranslationAgreement

- Co-publicationAgreement
- ReprintAgreement
- Illustrator's Agreement
- o Permissionsagreements
 - UniversityPressMaterialwithCharge
 - UseUniversityPressMaterialwithoutCharge
 - UseinDissertation
- o Journals
 - AgreementforP ress-OwnedJournals
 - AgreementforSociety -OwnedJournals
 - DistributionAgreements
 - ConsenttoPublishForms
 - FirstSerialRightsAgreements
 - PermissionsAgreements
- o Marketing
 - SalesAgreementwithIndividualSalespersons
 - SalesAgreementwithSalesOrgani zations
 - SalesAgreementforRepresentationofUniversityPublishers
- ReleaseAgreement
- SalaryReimbursementAgreement
- SoftwareDevelopmentAgreement
- SoftwareDistributionAgreement
- SoftwareLicenseAgreement –End -User
- SoftwareLicenseAgreement -Source Code
- SponsoredClinicalStudyAgreement
- SponsoredLaboratoryStudyAgreementorTestingAgreement
- SponsoredResearchAgreement -NoIP
- SponsoredResearchAgreement -Univ.OwnsIP
- SponsoredResearchAgreement -JointIPShortForm
- SponsoredResearchAgree ment -JointIPLongForm
- SponsoredResearchAgreement -LongForm
- SponsoredResearchAgreement -ShortForm
- SponsoredResearchAgreement
- TeamingAgreement
- TechnologyLicenseAgreement
- TestingAgreement
- TransmittalForms
- UniformBiologicalMaterialTransfe rAgreement
- VideoDistributionAgreement
- VisitingScientistAgreement

[AnnexIIfollows]

WIPO/INV/MTY/02/15

ANNEXII

SAMPLEPATENTLICENSEAGREEMENT

| THIS | AgreementisbetweentheUniversityof | and | | |
|--|--|---|--|--|
| a | corporationhavingaprinci ("Licensee"). | palplaceofbusinesslocatedat | | |
| TABLEOFCONTENTS | | | | |
| | RECITALS | | | |
| 1. | EFFECTIVEDATE | | | |
| | DEFINITIONS WARP ANTEN SUPERIOR PROJECTION AND ANTEN SUPERIOR PRO | AIDDEDDEGENEATIONG | | |
| | WARRANTY,SUPERIORRIGHTSANDREPRESENTATIONS LICENSE | | | |
| 4. 5. | PAYMENTSANDREPORTS | | | |
| <i>5</i> . 6. | COMMONSTOCKANDEQUITYOWNERSHIP | | | |
| 7. | | | | |
| 8. | INFRINGEMENTBYTHIRDPARTIES | | | |
| 9. | | | | |
| 10. | PATENTMARKING | | | |
| 11. | INDEMNIFICATION | | | |
| 12. | USEOFNAME | | | |
| 13. | CONFIDENTIALINFORMATIONAL | NDPUBLICATION | | |
| | PATENTSANDINVENTIONS | | | |
| | ALTERNATEDISPUTERESOLUTIO | N . | | |
| 16. | | | | |
| | SIGNATURES | | | |
| | RE | CITALS | | |
| $A. University owns certain Patent Rights and Technology Rights related to Licensed Subject Matter, which were developed at The University of \("University").$ | | | | |
| B. UniversitydesirestohavetheLicensedSubjectMatterdevelope dandusedforthe benefitofLicensee,Inventor,University,andthepublicasoutlinedinUniversity's IntellectualPropertyPolicy. | | | | |
| C. | LicenseewishestoobtainalicensefromU | iniversity to practice Licensed Subject Matter. | | |
| NOW,THEREFORE, inconside rationofthemutualcovenantsandpremisesherein contained,thepartiesagreeasfollows: | | | | |
| 1. | EFFECTIVEDATE | | | |
| ThisAgreementiseffective("EffectiveDate"). | | | | |

