

IPR In Southeast Asian Biotechnology

Frederic H. Erbisch¹

The paper briefly reviewed the different protections given to intellectual properties (IP): copyright, patent, trademark, plant variety protection. With the advent of biotechnology development, concerns about patenting and licensing have increased. These concerns include: ability to exchange research materials, privatization of blocks of technology which may result in reduced availability of new biotechnologies, the costs associated with products utilizing biotechnology, implied licensing of all biotechnologies, and the impacts of IPs on the developing country's food supply and economy. The paper likewise briefly reviewed the IP protection available in Southeast Asia. It noted that most countries have adequate copyright and trademark laws in place. Although many countries have patent laws, their patent officers may not be able to effectively evaluate biotechnology patent applications. Plant variety protection laws or their equivalent are in various stages of development. Management of IPs at the local or institutional level was discussed. The need for an education/awareness program for researchers, administrators, and other concerns on research and intellectual property policies were emphasized.

Introduction

In the mid-1800's the United States government established the Land Grant system through which support was to be provided in agriculture and in engineering. Through this system colleges were established to provide this support. Michigan State University was the first such Land Grant college to be established wherein the college extensive agriculture research programs and outreach services were developed. Generally, new and improved crops and technical advances were given at no charge to the farmer, and as a result, a Land Grant philosophy was developed. This philosophy stated that whatever was developed was to be given at no charge to the farmer. Essentially this philosophy was followed until recently when industry became commercially interested in high tech agriculture/plant biology developments. These developments are often protectable through patenting and trademarking. When so protected, these developments are restricted in use by the owner allowing the owner to commercialize them. Consequently, the farmer must pay for such developments in order to use them.

These protectable developments are termed intellectual properties and their use is defined under the term "intellectual property rights" (IPR). Intellectual property protection is generally obtained through a governmental agency such as the United States Patent and Trademark Office. Such protection is available only in those countries where application is made and protection granted.

This trend in protecting intellectual properties in the agrisciences is affecting the entire world. It is making researchers more aware of the potential value of their work, it is resulting in a major reorganization of the agribusiness industry, and causing concern for farmers and governments in the availability and cost for agriproducts. This paper will discuss these impacts from the basis of intellectual property management, and particularly its impact in Southeast Asia.

¹ Former Director, Office of Intellectual Property, Michigan State University, East Lansing, Michigan, USA.

Intellectual Properties

Intellectual properties are ideas. When these ideas are reduced to tangible forms they, if new and novel, can be protected. This protection is such that the owner of the intellectual property is able to restrict its use with maximum restriction being that no one is allowed to manufacture, grow or sell the intellectual property. These forms of protection include copyright, trademark, plant variety, and patent. A brief description of each protection form, its cost, and use in agriculture will be given using experience from the United States.

Copyright protection is given for a number of things including written works, music, dance, photographs, paintings, and computer programs. Copyright protection is given when the creation is completed. There is no cost associated with obtaining this protection. The creator should appropriately mark the creation if the copyright is to be enforced (it is not necessary to do so, but is helpful if violations of the protection occur). Marking can be done by writing the word "copyright" followed by the name of the owner and the year when the copyright was granted. The copyright can be registered with the U.S. Copyright Office by completing a simple form and submitting with it a nominal fee of \$20.00 US Dollars. The agency will assign the copywritten creation a number, which should be attached to the creation. Copyright protection, which prevents anyone from copying the creation without the creator's permission, extends during the creator's lifetime plus seventy-five years

Trademark protection is provided for logos, symbols, and short phrases. Trademark protection is only granted after application, review, and acceptance by the trademark office. The initial cost for a trademark is less than \$2,500 US Dollars. In order to keep the trademark protected it is necessary to use it commercially and to pay periodic maintenance fees. Trademark protection prevents anyone else or any company from using the protected mark for their product or product line without permission of the owner. The agency in the United States handling trademarks is the U.S. Patent and Trademark Office.

Plant variety protection is given to sexually reproducing plants which are different from any other plant. In most cases, this protection is given to crop plants. An application must be prepared which details the particulars of the new variety, and if the office granting such protection agrees that the variety is new and unique, protection is granted. In general, this protection prevents anyone from growing or selling the variety without the owner's permission. In the United States the cost of obtaining plant variety protection from the U.S. Department of Agriculture is approximately \$3,000 US Dollars. The protection extends for 20 years for herbaceous plants and 25 years for woody plants.

Patents are granted for those creations which are new or novel, are unique, and have a use. These creations can range from mechanical devices, new chemicals or other new compositions, and genetic materials to methods and/or processes for accomplishing certain tasks. The protection granted by the U.S. Patent and Trademark Office is 20 years from the date of filing a patent application. The cost of obtaining patent protection can be very expensive. Costs may range from \$5,000 US Dollars to many thousands of dollars more with the average cost ranging from \$15,000 to \$20,000.

