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LICENSING TECHNOLOGY FROM ACADEMIA AND GOVERNMENT

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A great number of new biotech companies are formed around patents derived from research at universities, research hospitals and other non-profit institutions. The Technology Transfer Office ("TTO") is thus a key player in the formation of such companies.

This chapter is for the benefit of two principals in biotech entrepreneurship:

- The "inventor": a university researcher (faculty member, student, post-doc, etc.) who makes a discovery or invention which, if developed, could be a useful product in furthering human health.

- The new company founder (entrepreneur, investor, etc.) who wishes to obtain a license to a university patent.

The term "university" will be used throughout this chapter to include all non-profit research institutions.

This chapter is based on my experience at MIT's technology licensing office ("the TLO") where I served as its director for 25 years before my retirement, plus my experience consulting and advising dozens of universities and research hospitals in the US, Europe, Asia and Latin America. The material will be based primarily on practice in US institutions. Policies and practices in other countries vary widely, but much can be learned by others from the US technology transfer system.

INTRODUCTION: WHAT DOES THE TTO DO?

The basic function

Technology transfer offices in universities have many different names (e.g., Technology Licensing Office, Innovation Office) and may perform many different functions in helping to advance technologies, build new companies, and some may even invest in new companies. However, all these offices have as core responsibilities the protection of inventions arising from university research through the filing of patents and the out-licensing of such patents to industry for development. This chapter will concentrate on these core responsibilities.

In the US, the majority of basic research is funded by the US Federal Government. A ground-breaking law passed in 1980 (known as the "Bayh-Dole Act") allowed universities to elect title to ("own") inventions from Federally funded research, provided that the university filed a patent on each invention it elected. The law also allowed the universities to grant licenses to such inventions and to collect fees and royalties arising from licenses. The law also mandated that a portion (unspecified) of the royalties be shared with inventors, and that the remainder going to the university to be used for "research and education". There are also a few restrictions and requirements in the law (see Text Box 1) but generally these restrictions are not significant hindrances for the universities or their licensees.

Text Box 1 Summary of major points of the Bayh-Dole Act (35 U.S.C. sections 201–211)

- Allows the research institution to take title to inventions from Federally funded research programs if the institution will file and prosecute patents on the invention.
  - Requires reporting of the invention to the government in a timely matter
  - If the institution does not file a patent, or abandons a filed patent, the invention reverts to government ownership
  - If the government agency takes title, inventors may petition the agency to waive ownership to them
- Allows the institution to grant licenses for commercial development and sale, including exclusive licenses, subject to government rights.
- The institution must grant the government a royalty-free, nonexclusive license for government purposes (only).
- If an exclusive license is granted to a company, the company must agree that products sold in the United States must have a "substantial component of the product" also manufactured in the United States.
- Allows the institution to take royalties in exchange for licenses to the patent.
- A portion of the royalties must be given to the inventors "as an incentive for inventing"; the portion is not specified in the law.
- The remainder of the royalties must be used by the institution for "research and education".
- Licenses must contain diligence terms to assure that the patent is used.
- The institution must report to the government licenses granted and licensees' progress in developing the patented technology.

Of greater significance is the stage of the inventions which the TTO manages. Invention disclosures from academic inventors are usually very early, with just enough data to justify publication in scientific journals ("scientific proof of principle.") These "university stage" inventions are far removed from an actual product and will usually require large investments by the commercial sector before the feasibility of commercial introduction can be demonstrated, with even more investment needed thereafter to bring the invention to market.

Given the early stage nature of university inventions, the most important function of the TTO is to provide conditions that will lead a company (or, more often, the founders and investors in startup companies) to take the risk of investing to bring the product candidate to market.

The primary incentive that the TTO can provide for a company to invest in a new invention is an exclusive license to a strong patent under commercially reasonable terms. If the company's investment pays off, and a product comes to market, the "first mover" company will be protected from competitors for the duration of the issued patent. This incentive is particularly important for "hard technologies" that will take many years and tens or hundreds of millions of dollars to bring to market. Pharmaceuticals and many break-through medical devices fall firmly in that category.

A secondary purpose of TTO licensing is to generate money from the fees and royalties that companies pay for the IP they license. Running a TTO is expensive, with the costs of drafting, filing and maintaining patents usually comprising 50% or more of the total expenses. The TTO needs their income to at least cover its costs. Most TTOs also hope to find a "blockbuster invention" that will result in a major contribution to their respective university's overall budget. Few achieve that.

WHAT YOU SHOULD KNOW AS AN INVENTOR

This section is directed to members of the university (faculty, students, post-docs, research scientists) who may make an invention. Particular attention is given to those issues affecting startups. Company founders and investors may also find this section useful as background to the next section which is devoted to the acquisition of intellectual property from universities.

When do you have a patentable invention?

In your research, or in your own reading, thinking, or discussions with people, you may conceive an idea which could (eventually, perhaps) lead to an important drug, device or diagnostic of potential importance in medicine. In most – though not all – cases, you may need to do some experimentation to show that the idea can work.

- How do you know if your concept/result(s) is potentially patentable?

  An "invention" according to patent law involves both a "conception" and a "reduction to practice".