2. DEFINITIONS

| AsusedinthisAgreement,thefollowingtermshave themeaningsstated: | | |
|---|--|--|
| 2.1 "Affiliate" means any business entity more than 50% owned by Licensee, any business entity which owns more than 50% of Licensee, or any business entity that is more than 50% owned by a business entity that owns more than 50% of Licensee. | | |
| 2.2 "LicensedField "means | | |
| 2.3 "LicensedProduct" meansanyproductSoldbyLicenseecomprisingLicensedSubject MatterpursuanttothisAgreement. | | |
| 2.4 " LicensedSubjectMatter "meansinventionsanddiscoveriescovered byPatentRights orTechnologyRightswithinLicensedField. | | |
| 2.5 "LicensedTerritory" meansthe | | |
| 2.6 "NetSales "meansthegrossrevenuesreceivedbyLicenseefromtheSaleofLicensed Productslesssalesand/orusetaxesactually paid,importand/orexportdutiesactuallypaid, outboundtransportationprepaidorallowed,andamountsallowedorcreditedduetoreturns (nottoexceedtheoriginalbillingorinvoiceamount). | | |
| 2.7 "PatentRights" means University's rights in informat ionordiscoveries covered by patents [and/orpatentapplications], whether domestic or foreign, and all divisions, continuations, continuations - in-part, reissues, reexaminations or extensions thereof, and any letter spatent that is sue thereon, which namea seither sole or joint inventor ("Inventor") and which relate to the manufacture, use or sale of[delete" and/orpatent applications" if none at this time] | | |
| 2.8 "SaleorSold "meansthetransferordisposalof aLicensedProductforvaluetoaparty otherthanLicensee. | | |
| 2.9 " TechnologyRights " meansUniversity's rights intechnical information, know processes, procedures, compositions, devices, methods, formulas, protocols, techniques, software, designs, drawings or datacreated by(Inventor) at University before the Effective Date relating to which are not covered by Patent Rights but which are necessary for practicing the invention covered by Patent Rights. | | |
| 3. WARRANTY:SUPERIORRIGHTS | | |
| 3.1 Exceptfortherights, if any, of the Government of the United States asset for the low, University represents and warrant sits be liefthat (i) it is the owner of the entire right, title, and interestinand to Licensed Subje ct Matter, (ii) it has the soleright to grant licenses there under and (iii) it has not knowingly granted licenses there under to any other entity that would restrict rights granted to License except as stated herein. | | |

3.2 LicenseeunderstandsthattheLi censedSubjectMattermayhavebeendevelopedunder afundingagreementwiththeGovernmentoftheUnitedStatesofAmericaand,ifso,thatthe Governmentmayhavecertainrightsinrelationthereto.ThisAgreementisexpresslymade

subject to the Govern ment's right sunder any agreement and any applicable law or regulation. If there is a conflict between an agreement, applicable law or regulation and this Agreement, the terms of the Government agreement, applicable law or regulations hall prevail.

- 3.3 LicenseeunderstandsandacknowledgesthatUniversity,bythisAgreement,makesno representationastotheoperabilityorfitnessforanyuse,safety,efficacy,abilitytoobtain regulatoryapproval,patentability,and/orbreadthoftheLicensedSubjectM atter.University, bythisAgreement,alsomakesnorepresentationastowhetherthereareanypatentsnowheld, orwhichwillbeheld,byothersorbyUniversityintheLicensedField,nordoesUniversity makeanyrepresentationthattheinventionscontinedinPatentRightsdonotinfringeany otherpatentsthatarenoworwillbeheldbyothersorbyUniversity.
- 3.4 Licensee, by execution hereof, acknowledges, covenants and agrees that it has not been induced in anyway by University, System, University tyorits employees to enter into this Agreement, and further warrants and represents that (i) it has exercised sufficient due diligence with respect to all items and is suespertaining to this Article 3 and all other matters pertaining to this Agreement; and (ii) Licensee has a dequate knowledge and expertise, or has utilized knowledge able and expert consultants, to exercise a dequately the due diligence, and agrees to accept all risks inherentherein.