All of these methods of protecting materials are used in agriculture. Some are more obvious than others, some are not usually noticed because one is so accustomed to seeing it. Examples of the use of each are provided. Three packages of Danvers carrot seed were purchased. Each package was prepared by a different seed company; NK Lawn & Garden Co., Lake Valley Seed Company, and W. Atlee Burpee & Co. The name of each company was trademarked as noted by a trademark symbol by the name and/or logo, so each was distinct and could not be confused with the other. The directions on the back of the packets described how to plant the seeds and although each gave the same planting instructions these instructions were presented quite differently. Each indicated their directions were copyrighted. Each company provided the same variety of seed but packaging and directions were distinct. This combination of factors is to influence the buyer into purchasing a company's seed initially and then to recognize it each time seeds of either Danvers carrot or some other variety were being purchased. It provides a means of recognition and valuation for the buyer. For example, if one were to buy all three packages of Danvers carrot seeds and plant them, and the carrots from one company grew better than the others, that buyer would continue to buy that company's seed. The buyer would tend not to buy seeds from the company whose seeds did not perform as well.

Plant variety protection is used by Michigan State University when new varieties of wheat, oats or beans are developed. Obtaining plant variety protection for these seeds allows the University to distribute these protected varieties as it believes is best. Recently three new varieties of wheat were developed and plant variety protection was obtained for all three. The University decided two varieties should be distributed publicly, should be grown and sold by the farmers, and the third variety was to be licensed privately where a single company would reproduce and sell the seed. These decisions were based upon several factors: ease of reproducing seed, need for high standards for the seeds and the potential market. The two public market varieties were easy to grow, maintain seed quality, and were similar to varieties already being used by farmers. On the other hand, the licensed variety was more difficult to reproduce, to maintain quality and was very new to the marketplace needing considerable marketing. In their own way, each variety was successful. Without plant variety protection, the University may not have been so successful in distributing these varieties nor would the farmers necessarily have benefited from them.

Patent protection for non-biological technologies in agriculture is common and not questioned. Most farm equipment is protected by patents; usually a number of patents protect a number of items on a piece of equipment. The University developed and patented a means of separating bedding sand and cow manure. The invention utilized several pieces of equipment already in the marketplace, putting them together in a unique manner to effect the separation. The company which licensed the University patent owned the patents for several of the pieces of equipment utilized. It did not own the patents for one part. The licensing company worked out an arrangement with the owners of the other patented equipment and now have on the market a unique machine which has various parts protected by three different organizations' patents. Licensing this technology was critical for the University because it could not manufacture the separator and sell it. It did not have in place the means of acquiring patents from others and, most importantly, it wanted the equipment available for the farmers to use. No objections were made about the patenting and licensing this arrangement.

Patenting of biotechnologies is quite new, but just as important as protecting mechanical inventions. Again, by patenting biotechnology developments, one can determine how these developments can be used. Many research organizations discover new biotechnologies, particularly new genetic materials and their use, but few are able to take them beyond the “bench top” or to the commercialization stage. Patenting and licensing allows the research organization to locate the best and most able to carry forward a research discovery of a product needed by the farmer. The University has isolated, characterized, and proven certain genetic materials important in drought and cold resistance. In order to carry these findings forward, it was necessary to find a partner who could get the genetic materials into commercially important plants and still retain certain rights for University researchers. By protecting and then licensing, this goal has been achieved. The biotechnology was protected by more than six patents or patent applications and was licensed to a company that had a number of milestones and goals to its name in order to meet the University’s expectations.

Today’s Concern For Intellectual Properties

As stated earlier, new mechanical devices or improvements for agriculture have routinely been patented and licensed. Patenting a new device or improvement and licensing it is not questioned or protested.

With the initiation of biotechnology development, there has been considerable concerns about patenting and licensing. These concerns include: the ability to freely exchange research materials, the privatization of blocks of technology resulting in drastically reduced availability of new biotechnologies, the costs associated with products utilizing the biotechnology, the implied licensing of all biotechnologies, and the question of how this might impact the developing country’s food supply and economy.

One of the main factors involved in causing this uneasiness is the aggressive nature of industry in developing biotechnologies. These agribusinesses are not only moving aggressively to acquire new biotechnologies, but are also active in consolidating and merging with each other, making it difficult to know from day-to-day who owns what. The aggressiveness is persistent because these companies must make a profit from sales of some form from the biotechnology they acquire. Universities, government agencies, and research institutions (basic research researchers) do not have a profit motive, thus, and these researchers are more interested in conducting research and exchanging research materials. It is these universities, government agencies, and research institutes that do most of the basic research, needed by industry to move forward. In turn, industry uses these basic research findings in its development work to a point where it can be used by the public. These researchers usually only continue their research until they have proven a point or a concept. They are seldom interested in doing development work because most researchers do not have the facilities or support to carry on the development work. These researchers find their reward in publishing papers in scientific journals, educating graduate students, and getting additional funds to continue their research. Meanwhile, industry is profit motivated and is not interested in publication or graduate student education. Industry does support some basic forms of research but only those which they can benefit from.