  Does that mean you must physically demonstrate the invention? No! If you can describe it in a patent application in a believable way that someone else could produce the invention without unknowns or further "inventing", then this can count as a "constructive reduction to practice"– and a patent may be granted. Of course, convincing data always help the US patent office render a favorable decision from the inventor standpoint. Then:

- Does the invention fulfill the criteria for patentability?
- Is it novel? (never been done before).
- Is it obvious (not a trivial extension of known knowledge).
- Is it "useful" (does it solve a problem that has never been solved that way).

If your answer to these questions is "yes", or "I think so", then you should assume the invention is patentable and proceed accordingly (see Who owns your invention, below).

Does patenting your invention interfere with publishing your research?

Absolutely not! But timing is critical. As explained in Chapter 18, patenting in most countries requires that a patent application be filed before there is any enabling public disclosure of the invention. But as soon as the patent is filed, subsequent publication is OK. This puts an obligation on both the inventor and the TLO to protect the intellectual property while also allowing rapid dissemination to the public of the scientific knowledge gained in the research:

- The inventor should notify the TLO of the invention at the earliest point possible prior to publication, giving a first draft of the intended publication and informing the TLO of the earliest likely date of public disclosure (remembering that poster sessions, abstracts, and even an enabling verbal description of an invention outside the organization can invalidate a patent).

- The TLO needs to make a rapid decision on whether it will file a patent on the invention, so that publication can occur promptly.

But what if you have already published? Is it too late to meet with the TTO? No, it is not too late because of the difference between US patent law and that of the rest of the world. US patent law, unlike the law in most foreign countries, has a "grace period": a patent may still be filed within one year of the first publication; but there will be no possibility of patents in most foreign countries in this circumstance. Thus rapid reporting of an invention, giving the TTO time to file a patent, is important if you want worldwide coverage of your invention.

Who owns your invention?

In the US, you own the patent on your invention until you assign it to another entity. But you may be required to assign it to your university under the following conditions:

If the research leading to the invention was sponsored in whole or in part by a grant or contract from the US Federal Government, you are required to assign the invention to the university if it is willing to file a patent on it; if not, the invention must be assigned to the Federal Government (see Text Box 1).

If the research was sponsored by another entity (industry, foundations, etc.), in most cases the university must own the invention in order to fulfill its contractual option or license obligations to the sponsors (for example, if the research is sponsored by a commercial company, the research agreement often grants the sponsor an option to negotiate for a license to patents arising from the program; see Acquiring a Licence from a University, below). If you make "significant use" of university funds or facilities, as defined in the university's policies, the university may claim ownership. ("Significant use" may exempt use of common facilities such as libraries.)

Some universities also take ownership of any invention in the general professional field of its employees (and subsidized graduate students), regardless of who sponsored the program or whether significant university-administered funds or facilities was used.

If you are unsure how your university's policy applies to your invention, ask the TTO. Most TTOs are not "grabby": they will not try to stretch their policies or trip you into assigning your patent if the facts of your situation favor you owning the invention. But note that having the university own your invention – even if not required – may be to your advantage: the university will pay for the patenting, ownership is unquestioned, and there may be reputational advantages for marketing your patent if it has university ownership.

- Royalty sharing policies
  All university IP policies have a formula for sharing the income the university makes from licensing patents ("royalties") with

the inventors. Most commonly, the inventors receive between 25 and 33 percent of the net income (after subtracting the university's costs for filing the patents). The remainder is divided (in formulas that vary widely) between the TTO (to pay for administration and filing of patents that don't get licensed or aren't licensed yet); and departments; schools; and the central administration of the university.

Reporting your invention

What to do if you make a discovery or invention and want to patent it?

- Write it down and date it.

- Fill out an invention disclosure form (see your university's TTO webpage) and file it with the TTO.
  Note: An invention disclosure form sent to the TTO is simply for the TTOs information; it has no legal status in protecting your invention.

- Keep the invention confidential until a patent is filed; assume any "enabling" discussion or written material available to anyone not part of your university counts as "public disclosure" (see Text Box 2).

- Promptly visit the TTO to discuss your invention.

What the TTO wants to know from you:

- What is the invention about? What is new about it?

- What is its significance? (What is its potential use?)

- Who are the co-inventors (if any)?

- Important: are you still working on this technology, or is the project finished?

Text Box 2 What type of public disclosure destroys patentability?

Timing
In most countries, any "enabling" public disclosure made before a patent application is filed destroys patentability.

For patenting in the US, there is one year "grace period" after public disclosure during which a patent application can be filed.

What counts as "public disclosure"?
Any enabling disclosure, whether orally or in writing (other than to a member of one's own organization).

This includes slides, poster sessions, abstracts, etc. in addition to formal publications.

What does "enabling" mean?
A disclosure does not bar patenting unless it is "enabling"; that is, the disclosure gives enough information that another person skilled in the same field could replicate the invention.

For example, simply saying "I invented a telephone, a machine that allows people to speak to each other over long distances" is not enabling. One would have to explain the materials and mechanical systems that allow such communication in order to be enabling. The non-enabling initial disclosure would not prevent later filing of a patent application.

- Very important: is there an upcoming "public disclosure" (publication, abstract, poster session, or even a laboratory presentation attended by others who are not members of your university)? What is the date of that public disclosure?

- Who sponsored and/or is sponsoring your (and any co-inventors') research? Government? A foundation? A company? Other sponsor?
  - The TTO will research the sponsorship agreement to identify any intellectual property obligations to the sponsor. If the co-inventor is not part of your university, the TTO may have to work out a "Joint Invention Agreement" with the co-owner.