4. LICENSE

- 4.1 UniversityherebygrantstoLicensee aroyalty -bearing,exclusivelicenseunder LicensedSubjectMattertomanufacture,havemanufactured,and/orsellLicensedProducts withintheLicensedTerritoryforusewithinLicensedField.Thisgrantissubjecttothe paymentbyLicenseetoUniversit yofallconsiderationasprovidedherein,andisfurther subjecttorightsretainedbyUniversityto:
 - a. PublishthegeneralscientificfindingsfromresearchrelatedtoLicensedSubject MattersubjecttothetermsofSection13,ConfidentialInformation;
 - b. UseLicensedSubjectMatterforresearch,teachingandothereducationally purposes. -related
- 4.2 LicenseemayextendthelicensegrantedhereintoanyAffiliateiftheAffiliateconsents tobeboundbythisAgreementtothesameextentasLicensee.
- 4.3 LicenseemaygrantsublicensesconsistentwiththisAgreementifLicenseeis responsiblefortheoperationsofitssublicenseesrelevanttothisAgreementasifthe operationswerecarriedoutbyLicensee,includingthepaymentofroyaltieswhetherorno t paidtoLicenseebyasublicensee.LicenseeshalldelivertoUniversityatrueandcorrectcopy ofeachsublicensegrantedbyLicensee,andanymodificationorterminationthereof,within 30daysafterexecution,modification,ortermination.Whenthis Agreementisterminated,all existingsublicensesgrantedbyLicenseeshallbeassignedtoUniversity.

5. PAYMENTSANDREPORTS

| 5.1 InconsiderationofrightsgrantedbyUniversitytoLicenseeunderthisAgLicenseeshallpayUniversitythe following: | greement, | |
|---|--|--|
| a. Anon -refundablelicensedocumentationfeeintheamountof\$payablewhenthisAgreementisexecutedbyLicensee; | ,dueand | |
| b. Anannuallicensereissuefeeintheamountof\$,dueaeachanniversaryoftheE ffectiveDatebeginningonthefirstanniver | | |
| c. Arunningroyaltyequalto%ofNetSalesforLicensedProductssoldly andprotectedbyavalidclaimincludedwithinPatentRights **Coronaltyequalto%ofNetSalesforLi censedProductsSoldbyacoveredbyTechnologyRights;and | OR** arunning | |
| d. Aminimumyearlyroyaltyof\$beginningoneyearafterapper firstSaleorofferforSaleofaLicensedProductbytheFoodandDrugAd oracomparable foreignregulatoryauthority. | | |
| 5.2 InconsiderationofrightsgrantedbyUniversitytoLicenseeunderthisAgreement, LicenseefurtheragreestopayUniversitythefollowingaftertheexecutionofasublicense hereunder: | | |
| Within 30 days after the executio nof the sublicense, a sublicense fee of% of any advance cash payment made to License ein consideration of the sublicense, excluding funds paid to License eforresearch and development purposes, or \$, which ever is greater; | | |
| . Within 30 day safter the execution of the sublicense, a sublicense fee constituting a cash payment equal to 10% of any non -cash consideration received by License efrom a sublicense e, such consideration to include, without limitation, equity in other companies or equity investments in License e. The value of an equity investment shall be calculated as the average market value of the class of stock involved for five consecutive days preceding the execution of the sublicense agreement. In cases where the sublicense agreement entralls for payment to License e of a premium over the market value, University shall also share 10% of the premium paid to License e; and | | |
| c. One-halfofthegrossrevenueroyaltypaymentsreceivedonNetSaleso ProductsreceivedbyLicenseefrom anysublicensee. | ofLicensed | |
| 5.3 DuringtheTermofthisAgreementandforoneyearthereafter,Licensees completeandaccuraterecordsofitsanditssublicensees'SalesandNetSalesof ProductsunderthelicensegrantedinthisAgreementi nsufficientdetailto payablehereundertobedetermined.LicenseeagreestopermitUniversityorits representatives,atUniversity'sexpense,toperiodicallyexamineitsbooks,lect recordsduringregularbusinesshoursfor thepurposeofandtotheextentnet verificationofanyreportrequiredunderthisAgreement.IftheamountsduetoUdeterminedtohavebeenunderpaid,Licenseeshallpaythecostoftheexamination accruedinterestatthehig hestallowablerate. | Licensed penabletheroyalties s dgersand cessaryfor Universityare | |