While basic research and commercial development may seem at odds, they are also very dependent upon each other. Without the basic research results, industry

would have little biotechnology development work. Without biotechnology development work, fewer graduate students would be employed after graduation and researchers would be scrambling to find sufficient research funds. These two sectors can actually benefit each other. Together they can develop the food crops that will 1) produce more food per plant, 2) produce pest and disease resistant plants, 3) produce plants which can grow in new areas (i.e., increased drought resistance) because they are able to withstand the rigors of an area, and, eventually, 4) produce plants, which yield large amounts of food materials on less land. All of these objectives need to be met in the near future in order to sustain the earth's growing population.

Basic research institutions and industry do not naturally work together in a harmonious manner. A number of steps must be taken to enable each of them to preserve their basic values and yet benefit from each other. The basic research institution must be able to publish, allow graduate students to experience collegial interactions and publish their theses, and promote funded research composed and directed by researchers. The industry partner must be assured of cooperation in converting basic research results into commercial development, of confidentiality of terms of data, and certain business activities that will be able to realize a profit from this effort. In order to do all this it, is important for both parties to put various agreements in place, to protect new intellectual properties, and to adhere to each party's terms and conditions as well as protection requirements.

Biotechnology Intellectual Property Management in Southeast Asia

In order to have a successful "marriage" between biotechnology basic research institutes and industry, particularly in intellectual property management, the following questions should be asked. First, what is required and is this available in Southeast Asia? Secondly, what impact will this interaction have on the government and the people of the Southeast Asian region.

In the United States this interaction between basic research and industry is developing fairly well. Some research institutions are working closely with industry. Industry on the other hand makes its biotechnology research available to the public. However, there are still many questions, concerns, and uncertainties in this relationship.

What must be in place in order to effectively handle biotechnology creations, distribute the creations, interact with industry, assist the biotechnician, and handle other opportunities associated with biotechnology? The following is a list of items needed to effectively deal with biotechnology. The items are briefly described related with biotechnology intellectual property management, and indicated in terms of status within the Southeastern Asia community. This discussion will also include the status of a particular term in the United States.

National Level:

1. Copyright laws. Most Southeast Asian countries have adequate copyright laws in place. Usually there is sufficient staff available to handle registration of copyrightable materials. However, few countries have the ability to enforce copyright protection continuously. Copyrights provide important protection for written descriptions of

products, processes, methods and directions. One especially important consideration is DNA sequencing. Usually the DNA sequence of a gene, such as gene fragment, plasmid, etc. is written, and copyright protection is important to preserve the creator's right to this material. Computer software is an important aspect of copyright protection too. It provides numerous uses in routine and specialized biotechnology applications and research procedures.

2. Trademark laws. Most countries have adequate trademark laws and offices to handle registration procedures. Similarly, trademark protection is a problem and few countries have adequate personnel to handle its enforcement. Trademarks are extremely important in product and company recognition especially now that the biotechnology field is growing. Agricultural products purchased are often done so because of product identification linked to a particular trademark. For example, "Roundup" resistant crop varieties are related to one company and are easily recognized by trademark. Likewise, trademarks in Southeast Asia are used for many products. However, this application to biotechnology developments for use outside the area is not well established. It is expected that as biotechnology programs expand further, the use of trademarks will also expand. In the United States and Europe trademark protection is used extensively in biotechnology applications as well as non-biotechnology areas.

3. Plant Variety Protection. New plant varieties, whether developed traditionally (breeding) or through biotechnological processes, are inadequately protected in Southeast Asia. This includes new crop varieties developed within the area as well as outside. At a meeting held this spring in the Philippines, a number of countries indicated that they had limited or no plant variety laws. If laws for plant variety protection are not in place, then there is no way in which new varieties can be protected or preserved for the creator of the new variety. The United States has plant variety protection laws, adequate staff to register new varieties as well as the ability to enforce these laws. Some people believe that protecting a variety means that it should be licensed and/or sold but not given to farmers for free. This is not true. Protection allows the owner of the protected variety to determine how to distribute the variety. The variety can be licensed, sold or given away. The owner of the protected variety has the prerogative to keep or give it away. However, the protected variety cannot be taken by anyone else without the owner's permission.

4. Patents. Many countries do have patent laws. However, protection for biotechnologies or plant varieties are not included. Patent offices in many developing countries are usually understaffed and unable to handle efficiently and effectively patent applications. Most of their patent examiners have little or no knowledge of biotechnology. Thus they are unable to handle and properly evaluate biotechnology patent applications. In addition to having inadequate staffing there are also not enough people able to enforce patent laws. In Southeast Asia most of the countries have biotechnology patent problems as well as inadequate patent offices and enforcers. Moreover, only a handful of people are trained to evaluate biotechnology patent applications. The United States is just the opposite. It has appropriate and adequate patent laws, proper staffing of patent examiners and enforcers, and is able to effectively evaluate biotechnology patent applications. Anyone who files for patent protection in the United States knows that despite the considerable cost, the technology filed for patent will be reviewed extensively and, if patented, will be protected. On the other hand, this is not true for filing biotechnology patent applications in many developing countries. The cost may be lower, but questions are raised regarding protection obtained. This doubt

can also affect potential interactions between scientists in developed and developing countries. Would a scientist who has developed a new biotechnology want to share this to someone who may not have the means to protect the intellectual property?