- Are you aware of publications that may cover parts of your invention by others?
- Who might license your invention?
  - Are you aware of any companies that might be interested? Do you have any contacts at those companies? (It's OK if your answer is "I don't know").
- Are you interested in starting a company based on this invention?
  - If so, who might be the co-founders?
  - Have you had any discussions with potential investors?

Evaluation and patent filing

The TTO will now evaluate your invention to determine whether it should spend money to file and prosecute a patent on the invention.

- Does it fit the criteria for patentability?

  If time allows (before any upcoming public disclosure), the TTO will do a "prior art search". It will search patent and literature databases to determine whether the invention is novel. Often, the inventor is asked to sit in on literature searches since he or she knows the most about the invention and therefore how other inventions may relate to it.

- Does it have commercial potential? Is the invention likely to garner investment (from an existing company or in a startup) to develop it and bring it to market?

If the answers are positive or "likely", the TTO will pair you up with a patent attorney to begin drafting a patent application. (If the TTO declines the patenting opportunity, the university's policies may allow the TTO to give the invention to you; however, in the case of Federally funded inventions, the university must first petition the government to allow such assignment.)

Marketing your invention for commercialization

Once the patent application is completed and filed with the government patent office (see Chapter 18 for how patents are prosecuted), the TTO may begin efforts to find a company to take a license to the patent to commercialize it. There are three potential routes:

- If the research was sponsored by a commercial company, the sponsorship agreement usually requires that the license be first offered to the sponsor – who may or may not take a license.
- An existing company, large or small may take a license.
- A new startup.

- Offer to sponsor.

  A commercial research sponsorship agreement may or may not give the sponsor some automatic right to at least a nonexclusive license; other rights (e.g., exclusivity) may be obtained by negotiation during an option period.

- If the TTO believes the patent can be licensed to an existing company, it will begin marketing it. This may involve contacting specific people at target companies (particularly people and companies that you know), or broadly publicizing the invention via listing on the TTO's home page and other databases.

  - A little known fact is that "cold calling" and/or broad publicizing is only rarely successful with very novel "breakthrough" biotechnology inventions at "university stage". This is because such inventions are too early, and therefore too risky, requiring too much investment (tens of millions of dollars – or more) before the company even knows whether the product will work. Nevertheless, such broad marketing is sometimes worth trying since it helps to publicize the university's expertise in the field of the invention; it and also lead to a company sponsoring further research within the university, even if the company eventually declines a license to commercialize the invention.

- Licensing to a new startup

  Most biotechnology startups from universities begin with one or more of the inventors enthusiastically supporting the concept of starting a company. This may be the principal investigator or one of his or her graduate students or post-docs.

  Support for such startups varies very widely among universities. Some may simply provide patent filing and licensing, while others may actively participate in founding the company and even investing capital in the company. In between are universities that provide education and coaching for faculty and students with entrepreneurial ambition and/or pre-company project support to advance the technology to reduce its risk and make it more attractive to potential investors. (Other chapters cover skills and information for biotech startups.)

Payments for your invention ("royalties")

(See below for sharing royalties between the university and the inventors.)

Royalties are a form of payment for use of intellectual property (in this case, a patent). They are usually paid over time, rather than a one-time payment. And usually the majority of the payments are related to sales of the eventually-developed product. Thus, the question: "What is this patent worth?" If asked long before the product is developed, it is relatively meaningless, since the value must take into account:

- The probability of the product development becoming successful.
- The cost of development.

- The cost of manufacturing and distributing the product.
- The price it can command in the market.
- The sales volume (taking into account competition, etc.).
- The amount that will be sold.
- And, finally, time: number of years it will take to reach the market.

None of these factors can be known with any certainty at the time of the license; thus, payments that largely depend on the success of the product in the market make sense to both parties.

Types of payments may include:

- License issue fee: an "upfront" payment at the time of licensing.
- License maintenance fees: an annual fee to keep the license. License maintenance fees are used to reduce the size of a one-time upfront fee. Once a product is on the market, license maintenance fees may be replaced by "running royalties".
- Running royalties: Payments directly related to the volume of sales of the product. Usually this is based on Net Sales. Thus, "X% of Net Sales of the Licensed Product". Running royalties may alternatively be based on the profitability of the product (for example, "Y% of Gross Margin") but this is rare. And sometimes the product is just a component of a much larger system, such that the sale price of the Licensed Product alone is not determined; in that case, the running royalty may simply be a set number of dollars per final system sold. (A fictional example: $1 per automobile for an improvement in windshield glass.)
- A portion of the payments the licensee receives in return for sublicensing the patent rights to third parties.

- In biotech, most particularly in licensing of pharmaceutical patents, universities often also require "milestone payments": substantial payments when particular development milestones are met (for example, IND approval by the FDA, first use in humans, beginning Phase III clinical trials, filing a New Drug Application (NDA) to allow marketing of the product (assuming FDA approval).

- For biotech startups, the university may require a share of the founders' equity in the company. This share usually consists of common shares unless the university is investing capital to buy preferred shares (such purchased shares are not considered a form of royalty payment.)

- Reimbursement to the university for its legal costs of filing and prosecuting the patent.

Each of the royalty payment types is discussed in more detail as it applies to the licensee company in Acquiring a Licence from a University, below, which switches perspectives and addresses the situation of a new biotech company acquiring a license to an invention from a university TTO for a new biotech company.