| 5.4 Within 30 days after March 31, June 30, September 30, and December 30. | er31,beginning | | |
|--|------------------|--|--|
| immediately after the Effective Date, License eshall deliver to University and the property of the property | atrueandaccurate | | |
| writtenreport, even if no payments are due University giving the particular softhebusiness | | | |
| conducted by Licensee and its sublicensee (s), if any exist, during the preceding three calendary and the conducted by Licensee and its sublicensee (s), if any exist, during the preceding three calendary and the conducted by Licensee and its sublicensee (s), if any exist, during the preceding three calendary and the conducted by Licensee (s), if any exist, during the preceding three calendary and the conducted by Licensee (s), if any exist, during the preceding three calendary and the conducted by Licensee (s), if any exist, during the conducted by Licensee (s), if any exist, during the conducted by Licensee (s), if any exist, during the conducted by Licensee (s), if any exist, during the conducted by Licensee (s), if any exist, during the conducted by Licensee (s), if any exist, during the conducted by Licensee (s), if any exist, during the conducted by Licensee (s), during the conducted by | | | |
| months under this Agreement as a rerelevant for the calculation of payments here under. That the calculation of payments here under the calculation of payments here are the calculation of payments here under the calculation of payments here are the calculation | | | |
| reportwillincludeatlea st: | | | |

| writtenreport, even if no payments are due Universit giving the particular softhe business conducted by License eand its sublicense (s), if any exist, during the preceding three calendar months under this Agreement as are relevant for the calculation of payments here under. That report will include at least st: | | | |
|--|--|--|--|
| a. the quantities of Licensed Subject Matter that it has produced; | | | |
| b. thetotalSales; | | | |
| c. thecalculationofroyaltiesthereon;and | | | |
| d. thetotalroyaltiescomputedandduetoUniversity. | | | |
| Simultaneously with the delivery of each report, License eshall pay to if any, due for the period covered by each report. | | | |
| 5.5 OnorbeforeeachanniversaryoftheEffectiveDate,irrespectiveofhavingafirstSale orofferforSale,LicenseeshalldelivertoUniversityawrittenprogressreportonLi censee's (andanysublicensee's)effortsandaccomplishmentsduringtheprecedingyearindiligently commercializingLicensedSubjectMatterintheLicensedTerritoryandLicensee's(and,if applicable,sublicensee's)commercializationplansfortheforthc omingyear. | | | |
| 5.6 AllamountspayableherebyLicenseeshallbepaidinUnitedStatesfundswithout deductionsfortaxes,assessments,fees,orchargesofanykind.Checksshallbepayableto [Componentnameandaddress]. | | | |
| 5.7 LicenseeshallreimburseUn iversityforallitsout -of-pocketexpensessofarincurredin filing,prosecuting,enforcingandmaintainingexclusivelylicensedPatentRightsandshall payallfutureexpensesforaslongas,inthecountriesinwhich,itslicenseremainsexclusive. | | | |
| 6. COMMONSTOCK:EQUITYOWNERSHIP [NOTE:Weadviseyoutocontactanoutsidecounselwithexpertiseincorporateand securitieslawbeforecompletingthisarticle.] | | | |
| 6.1 InconsiderationoftherightsgrantedtoLicenseebyUniversityinthisAgreement, Licenseeshall,onexecutionofthisAgreement,issuetoUniversityfullypaid, non-assessablesharesofitscommonstock(equaling%ofallsharesofitscommonstock),at\$parvalue. | | | |
| 6.2 University shall name directors to serve o nthe Board of Directors of Licensee in proportion to the number of sharesheld by University relative to the total number of issued shares, provided that University shall always have at least one seat on Licensee's Board. | | | |
| 6.3 Inaddition,Licenseehereby grantsUniversityaone -yearoption,exercisableatitssole discretion,topurchaseuptoanadditionalsharesofitscommonstockatafixed purchasepriceof\$pershareonthesamegeneraltermsandconditionsasare | | | |

applicable to the round as all or part of the optioned shares, by giving Licensee 60 days written notice, specifying the number of shares that it wishes to purchase and the proposed date of purchase.