Local Level:

1. Policies. The proper handling of intellectual properties is best done under policies established by the research institute or agency. The policies describe how intellectual properties are to be handled, by what office or individual, how assistance is provided, and by whom. It also describes ownership of newly developed intellectual properties, and who reviews agreements and contracts regarding acquiring and/or licensing out intellectual properties. Policies comply with national and international intellectual property laws. These policies give the researcher direction on how to handle intellectual properties, show the researcher who handles the “paperwork”, provide guidance for acquiring intellectual properties necessary to conduct a research program, give limitations on how contracts and licenses can be drafted and/or negotiated, and how costs and/or receipts are handled. An example of a simple patent policy is the one currently being used by Michigan State University. This policy is as follows:

“Except as otherwise provided by Board-approved policies or legal instruments, any discovery or invention which results from research carried on by, or under the direction of, any employee of the University and having the cost thereof paid from University funds or from funds under the control of, or administered by the University, or which comes as a direct result of the employee's duties with the University, or which has been developed in whole or in part by the utilization of University resources or facilities, shall belong to the University and shall be used and controlled in such a manner as to produce the greatest benefit to the University and the public.

For purposes of this policy, the term "employee" shall include all faculty, staff and students (including postdoctoral appointees, graduate and undergraduate students) engaged in research conducted under the conditions defined above.

Patenting and licensing expenses for each patent will be recovered from its royalty earnings and distributions will be made from the net royalties remaining. Net royalties from licensed inventions will be distributed according to the following schedule:

Net Royalty Income on a Particular Patent	Inventor(s)	Academic Units	University
First \$1,000	100%	0	0
Next \$100,000	33 1/3%	33 1/3%	33 1/3%
Next \$400,000	30%	30%	40%
Next \$500,000	20%	20%	60%
All Additional			
Net Royalties over \$1,001,000	15%	15%	70%

The administration of Michigan State University patent matters, including technological know-how that may be licensable but may not be patentable, shall be the responsibility of the President. Patent matters include such activities as accounts, records, and negotiations. Particular patents or items of technological know-how may be transferred to the Michigan State University Foundation for administration. The President has delegated this authority to the Vice President for Research and Graduate Studies.

In addition to this policy are policies at the University concerning copyright, publication, conflict of interest, and other pertinent matters. The researcher knows that it will not be his/her responsibility to negotiate contract terms, draft patent applications, sign documents, etc. and that the research program is the most important duty for the researcher. The researcher knows that if proprietary materials are needed for the research project, there will be an office and/or individual who will handle all legal matters such as drafting a materials transfer agreement, which allows researchers from several institutions to work together (see Attachment A), and who will put together an agreement dealing with intellectual property matters for a potential research project (see Attachment B). Because intellectual property policies, along with appropriate laws, do exist at research institutions and in industry in the United States the interactions between these groups are facilitated. Grey areas still exist under these conditions, but these can be negotiated and usually overcome so parties can work together successfully.

Interactions with a number of Southeast Asian research institutes, agencies, and universities have shown that few have appropriate policies in place to handle intellectual property matters. On the other hand, some that do have policies in place have no staff, because of budget cuts to manage these policies or work with research staff. Research staff expressed concern over intellectual property matters, which are adversely affecting their research programs.

2. Education. In addition to having research and intellectual property policies, all parties must be educated in the importance of these policies, their use, and application to research and development. This educational program should include a familiarity with national and international intellectual property laws which promotes awareness of the importance of intellectual property protection for research efforts. Great strides in intellectual property education are being made in Indonesia, Philippines, People's Republic of China, and Thailand. India and Bangladesh have initiated programs and will have key government representatives in intellectual property management training programs.

Recently, a document was received which contained a statement showing a researcher's naivete regarding the value of intellectual property. This statement was essentially as follows: "Do not worry about protecting any intellectual property developed in the laboratory since we are from a poor country, the intellectual property will have very little value." This statement is absolutely false. Valuable intellectual properties can come from any country regardless of its economic state. Awareness of the potential value of an intellectual property is important and education can help in its assessment. As a result of this statement, an intellectual property education/awareness program was initiated for researchers from Central and South America who were involved in a cowpea research program. Today, the researchers are taking a much different view of their endeavors. Researchers in Europe and the United States are fairly well versed on the importance of intellectual property rights. Southeast Asia on the other hand, is beginning to make progress in this area.