ACQUIRING A LICENSE FROM A UNIVERSITY: FOR BIOTECH FOUNDERS AND INVESTORS

Approaching the TTO

Universities want to license their patents! Unlike companies that may file patents in order to exclude others from practicing their technology, universities file patents only in the hopes of licensing them to companies for development and commercialization of the technology. Thus, if you are a qualified licensee, you will be welcomed by the TTO.

Most TTOs, however, are not particularly welcoming to "shoppers" ("Can I look through your inventions for something I can build a business on."). A potential licensee need not know specifically which invention he or she is interested in licensing, but he or she should be as specific as possible about the field and subfield for which they are seeking new technology. He or she should also have the technical qualifications to discuss candidate inventions with the TLO and inventors. Potential founders or CEOs of a new company are also welcome if they have strong business expertise in a particular field.

When venture investors visit a TTO the first question they may be asked is: "Are you genuinely interested in very early stage technology?" Many investors characterizing themselves as "early stage" investors mean that they will invest in a company before product sales but are unprepared for and not interested in "university stage" inventions where a commercializable prototype does not yet exist, or, in the case of biopharmaceuticals, the invention may not yet have been tested on an animal model, much less a human.

What if I am an inventor of the technology – or an investor or executive working with the inventor to form a new company to develop his or her invention?

Most university TTOs will give strong preference to granting a license to a company in which the inventors are founders – subject to any IP rights of the sponsor of the research (if non-Federal), and occasionally subject to a specific university's policy on first publicizing the invention in the name of "open access". The preference to license to an inventor's company is never absolute, but exists because the university assumes that the inventors have the best scientific knowledge of the invention and are most passionate about seeing the invention find practical use.

That said, any license to an inventor's company will require, as in licenses to third parties, that the company demonstrate a reasonable plan for development of the product, the potential ability to raise money to carry out the plan, and the willingness to negotiate fair and reasonable license terms.

License

License, option and/or term sheet

A company may be very interested in a technology, but not ready to negotiate a license agreement. It may need time to assess the strength of the patent, to explore the market, or to run a few experiments. Or a new company may not yet have enough funds to hire an attorney (or other expert) to advise on a license agreement. They may choose, instead, to take an exclusive option and/or to negotiate a term sheet.

Exclusive option: In an exclusive option agreement, the university agrees not to license the technology to any other party for a limited amount of time (typically six months to two years, sometimes with rights to extend the time for additional fees). At any time during the exclusive option period, the company can request to begin negotiations for a full license. Sometimes the right to begin negotiations depends on the company raising a set amount of capital.

In return for the option, the company agrees to pay an option fee and, most commonly, to reimburse the university for patent costs incurred during the option period. The option agreement may or may not allow the company to practice the technology for experimental purposes during the option period. An option agreement may, under some circumstances, include an attached term sheet. Universities may be reluctant to put in the effort to negotiate a detailed term sheet for a very early stage company if there is not a high probability of the company raising capital.

Term sheet: A term sheet summarizes the major terms of an intended license agreement – details of the patent rights and any other assets to be licensed such as field of use; financial terms; and some or all performance (diligence) requirements. A preliminary term sheet is the university's initial "ask". A signed term sheet has negotiated terms that both sides have agreed will be included in the final license agreement, although subject to good faith amendments.

An exclusive or non-exclusive license?

- Exclusivity

  If the invention is a core technology of a company, the company will want an exclusive license to protect itself from competitors. Investors will likely demand that such protection exists and will be very wary of any exceptions to the exclusivity. Nevertheless, most universities will require certain "retained rights" as carve-outs from the exclusive license. These include:

  - The non-exclusive royalty-free license to the US government required by the Bayh-Dole Act (see Text Box 1) if the invention came from Federally funded research. Some lawyers and/or investors may worry about this license, but since the license is only for government purposes, it does not usually present a commercial threat.
  - The right of the university itself to practice under the patent for research and education purposes only. Some universities may require that this right extend to all other non-profit research organizations.
  - Occasionally, the patent will have originated in a program sponsored by a commercial entity and a non-exclusive royalty-free license may have already been promised or granted to the research sponsor. This can be a major hindrance to securing investment, since the sponsor would have the possibility of entering the market if the new company shows success with the technology. If the sponsor is in a completely different market from that of the new company, and is very unlikely to make a competing product, this hindrance may be acceptable. Or, with great difficulty, the TTO may bargain with the sponsor to give up its nonexclusive license in return for other considerations

Exclusive licenses usually include the right to sublicense, an important consideration for a biotech company that will likely seek development and/or marketing partnerships with pharmaceutical companies. Exclusive licenses usually also include the right of the licensee to sue infringers (in conjunction with the patent owner). Nonexclusive licenses usually do not carry sublicensing rights (although there are exceptions), nor can a nonexclusive licensee sue infringers of the patent.

Non-exclusive licenses

These usually confer only the right to practice under the patent, with no protection from competitors. Essentially, the nonexclusive licensee is paying only for the right *not* to be sued for infringing the patent. Nonexclusive licenses may be acceptable if the company has other patents protecting its products or other barriers to competitions. Royalty rates are often lower than for an exclusive license and development milestones less demanding (or nonexistent). Sometimes the university may be reluctant to grant a nonexclusive license if it believes there may be an exclusive licensee who will be willing to commit to developing the product. Even a single nonexclusive license will "handicap" the patent, making it more difficult for the later "almost exclusive" licensee to attract investors. Under these circumstances, if a nonexclusive license is granted at all, the royalties may be high so as to compensate the patent owner for the handicap.