7. TERMANDTERMINATION

- 7.1 ThetermofthisAgreementisfromtheEffectiveDatetothecompleteendoftheterm ortermsforwhichPatentRightshavenotexpiredor,ifonlyTechnologyRightsarelicensed andnoPatentRightsareapplicable,foratermof 15years.
- 7.2 AnytimeaftertwoyearsfromtheEffectiveDate,Universityhastherighttoterminate theexclusivityofthislicenseinanynationalpoliticaljurisdictionintheLicensedTerritoryif Licensee,within90daysafterreceivingwrittennot icefromUniversityofintended terminationofexclusivity,failstoprovidewrittenevidencesatisfactorytoUniversitythat Licenseeoritssublicenseeshavecommercializedorareactivelyattemptingtocommercialize alicensedinventioninsuchjurisdition(s).
- 7.3 AtanytimeafterthreeyearsfromtheEffectiveDateUniversityhastherightto terminatethislicenseinanynationalpoliticaljurisdictionintheLicensedTerritoryif Licensee,within90daysafterreceivingwrittennoticefromUniversi tyofintended termination,failstoprovidewrittenevidencesatisfactorytoUniversitythatLicenseeorits sublicenseeshavecommercializedorareactivelyattemptingtocommercializealicensed inventioninsuchjurisdiction(s).
- 7.4 Thefollowingdefi nitionsapplytoArticle7:(i)"Commercialize"meanshavingSales ofLicensedProductsinsuchjurisdiction;and(ii)"Activeattemptstocommercialize"means havingSalesofLicensedProductsoraneffective,ongoingandactiveresearch,development, manufacturing,marketingorsalesprogramasappropriate,directedtowardobtaining regulatoryapproval,productionorSalesofLicensedProductsinanyjurisdiction,andplans acceptabletoUniversity,atitssolediscretion,tocommercializelicensedinve ntionsinthe jurisdiction(s)thatUniversityintendstoterminate.

7.5 This Agreement shall terminate earlier:

- a. automaticallyifLicenseebecomesbankruptorinsolventand/orifthebusinessof Licenseeisplacedinthehandsofareceiver,assigneeort rustee,whetherbyvoluntary actofLicenseeorotherwise:or
- b. on 30 days' written notice from University if Licensee breaches or defaults on its obligation to make payments (if any aredue) or reports, in accordance with the terms of Article 5, unless, before the end of the 30 day period, Licensee has remedied the default or breach and so notifies University, stating the manner of the remedy; or
- c. on 90 days' written notice if Licensee breaches or defaults on any other obligation under this Agreement unle ss, before the end of the said 30 -day period, Licensee has remedied the default or breach and so notifies University, stating the manner of the remedy; or

- d. atanytimebymutualwrittenagreementbetweenLicenseeandUniversity,on 180 days'writtennotic etoallpartiesandsubjecttoanytermshereinthatsurvive termination;or
- e. undertheprovisionsofParagraphs7.2and7.3ifinvoked.

7.6 Ifthis Agreement is terminated for any cause:

- a. nothinghereinshallbeconstruedasreleasingeitherpartyfrom anyobligation incurredpriortotheeffectivedateofthetermination;
- b. aftertheeffectivedateofthetermination, Licenseemaysellall Licensed Products and parts thereofthat it has on hand on the date of termination, if it paysear nedroyalties thereon according to the terms of Article 5; and
- c. LicenseeshallbeboundbytheprovisionsofArticles11(Indemnification),12(Useof UniversityandComponent'sName)and13(ConfidentialInformation)ofthis Agreement.