3. Customs. Handling of new products and processes, whether of biotechnological origin or not, are often controlled by customs of an area. Landgrant universities in the United States, like Michigan State University, initially provided the farmer with new crop varieties and other agricultural improvements at no cost. This “free for all” philosophy was supported by the government. Eventually, machinery improvements were licensed to companies who could provide the equipment to farmers because few, if any, farmers had the capability to build farm equipment. Even into the early 1990s Landgrant universities were providing seeds of new crop varieties at no or little cost to farmers. Farmers came to expect free access to new crop varieties; it was the custom. As biotechnological developments became important in new crop variety development and the development of these new varieties became more demanding and costly, Landgrant universities stopped the free distribution of these products. Farmers were upset and demanded that these new varieties be made available to them at little or no cost – they said, “this is the Landgrant philosophy”. It became necessary to educate the farmer on the need to handle biotechnologically developed crop seeds differently than seeds developed through traditional breeding. The time and expenses of developing these genetically engineered varieties were two important factors to consider. The safety of these new varieties needed to be ascertained more carefully because government standards must be met. As the farmer learned about the advances through biotechnology, he/she understood better why the Landgrant philosophy was no longer applicable. Also, the university had to review its procedures on releasing new varieties to be sure it interacts properly with the farmers it serves to provide those varieties at little or no cost.

In Southeast Asia the custom is to provide crop seeds at little or no cost to the farmer. From this comes the idea of not protecting new varieties or biotechnology developments because if protected, they cannot be given away as is the custom. This is not true. Through protection one is able to determine how to handle the development. It can be given away, it can be sold, it can be licensed or can be held from anyone who wants to use it. If a biotechnological advancement is made, which benefits the farmer of an area, protecting this development does not prevent the developer from giving it to the farmer. It does however, prevent someone else from coming in and claiming this same development and making restrictions, which may prevent the original developer from distributing as planned. It would also allow the developer to license the biotechnological advance to others and expect a financial reward for allowing the use of the biotechnology elsewhere. It is important to respect customs, but it also necessary to advance and to be alert with possibilities beyond meeting customs. In order to do this it is necessary to 1) educate researchers to look beyond the immediate goal of biotechnologies for free, and to look for other ways to extend the use of the biotechnology; 2) educate the farmer that it is not possible to provide everything for free or only to the farmer, and that looking beyond the farmer’s immediate needs, the farmer may actually gain more; and 3) educate government officials so they understand that biotechnology developments may have ramifications far outside their country benefiting people throughout the world, and possibly bring additional revenue to the research and development program. This type of effort is being initiated in several Southeast Asian counties. However, more needs to be done to be able to obtain full realization of biotechnology utilization.

Summary

Understanding of intellectual property protection particularly for biotechnological developments is growing in Southeastern Asia. Through this awakening, plant variety protection laws are being drafted, patent laws are being updated, staff training is beginning, researchers are becoming aware of the importance of intellectual property protection, and government officials are beginning to realize the benefits biotechnology improvements can bring to their constituency and, perhaps the world. While the region is not as established as that of Europe or the United States in intellectual property awareness, utilization, and management, it is important to note its progress. Furthermore, developed countries are likewise encouraged to work in support of the developing efforts in Southeast Asia.

Attachment A

PARTNERS MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement (hereinafter "MTA") is entered into by and amongst the partners of the Research Program entitled _____.
The partners are comprised of _____,
_____, and _____,
(hereinafter "Partners").

The Partners agree as follows:

1.0 **Definitions.** The following definitions will apply to this MTA:

- 1.1 "Agreement" means the Intellectual Property Disposition Plan and any related research agreement for the above listed Research Program.
- 1.2 "Derived Materials" means Outside Materials which have been genetically or chemically manipulated by a Partner to change their molecular or genetic structure, their properties in genetic constructs, or their function when expressed or present functionally in a cellular environment.
- 1.3 "Effective Date of this MTA" means effective upon signature by all parties below.
- 1.4 "Outside Materials" means all tangible property including, but not limited to promoters, enhancer sequences, expression elements, structural genes and gene fragments, fusion sequences, operons, vectors, plasmids, genetic cassettes and constructs, recombinant chimeric sequences, shuffled genes and operons obtained from a third party (a non-partner party) which is in the public domain, or was obtained by license or assignment.
- 1.5 "Partner Transfer Form" (herein after PTF) means a form containing a description of materials to be transferred, the Transferor and the Recipients, the purpose of the transfer, the intended use, and the date of transfer, and the additional information specified in paragraph 2.0 if the materials are Outside Materials or Derived Materials. Each MTA shall have a PTF attached.
- 1.6 "Research Data" means all data, sequences, test results, schematics, and any other information obtained or developed in the course and performance of the Research Program.
- 1.7 "Research Materials" means all tangible property obtained or developed in the course of performance of the Research Program including genes, deposits of any type, and research tools and methods.
- 1.8 "Research Program" means the research effort described in the proposal attached to this MTA, named in the introduction to this MTA.
- 1.9 "Transfer Materials" means the transfer from a Partner (hereinafter "Transferor") to one or more Partners (hereinafter "Recipient(s)") of any Research Materials (including any materials from a Transferor to be shared among the Partners but may have been developed prior to the initiation of the Research Program, or developed during the research term), Outside Materials, or Derived Materials.