As discussed above, nonexclusive licenses do not usually allow sublicensing. The company should be strategic about potential partnerships, and bargain for the right to sublicense in conjunction with a product developed by the company. Alternatively, the university may agree to grant a nonexclusive license to any future partner under reasonable terms.

Field of use

If the patented technology has many different applications, the university may want to limit your license to specific applications. An example is a three-dimensional imaging technique potentially applicable in a wide variety of fields: from automobile designs to imaging of tooth sockets for dental implants. The new company, aiming to operate in the dental field may be willing to accept "all dental applications". However, if the company's expertise is potentially broader, it may bargain with the university for "all medical applications", having in mind, perhaps, imaging of the ear canal for fitting hearing aids.

"Platform" technologies for pharmaceutical development may be applicable to treatment for a number of different diseases. The university may want to limit the license to a single disease, arguing that it is in the best interest of the public to have many different companies producing products under the patent (and in the best financial interest of the patent owner to have multiple products paying royalties.)

However, there are many reasons for the company to argue for a wider field of use:

- If the company is limited to one product (or a single disease state), the fate of the company is "binary" – if the first product fails, the company and the investors' capital dies. The company cannot pivot to a more promising target/disease.

- If success of the patented technology depends on the company also developing complex complementary technology (for example, new delivery technology), that work (and investment) will not be shared in attacking new targets but will instead have to be developed again by the other licensee(s). This is both wasteful and, in the case of very complex complementary technology, the effort to develop it may not be justified by the sales potential of a single product.

- Having a license to a range of disease states allows the new company to form partnerships with other companies, sharing not only the patent, but the complementary technology and know-how it develops.

- Sophisticated investors will often insist on the company having a relatively broad field of use to its licenses, conscious of the disadvantages of licenses restricted to a single disease.

Royalties

Negotiation of royalties is a classic bargaining situation, with the university wanting to maximize its income and the company wanting to pay as little as possible. For early stage technology, it is usually impractical (if not impossible) to calculate the full value of the patent at the time of licensing. Neither the number of products to be sold, nor price, nor cost of manufacture are known. Also, the time and cost of development cannot be estimated with any degree of accuracy, and the probability of success is anyone's guess. Thus, classic calculations of Net Present Value (NPV) are probably not worth doing. As a result, university patents are not usually "sold" for a one-time fee, but are instead licensed under a time-dependent mixture of payments.

Most biotech royalty payments are based on "comparables" – either what the university has successfully gotten before (assuming they have sufficient experience to be representative); what others have negotiated (available from various databases), or what the company believes to be reasonable, with the university accepting the company's offer, the latter being uncommon.

The types of royalties to be paid for a typical biotech license from a university are listed in What you should know as an inventor, above. From the company's point of view, its preferences in trade-offs between types of payment and timing vary with circumstances.

"Upfront" payment (License Fee)

If the company is cash-constrained at the time of licensing (for example, having only seed capital at the time of the license). If so:

- Can the initial License Fee be delayed? (Until a certain amount of capital is raised, and/or a certain date?)

- Can payment of patent costs (particularly costs incurred before the license) be delayed?

- Should the company offer higher running royalties in return for a lower License Fee? (See Payments for sublicensing, below.)

Annual fees ("license maintenance fees")

Probably desirable to try to keep these low in early years, while allowing them to rise over time, when the company will presumably have more cash.

These annual fees may be offset by running royalties, either for the year they are due, or in total (to be negotiated).

Milestone payments

These usually mark events that show that the initial promise of the technology is growing in certainty. These may include initial test results in animals, approval for testing in humans, first test results in humans, Phase II or Phase III clinical trials initiating, and FDA approval for marketing, among other milestones.

The major problem with high "early" milestone payments is that they occur before product is sold and therefore before the company is generating sufficient revenue (if any) to cover heavy milestone payments. Milestone payments need to be negotiated to take this into account, usually growing larger with success in development of products.

Milestone payments may (or may not) be credited against ultimate running royalties on sales.

Running royalties

As mentioned above, running royalties are, by definition, payments that depend on the level of product made or sold. Usually, the royalty in a university license is a percentage of net sales of the licensed product (with exceptions, see What you should know as an inventor, above). A typical range for pharmaceuticals based on "platform" technology is 2–4%. The percentage may be higher if the patent claims cover the specific composition of the product sold. And they may be somewhat higher for medical devices or software.

A critical consideration in a biotech company's negotiation of running royalties for a pharmaceutical product is "head room" for partnering. Most biotech companies will not ultimately be the manufacturer or marketer of the final pharmaceutical; the final product will instead be made and marketed by a larger pharmaceutical partner. The marketing partner will pay a "reasonable" royalty to the biotech company, who must then pay the university. If the university's required royalty is too high, there will not be room for adequate profit for the biotech company to repay itself (and its investors) for the development cost.

Payments related to sublicensing

The situation: the owner of the patent (licensor – the university) grants a license to a biotech company (the licensee), who may grant one or more sublicenses to third parties (sublicenses) to practice under the patent. Sublicensees are expected to pay fees or royalties to the licensee for use of the patent. The original license agreement requires the licensee to share sublicensee revenue with the university. What is owed to the university?