8. INFRINGEMENTBYTHIRDPARTIES

- 8.1 Licensee, atitsexpense, shallen force any patent exclusively licensed here under against infringement by third parties, and it is entitled to retain recovery from such enforcement. Licensees hall pay University aroyal tyon any monetary recovery if the monetary recovery is ford a mage sor are a sonable royal tyin lieuthere of. If Licenseedoes not files uitagainst a substantial infringer of a patent within six months of knowledge thereof, then University may enforce any patent license dhere under onbehalf of itself and Licensee, University retaining all recoveries from such enforcement and/or reducing the license granted here under to no exclusive.
- 8.2 Inanyinfringementsuitordispute, the parties agree to cooperate fully with each other. At the request and expense of the party bringing suit, the other party shall permit access to all relevant personnel, records, papers, information, samples, specimens, etc., during regular business hours.

9. ASSIGNMENT

Exceptinconnectionwith the sale of substantially all of Licensee's assets to a third party, this Agreement may not be assigned by Licensee without the prior written consent of University, which shall not be unreasonably withheld.

10. PATENTMARKING

License eshall permanently and legibly mar kall products and documentation manufacture dor sold by it under this Agreement with such a patent notice as may be permitted or required under Title 35, United States Code.

11. INDEMNIFICATION

LicenseeagreestoholdharmlessandindemnifyUniversi ty,itsRegents,officers,employees andagentsfromandagainstanyclaims,demandsorcausesofactionwhatsoever,including withoutlimitationthosearisingonaccountofanyinjuryordeathofpersonsordamageto propertycausedby,orarisingoutof, orresultingfrom,theexerciseorpracticeofthelicense grantedhereunderbyLicensee,itsAffiliatesortheirofficers,employees,agentsor representatives.

12. USEOFUNIVERSITYANDCOMPONENT'SNAME

LicenseemaynotusethenameofUniversitywit houtexpresswrittenconsent.

13. CONFIDENTIALINFORMATIONANDPUBLICATION

- 13.1 UniversityandLicenseeeachagreethatallinformationcontainedindocumentsmarked "confidential"andforwardedtoonebytheother(i)shallbereceivedinstrictconfid ence, (ii) shall beusedonlyforthepurposesofthisAgreementand(iii)shallnotbedisclosedby therecipientparty,itsagentsoremployeeswithoutthepriorwrittenconsentoftheother party,excepttotheextentthattherecipientpartycanestabl ishcompetentwrittenproofthat suchinformation:
 - a. wasinthepublicdomainatthetimeofdisclosure;
 - b. laterbecamepartofthepublicdomainthroughnoactoromissionoftherecipient party,itsemployees,agents,successorsorassigns;
 - c. waslawfullyd isclosedtotherecipientpartybyathirdpartyhavingtherightto discloseit;
 - d. wasalreadyknownbytherecipientpartyatthetimeofdisclosure;
 - e. wasindependentlydevelopedbytherecipient;
 - f. isrequired, by lawor regulation, to be disclosed.
- 13.2 Eachparty's obligation of confidence hereunders hall be fulfilled by using at least the same degree of care with the other party's confidential information as it uses to protect its own confidential information. This obligations hall exist while this A greement is inforce and for a period of three years thereafter.
- 13.3 Universityshallsubmititsmanuscriptforanyproposedpublicationofresearchrelated toLicensedSubjectMattertoLicenseeatleast30daysbeforepublication,andLicenseeshall havetherighttoreviewandcommentonthepublicationinordertoprotectLicensee's confidentialinformation.AtLicensee's request, publications hall bedelayed for up to

60 additionaldaystoenableLicenseetosecureadequateintellectualpropertypro tectionof Licensee'spropertythatwouldbeaffectedbythepublication.