- 1.10 “Work Plan” means the annual research work plan within the Research Program as defined by the MTA.
- 2.0 **Material Transfer.** Any Transfer Materials which may be useful to or in furtherance of any research objective under the Research Program may be transferred by one or more Partners to another Partner at any time during the Research Term. Any information accompanying the transfer or provided separately for the use of the Transfer Materials, or adapting them to particular applications shall be designated confidential in accordance with the Agreement. The transfer will be accompanied by a PTF containing the information set forth in paragraph 1.9 above. The PTF will contain further information about the origin of the Transfer Materials, the existence and terms of a license, and the retransfer provisions which may apply to the Partners.
- 3.0 **Effect of Transfer.** The transfer of materials shall not affect the ownership or other rights which the Transferor may possess, and the Recipient acquires no rights therein by virtue of the transfer. In the event that a commercial product incorporates Transfer Materials, and such use of the material is outside the scope of the intellectual property provisions of the Agreement, then the commercializing party may negotiate a separate agreement with the Transferor or third party.
- 4.0 **Research Data.** Research Data generated by a Partner or through a collaboration of a Transferor and a Recipient shall be shared information, and not be treated differently than any other information obtained under the Research Program.
- 5.0 **Use of Transfer Materials.** Transfer Materials shall be used pursuant to the work plan as part of the Research Program. A Recipient agrees that, unless otherwise understood in a separate agreement between the Transferor and the Recipient, the Transfer Materials can and will be used only in conjunction with the Research Program, and not for other research activities that may be in progress in the Recipient’s laboratories or in the same laboratory. Laboratory personnel will be instructed that such use is restricted, and the Transfer Materials may not be used in a companion, related, or different project even if it would appear scientifically expeditious to do so. Pursuant thereto, the parties to this MTA will exercise diligence in preventing the inadvertent introgression of Transfer Materials into constructs, cassettes, cells of organisms, and the like used in laboratory research other than the Research Program. A Recipient of Transfer Materials (and any data generated therefrom) as it would for any other confidential information. It is further agreed that no Transfer materials will be released to any third party without notification of and approval of the Transferor unless otherwise required by law or court order.
- 6.0 **Warranty.** Any Transfer materials delivered hereunder is experimental in nature. Transferor MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF Transfer Materials WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OF OTHER RIGHTS.

7.0 **Term and Termination.** The term of this MTA shall be commensurate with the term of the Agreement and any extensions. In the event of termination according to the provisions of the Agreement, or upon their expiration, any Transfer Materials are subject to a third party contractual obligation of return or destruction, the Transferor and any Recipient will undertake to comply with such obligations. Any Recipient hereby accepts the same scope and degree of responsibility to comply with such obligations as the Transferor itself. Upon termination or expiration of the Agreement each Partner will construct a written or computer ready inventory of all Transfer materials in their respective possession.

8.0 **Handling.** All Transfer materials will be transferred, maintained, and disposed of in accordance with all applicable state and federal requirements and guidelines.

WHEREFORE, the Partners have executed this MTA as of the Effective Date.

Organization _____
By _____
Name _____
Title _____
Date _____

Organization _____
By _____
Name _____
Title _____
Date _____

Organization _____
By _____
Name _____
Title _____
Date _____

Organization _____
By _____
Name _____
Title _____
Date _____

Attachment B

INTELLECTUAL PROPERTY DISPOSITION PLAN

This Agreement between _____ business concern organized as a Corporation under the laws of _____ and having a principal place of business at _____, ("COMPANY") and _____, a non-profit, research institution of _____ having a principal place of business at _____ ("INSTITUTION") is entered into for the purpose of allocating between the parties certain rights relating to a _____ project to be carried out by COMPANY and INSTITUTION (collectively known as the "PARTIES" and individually as the "PARTY") under a funding agreement that may be awarded by _____ to fund a proposal entitled _____ ("PROPOSAL") submitted by [INSTITUTION/COMPANY chose one here and adjust throughout] on or about _____.

1. Applicability of this Agreement.

(a) This Agreement shall be applicable only to matters relating to the funding agent referred to in the preamble above.

(b) If a funding agreement for the PROPOSAL is awarded to INSTITUTION/COMPANY based upon the PROPOSAL referred to in the preamble above, INSTITUTION/COMPANY will promptly provide a copy of the funding agreement to INSTITUTION/COMPANY and INSTITUTION/COMPANY will make a sub-award to INSTITUTION/COMPANY in accordance with the funding agreement, the PROPOSAL, and this Agreement. If the terms of such funding agreement appear to be inconsistent with the provisions of this Agreement, the PARTIES will attempt in good faith to resolve any such inconsistencies. However, if such resolution is not achieved within a reasonable period, INSTITUTION/COMPANY shall not be obligated to award nor INSTITUTION/COMPANY to accept the sub-award, as the case may be. If a sub-award is made by INSTITUTION/COMPANY and accepted by INSTITUTION/COMPANY, this Agreement shall not be applicable to contradict the terms of such sub-award or of the funding agreement awarded by _____ except on the grounds of fraud, misrepresentation, or mistake, but shall be considered to resolve ambiguities in the terms of the sub-award.