Sublicenses can be divided into two types:

- *"Naked" sublicensing*
  The licensee grants a sublicense only to the patent. Royalty sharing formulas under this circumstance are relatively simple;

the university may ask for just a set percentage of all fees or royalties paid by the sublicensee to the licensee ("X% of all monies paid to licensee for sublicenses"); or the formula may include a combination of a set running royalty on Net Sales plus a fraction of all other payments for the sublicense ("Y% of all monies paid to licensee for sublicenses, with the exception of running royalties" plus "A running royalty of Z% of Net Sales of the Licensed Product sold by the sublicensee")

- *"Bundled sublicensing"*
  Frequently in sublicenses from a biotech company (the licensee) to a pharmaceutical company (sublicensee), the licensed patent is sublicensed in conjunction with a bundle of other assets, including, for example, a developed prototype of a product, details for manufacturing, other patents owned by the company, options to future patents and technology, "know-how" developed by the company, or even clinical trial data. Payments from the sublicensee to the original licensee may include, for example, a license issue fee, money for further research and development by the licensee company, milestone payments of various types, or royalties on sales by the sublicensee. Upfront payments may or may not be credited against royalties.

Coming up with a fair formula in advance of a bundled sublicensing situation (that is, at the time the original license is made) is very difficult. A compromise may be to use the same "pass through" royalty on Net Sales ("Z% of Net Sales whether by licensee or its sublicensee") plus an agreement to negotiate later what portion of the bundle payment is attributable to the Licensed Patent. Thus: "Y% of the fraction of total payments attributable solely to the Licensed Patent when the Patent is sublicensed in conjunction with a license to other assets developed by the company". Such a clause will be followed by additional language clause in the license requiring the parties to meet and negotiate "the fraction attributable" at the time of the sublicense.

Equity

The company may offer, or the university may demand, equity (shares of stock) in the company as one form of payment for the patent. The IRS has ruled that universities may take such payment (in lieu or partial lieu of royalties) without tax consequences for the non-profit university. Although, for other reasons, not all universities (especially not all state universities) are able to accept shares of stock.

Although companies want to retain as much stock as possible for investors and employees, having the university be "partial owners" of the company can be advantageous to the company. The "brand" of the university adds cachet to the company and may help attract investors.

In the absence of cash investment by the university in the company, the stock given to the university is almost always common shares, rather than preferred. Typically, equity "as a form of royalty" is combined with cash running royalties and other license fees. As a result, the amount of stock given is relatively small – giving only a small ownership stake in the company (typically two to five percent, with exceptions). Some mild anti-dilution provisions may be included up to a threshold level of total investment in the company.

A substitute for equity: "Change of Control Fee"

Because of the complexity in the negotiation of equity clauses, and undoubtedly because of disappointment when initial equity stakes taken by a university are diluted to miniscule percentage ownership in the company after multiple rounds of investment, some universities are foregoing equity in favor of a "Change of Control Fee". This specifies a payment at the time the company is acquired, or when company shares are listed on a public stock exchange. Typically, it will be a small percentage of the acquisition price of the public market's valuation of the company at the time of its initial public offering.

Essentially, this Change of Control Fee is a "full ratchet anti-dilution clause". Some companies and their investors have been willing to accept it if the percentage is small enough. One percent is a common amount.

Patent prosecution and maintenance

Most universities insist on maintaining control of patent prosecution, with the licensee company reimbursing the university for legal costs and patent office fees for filing and maintenance. The license agreement should specify that the company be copied on correspondence between patent attorneys and the patent office. The company itself should also keep the university regularly updated during patent prosecution on any of its results that might be useful in the prosecution.

The choice of in which countries to file and maintain patents is most commonly a joint decision between the licensee and the university reflecting future sales plans of the company. Patents in some companies may be abandoned by mutual consent if costs are no longer justified. If the license involves a number of patents, certain of them may no longer be relevant to the company, and the company may wish to remove some of them from the license to avoid future costs.

Reimbursement for patent costs

This is usually non-negotiable for exclusive licenses. The university TTO needs to recycle what it spends on patents so as to be able to support new inventions and to maintain patents that have not yet been licensed. However, the university often distinguishes between "back costs" (expenditures before an option or license is granted) and "going forward costs". "Going forward costs" must be reimbursed promptly (otherwise, the TTO is essentially investing in your company). But "back costs" may sometimes be delayed until the new company raises capital (or by a date certain in the future, whichever comes first).

Diligence and performance milestones

When a university grants an exclusive license to a patent, it wants to assure that the licensee has the will and the resources to develop the product. In the case of exclusive licenses to Federally funded technologies, the university is required by law to monitor diligence during the drug development process. The "Diligence" section of the license agreement sets forth development milestones and dates by which they must be achieved. If the dates are not met (and the default not remedied by a "cure period" specified in the license agreement) the university may have the right (but not the obligation) to terminate the license or to render it nonexclusive.

For simple device technologies (unusual for biotechnology patents) the development milestones may include (with dates specified) the following:

- First working prototype.
- First use on large animals.
- First use on humans.
- First approval for marketing.
- First commercial sales, and may even specify minimum dollars of sales by a certain date.