14. PATENTSANDINVENTIONS

14.1 If,afterconsultationwithLicensee,bothpartiesagreethatapatentapplicationshould befiledforLicensedSubjectMatter,Universityshallp repareandfiletheappropriatepatent applications,andLicenseeshallpaythecostofsearching,preparing,filing,prosecutingand maintainingsame.IfLicenseenotifiesUniversitythatitdoesnotintendtopaythecostofan application,orifLicens eedoesnotrespondormakeanefforttoagreewithUniversityonthe apportionmentofrightsinthesubjectinvention,thenUniversitymayfileanapplicationatits ownexpenseandLicenseewillhavenorightsintheinvention.Universityshallprovide LicenseeacopyofanypatentapplicationforwhichLicenseehaspaidthecostoffiling,as wellascopiesofanydocumentsreceivedorfiledwiththerelevantpatentofficeduringthe prosecutionthereof.

15. ALTERNATIVEDISPUTERESOLUTION

| 15.1 A | ydi sputeorcontroversyarisingoutoforrelatingtothisAgreement,itsconstruction | |
|-------------------|--|----|
| oritsac | llorallegedbreachshallbedecidedbymediation.Ifthemediationdoesnotresult | |
| | tionofsuchdisputeorcontroversy, its hall be finally decided by an appropriate | |
| | alternativedisputeresolution, including, without limitation, arbitration, conducted | |
| | of,inaccordancewiththeCommercialDisputeResolutionProcedures | |
| | ww.adr.org/rules/commercial_rules.html]o ftheAmericanArbitration | |
| _ | on. Thearbitration panels hall include members knowledge able in the evaluation of | |
| | _technology.Judgmentontheawardrenderedmaybeenteredinthehighestcourt | |
| orforu | avingjurisdiction, stateor Federal The provisions of this Article 15 shall not | |
| applyto whicha | ecisionsonthevalidityofpatentclaimsortoanydisputeorcontroversyregarding treatyorlawprohibitssucharbitration. Thearbitrationdecisionshallbe dbyacourtofla whavingjurisdictiontobebindingonandenforceablebythe | |
| 16. (| NERAL | |
| Licens unders | sAgreementconstitutestheentireandonlyagreementbetweenthepartiesfor SubjectMatterandallotherpriornegotiations,representations,agreement adingsaresupersededbyit.Noagreementsalteringorsupplementingtheterms ybemadeexceptbyawrittendocumentsignedbybothparties. | |
| | ynoticerequiredbythisAgreementshallbegivenbyprepaid,firstclass,certif inreceiptrequested,addressedinthecaseofUniversityto: | ed |
| - | nthecaseofLicenseeto: | |

| ATTENTION: | <u> </u> | |
|---|---|--|
| FACSIMILIE: | | |
| PHONE: | _ | |
| orsuchotheraddressesasmaybegivenfromti provision. | metotimeunderthetermsofthisnotice | |
| 16.3 LicenseeshallcomplywithallapplicatinconnectionwithitsactivitiesunderthisAgr | | |
| 16.4 ThisAgreementwillbeconstruedandenforcedinaccordancewiththelawsofthe UnitedStatesofAmericaandoftheStateof | | |
| 16.5 FailureofUniversitytoenforcearight waiverofthatrightorasentitlementtoassertth situationinvolved. | underthis Agreements hall not operate as a natright later in relation to the particular | |
| 16.6 Headingsareincludedhereinforconve Agreement. | enienceonlyandshallnotbeusedtoconstruethis | |
| 16.7 IfanypartofthisAgreementisforanyre shallneverthelessremainenforceable. | asonfoundtobeunenforceable, allother parts | |
| INWITNESSWHEREOF ,thepartiesher representativestoexecutethisAgre ement | - | |
| University | (LICENSEE) | |
| By | By | |
| Name: | Name: | |
| | Title: | |
| Date: | Date: | |
| | | |
| ApprovedastoForm: | | |
| ByOfficeofGeneralCounsel | | |
| Date: | | |
| | | |
| ApprovedastoContent: By | | |
| Name: | | |
| Date: | | |

[End of Annexes and of document]