(c) The provisions of this Agreement shall apply to any and all consultants, sub-contractors, independent contractors, or other individuals employed by COMPANY or INSTITUTION for the purposes of this project.

(d) COMPANY warrants that the proprietary interests of any INSTITUTION employee in the COMPANY or the proposed project or the PROPOSAL have been disclosed as required by INSTITUTION policies and procedures. COMPANY acknowledges that if the involvement of INSTITUTION employees in the COMPANY constitutes a conflict of

interest, any sub-contract resulting from this submission must be submitted to the INSTITUTION'S _____ for review and may need to be approved by INSTITUTION's _____. COMPANY further acknowledges that if approval is not obtained, INSTITUTION will withdraw this PROPOSAL.

2. Background Intellectual Property.

COMPANY obtains no rights under this Agreement to background patents held by INSTITUTION or to related inventions or discoveries which are not conceived or made by one or more employees of INSTITUTION in the performance of this project ("INSTITUTION Background Intellectual Property"). To the extent it is able to do so, INSTITUTION will negotiate with COMPANY to provide COMPANY with rights, under reasonable terms and conditions to be negotiated, to use INSTITUTION Background Intellectual Property where necessary to allow the practice or commercialization of rights acquired by the COMPANY in the Project Intellectual Property as set forth below.

3. Project Intellectual Property.

(a) "Project Intellectual Property" means the inventions, patent applications, patents, copyrights, trademarks, mask works, trade secrets, and any other potentially legally protectable information, including computer software, first made or generated during the performance of this Agreement and the funding agreement.

(b) Unless otherwise agreed in writing, Project Intellectual Property shall be owned by the PARTY whose employees make or generate the Project Intellectual Property. Jointly made or generated Project Intellectual Property shall be jointly owned by the PARTIES unless otherwise agreed in writing.

(c) Project Intellectual Property shall be commercialized pursuant to the terms of a license agreement to be negotiated in good faith by the PARTIES. Expenses and other liabilities associated with the protection, development and marketing of any product, process, or other innovation or invention will be borne by the COMPANY that exercises its option to obtain exclusive commercial exploitation of Project Intellectual Property as provided below.

(d) The PARTIES agree to disclose Project Intellectual Property to each other, in writing. The PARTIES acknowledge that they will make this disclosure to each other within three (3) months after their respective inventor(s) first disclose the invention in writing to the person(s) responsible for patent matters of the disclosing PARTY. All written disclosures of such inventions shall contain sufficient detail of the invention, identification of any statutory bars, and shall be marked confidential, in accordance with 35 U.S.C. Section 205. (Or whatever patent laws would apply)

(e) Each PARTY hereto may use Project Intellectual Property owned by the other PARTY non-exclusively and without compensation in connection with research or development activities for this project, including inclusion (consistent with the requirement to protect Project Intellectual Property by patent, copyright and/or trademark) in project reports and proposals for continued funding of this project for additional periods.

(f) COMPANY will have an option to commercialize the Project Intellectual Property owned by INSTITUTION. The following terms will be included in the license agreement unless other provisions are mutually agreed to in writing:

(1) Where Project Intellectual Property of INSTITUTION is a potentially patentable invention, COMPANY will have an exclusive option for a sole license to such invention, for an initial option period of three (3) months after such invention has been reported to COMPANY. COMPANY may, at its election and subject to the patent expense reimbursement provisions of this section, extend such option for an additional three (3) months by giving written notice of such election to INSTITUTION prior to the expiration of the initial option period.

During the period of such option following notice by COMPANY of election to extend, INSTITUTION will pursue and maintain any patent protection for the invention requested in writing by COMPANY and, except with the written consent of COMPANY or upon the failure of COMPANY to reimburse patenting expenses as required under this section, will not voluntarily discontinue the pursuit and maintenance of any United States patent protection for the invention initiated by INSTITUTION or of any patent protection requested by COMPANY.

For any invention for which COMPANY gives notice of its election to extend the option, COMPANY will, within thirty (30) days after invoice, reimburse INSTITUTION for the expenses incurred by INSTITUTION prior to expiration or termination of the option period in pursuing and maintaining (i) any United States (or appropriate country) patent protection initiated by INSTITUTION and (ii) any patent protection requested by COMPANY. COMPANY may terminate such option at will by giving written notice to INSTITUTION, in which case further accrual of reimbursable patenting expenses hereunder, other than prior commitments not practically revocable, will cease upon INSTITUTION's receipt of such notice.