But for university-stage biotechnology patents, these milestones are impractical because of the early stage of the technology and the many years that will pass before a product is available to the market. This is particularly true for platform technology where the composition of the first product may not even be known. The university and the company must work together to devise surrogate milestone markers that show that the company is making progress. These milestones may include, for example, experiments that demonstrate the applicability of the technology for curing a certain disease or other relevant scientific progress. Frequently, the milestones also include business progress, including, for example:

- Raising investment: Company shall raise $X million in investment capital by [Date 1} and an additional $Y million in investment capital by [Date 2]. Achievement in raising capital shows first that sophisticated investors have examined the company and found it and its products to be promising ("market approval") and that the company has enough monetary resources to move ahead at an acceptable pace.

- And/or: "By {Date 3] Company shall be employing a minimum of "Z" full time employees devoted directly to the development and/or manufacturing of a Licensed Product."

- Or: "Company shall form a *bona fide* partnership with a major pharmaceutical by [Date 4] for the development and marketing of a Licensed Product."

- For platform technologies which will be used by third parties for development of product: "By [Date 5] Company shall achieve "X" *bona fide* sublicenses at reasonable commercial rates for development of Licensed Products."

Such diligence milestones need to have sufficient time built into them that the company is most likely to achieve them. It is to neither party's advantage to have the company fail to meet unrealistic milestones.

Term and termination

University patent licenses are most commonly for the stated term of the patent ("until the last to expire of the licensed patents") unless sooner terminated by either party. (Some agreements include a license to the university's know-how or other proprietary information which may extend royalty obligations further, but those licenses are beyond the scope of this chapter.)

The licensee (company) can usually terminate the license at any time. However, the university can terminate during the term of the patent only if the company breaches the agreement. Termination for cause by the university usually requires notification by the university and a cure period during which the company may be able and willing to cure the breach.

Warranties

Universities cannot warrant that their technology will work. They are not selling or licensing products *per se*, but only access to the patent rights for potential commercializable products. They cannot warrant that the patent rights are valid, or even that the claims of pending patents will issue.

The university also cannot warrant that practice under the licensed patent will not infringe another's patent; they simply don't know – and "freedom of action" opinions from qualified attorneys are too expensive for a university to purchase. A large university cannot even warrant that a licensed patent will not infringe any of the patents that the university itself owns; again, it simply doesn't know.

That said, the company may ask for a university statement that, to the best of TTO's knowledge at the time of the license, practice under the licensed patent will not infringe any of the university's other patents extant. Such assurance will be done only on a good-faith basis, since the TTO will have limited knowledge, and no guarantees can be made. The same assurance may be requested from the inventors of the licensed patents with respect to their own patents.

Indemnification

Indemnification of the university by the company is an absolute requirement in almost all licenses. If something goes wrong in the development or use of the product, the company's insurance must protect the university from paying to defend itself, or from damages assessed. The indemnification clause is a "non-negotiable" clause insisted on by the university's central legal office.

A company should not waste time fighting these clauses, with one exception: product liability insurance for medical products used on humans can be very expensive – and very burdensome to a young company. Some universities will allow the company to delay buying such insurance until just before the first use of the product on humans

Use of names clause

Universities are very protective of their brand. Although they are often very proud of the new companies formed from their research and intellectual property, they normally do not want their names used in conjunction with commercial entities. Product liability risks may increase, and university reputations can be damaged. They also do not want to be seen as favoring any one commercial entity over another, and any hint of product endorsement by the university will likely be met with vehement objection.

Company names and product names and logos that refer to the university name or its logos are usually forbidden and "clever workarounds" can induce hostility. Mention of the university in press releases from the company or on company websites must have prior approval from the university. Violation of the "non-use of names" clauses can be a breach of the license agreement, and result in termination of the license.

In return for these protective requirements, the university will agree to give the same courtesies to the company and will keep the actual terms of the license confidential, except to the extent that may be required by law.

A final note: Taking care of the company's license

An exclusive license to a major asset of the company – sometimes the only concrete asset that a new company owns. It is a long-lived asset, which may change over time, depending on circumstances. Good licensing practice involves an annual review of the license, always with a view toward its future use, especially in a merger.

Annual fees, royalty reports and required progress reports should be docketed. A regularly scheduled, annual, or at least biennial, discussion with the TTO allows for the effective maintenance of the relationship and can head off future misunderstandings. A license agreement with a university is a long-term partnership which needs to be nurtured.

SPONSORING RESEARCH AT THE UNIVERSITY: IMPORTANT TERMS OF THE AGREEMENT

Universities have resources that a new company may not have: laboratories, specialized equipment, and highly skilled manpower (including a faculty member who may be one of the inventors). Collaborative research with the university laboratory from which the invention arose offers a relatively inexpensive opportunity to carry out further research and early development of the technology.

Some universities allow such collaboration, and sometimes even require a certain amount of research support as part of the license agreement. Other universities have conflict of interest regulations that forbid such collaborations if either the faculty member or the university own equity in the sponsoring small company.

With those universities which allow such collaborations, the research will be governed by a Sponsored Research Agreement which may be administered by the TTO or by the Grants and Contracts office of the university. (This discussion does not cover certain kinds of "contract research" where the work is specified by the company with a set protocol, such as in clinical trials for regulatory approval, or tests done in specialized testing laboratories of the university).

Relevant terms of the sponsored research agreement

- *Principal investigator*
  Research projects at universities are usually planned and carried out under the supervision of the Principal Investigator (usually a professor or very senior scientist). His or her technical knowledge in the topic of the research and, equally important, his or her interest in the project are critical for success. The principal investigator defines the work plan and supervises other students or employees working on it. The sponsor usually has the right to terminate the agreement if the Principal Investigator is no longer available to work on it and the university and sponsor cannot agree on a replacement.