At any time prior to the expiration or termination of an option, COMPANY may exercise such option by giving written notice to INSTITUTION, whereupon the PARTIES will promptly and in good faith enter into negotiations for a license under INSTITUTION's patent rights in the invention for COMPANY to make, use and/or sell products and/or services that embody, or the development, manufacture and/or use of which involves employment of, the invention. The terms of such license will include: (i) payment of reasonable royalties to INSTITUTION on sales of products or services which embody, or the development, manufacture or use of which involves employment of, the invention; (ii) reimbursement by COMPANY of expenses incurred by INSTITUTION in seeking and maintaining patent protection for the invention in countries covered by the license (which reimbursement, as well as any such patent expenses incurred directly by COMPANY with INSTITUTION's authorization, insofar as deriving from INSTITUTION's interest in such invention, may be offset in an amount to be negotiated by the parties in good faith against the accrued royalties in excess of any minimum royalties due INSTITUTION); and, in the case of an exclusive license, (iii) reasonable commercialization milestones and/or minimum royalties.

(2) Where Project Intellectual Property of INSTITUTION is other than a potentially patentable invention, COMPANY will have an exclusive option for a license, for an option period extending until three (3) months following completion of INSTITUTION's performance of that phase of this project in which such Project

Intellectual Property of INSTITUTION was developed by INSTITUTION. COMPANY may exercise such option by giving written notice to INSTITUTION, whereupon the parties will promptly and in good faith enter into negotiations for an appropriate license under INSTITUTION's interest in the subject matter for COMPANY to make, use and/or sell products or services which embody, or the development, manufacture and/or use of which involve employment of, such Project Intellectual Property of INSTITUTION. The terms of such license will include: (i) payment of reasonable royalties to INSTITUTION on sale of products or services that embody, or the development, manufacture or use of which involves employment of, the Project Intellectual Property of INSTITUTION and, in the case of an exclusive license, (ii) reasonable commercialization milestones and/or minimum royalties.

(3) Where more than one royalty might otherwise be due in respect of any unit of product or service under a license pursuant to this Agreement, the parties shall in good faith negotiate to ameliorate any effect thereof that would threaten the commercial viability of the affected products or services by providing in such license(s) for a reasonable discount or cap on total royalties due in respect of any such unit.

4. Follow-on Research or Development

All follow-on work, including licenses, contracts, subcontracts, sublicense or arrangements of any type, shall be consistent with the provisions regarding Project intellectual Property rights in this Agreement and insure that the PARTIES retain such rights granted herein.

5. Confidentiality/Publication.

(a) Except as otherwise required by law or court order, Background Intellectual Property and Project Intellectual Property of a PARTY, as well as other proprietary or confidential information of a PARTY, disclosed by that PARTY to the other in connection with this project shall be received and held in confidence by the receiving PARTY and, except with the consent of the disclosing PARTY or as permitted under this Agreement or as required by law or court order, shall neither be used by the receiving PARTY nor disclosed by the receiving PARTY to others for a period of three (3) years, provided that the receiving PARTY has written notice within ten (10) days of disclosure that such information is regarded by the disclosing PARTY as proprietary or confidential. However, these confidentiality obligations shall not apply to use or disclosure by the receiving PARTY after such information is or becomes known to the public without breach of this provision or is or becomes known to the receiving PARTY from a source reasonably believed to be independent of the disclosing PARTY or is developed by or for the receiving PARTY independently of its disclosure by the disclosing PARTY.

(b) Subject to the terms of paragraph (a) above, either PARTY may publish its results from this project. However, the publishing PARTY shall provide the other PARTY a thirty (30) day period in which to review proposed publications, identify proprietary or confidential information, and submit comments. The publishing PARTY shall not publish or otherwise disclose proprietary or confidential information of the other PARTY and the publishing PARTY will give full consideration to all comments before publication. Furthermore, upon request of the reviewing PARTY, publication will be deferred for up to

one hundred twenty (120) additional days for preparation and filing of a patent application which the reviewing PARTY has the right to file or to have filed at its request by the publishing PARTY.

6. Liability.

(a) Each PARTY disclaims all warranties running to the other or through the other to third parties, whether express or implied, including without limitation warranties of merchantability, fitness for a particular purpose, and freedom from infringement, as to any information, result, design, prototype, product or process deriving directly or indirectly and in whole or part from such PARTY in connection with this project.

(b) COMPANY will indemnify and hold harmless INSTITUTION with regard to any claims arising in connection with commercialization of the results of this project by or under the authority of COMPANY.

7. Termination.

(a) This Agreement may be terminated by either PARTY upon thirty (30) days written notice to the other PARTY. This Agreement may also be terminated by either PARTY in the event of the failure of the other PARTY to comply with the terms of this Agreement.

(b) In the event of termination by either PARTY, each PARTY shall be responsible for its share of the other PARTY's costs incurred through the effective date of termination, as well as its share of such costs incurred after the effective date of termination, and which are related to the termination. The confidentiality, use, and/or non-disclosure obligations of this Agreement shall survive any termination of this Agreement.

**AGREED TO AND ACCEPTED--
COMPANY**

By: _____ Date: _____
Print Name: _____
Title: _____

INSTITUTION

By: _____ Date: _____
Print Name: _____
Title: _____