- *Work plan*
  Major universities will usually require that the work to be done has "academic value" – suitable for graduate students and potentially publishable. The work plan is specified by the principal investigator and results are on a "best reasonable efforts" basis.

- *Confidentiality*
  Most major universities will strictly limit confidentiality terms, in the interest of an "open environment" in which investigators can freely talk to each other. (This is particularly important for students.) And almost all academic research institutions will insist on the right to publish results promptly. A certain period of withholding from publication (beyond that needed in order to file patents on any inventions) may or may not be allowed.

- *Publication*
  As noted above, most major US universities insist on the right to publish their research results A review period for the sponsor to identify patentable inventions is granted, as is the sponsor's

right to require deletion of confidential material that originated with the sponsor. Most will not allow the sponsor to otherwise limit the contents of the publication emanating from the university.

- *Costs*
  Costs of the research will involve "direct costs" attributable directly to the sponsored program: salaries, benefits, research reagents, travel, and the like, plus overhead costs (indirect costs such as heat, light, administrative costs, etc.). Research Universities in the US each have a Federal Government-audited, indirect research cost rate unique to that university government. The Federal government does not cover the overhead of the whole research enterprise, but only the fraction of research attributable to government-sponsored programs. The result is that the audited overhead is expressed as a percentage added to the direct costs of each product and is known as the "indirect cost rate". Indirect cost rates vary greatly between universities, varying between 40% and 90%, depending on the infrastructure of the university.

  The total cost of a project (excluding any major pieces of equipment) will be the direct cost plus the indirect cost. Thus, a project with direct costs of $100,000 and an indirect cost rate of 60% will have a total cost of $160,000.

  – Are overhead rates negotiable? Most universities will use the same, government-audited indirect cost rate for industrially-sponsored research. Most of the major universities will not negotiate lower overhead rates for industry because the university must cover any shortfall in total overhead with its own funds, effectively subsidizing the private company's development. But there are occasional exceptions.

- *Intellectual Property*
  Although policies on IP granted to industrial research sponsors vary among universities (as will be discussed in this section)

the policies within a given university are not changeable by negotiation. An astonishing amount of effort (and money to lawyers) is wasted in research agreement negotiation when companies try to get a university to change an unchangeable policy. Universities are extremely reluctant to make exceptions for one sponsor, since the exceptions will rapidly spread to all, and the negotiating TTO or other administrators lack the authority to grant such exceptions. It therefore behooves the company to explore on the university's website and perhaps by good faith discussions what the policies are – and which terms are negotiable and which are absolute.

Most universities will require that patents on inventions made by university staff under a sponsored research agreement will be assigned to the university. A few will allow the sponsor to own patents arising from the research in return for paying a premium indirect cost rate on the research or will grant a royalty-free exclusive license. But these are rare exceptions.

For the vast majority of universities that retain ownership of such patents, a variety of options to licenses are granted to the sponsor. Among the variations granted (differing by university) are:

– Nonexclusive license for research only; usually royalty free with no costs.

– Nonexclusive licenses for commercial use, royalty free.

– Nonexclusive license for commercial use, royalty free if the sponsor pays the patenting costs.

– Nonexclusive license with royalty to be negotiated.

– Exclusive license with field of use; royalties and fees; and diligence requirements to be negotiated.

Upon request by the sponsoring company, some universities are able to pre-negotiate royalties for the patents which may arise from the sponsored research; others are constrained by certain IRS rules on research done in buildings supported by tax-free bonds. However, even for those universities able to pre-negotiate royalties, the process can be very frustrating for both the university and the sponsor since they are negotiating for a yet-to-be-invented patent whose characteristics and utility are not currently known. Compromise and trust on both sides are needed to reach a well-balanced agreement given the vagaries involved.

Use of names

See Use of names clause, above. Restrictions on use of the company's name in research collaboration agreements usually mirrors those in license agreements.

Final note on sponsored research

Sponsorship of research at a university is very different from development or testing agreements with commercial laboratories; it is not just "work for hire" and the direction of the work plan can change based on experimental results. Success to the sponsor's satisfaction often depends on a personal relationship between the principal investigator and the company. Written progress reports are required by the research agreement, but supplementing these with frequent meetings between the university team (particularly the principal investigator) and senior technical and management personnel will usually vastly enhance the value of the research. The company should appoint a project liaison person with technical knowledge and substantial interest in the program to keep in touch with the university team; and the company should be very wary of skimping on the travel budget if they are not in the same city as the university.

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APPENDIX 1 EXCLUSIVE PATENT LICENSE AGREEMENT

[NAME OF UNIVERSITY]

[NAME OF COMPANY]

Note: This license agreement template is given as an example. It is not to be construed as legal advice, and the author makes no warranty that it is fit for use.

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EXCLUSIVE PATENT LICENSE AGREEMENT

This Agreement, effective as of [date] (the "EFFECTIVE DATE"), is between the [full name of University], a [state of incorporation of the university] non-profit corporation, with a principal office at [university address] and ______________________________ ("COMPANY"), a [state of incorporation] with a principal place of business at ______________________________________.

RECITALS

WHEREAS, [University] is the owner of certain PATENT RIGHTS (as later defined herein) relating to [University] Case No. _______, "________________________" by __________________ and has the right to grant licenses under said PATENT RIGHTS; and

WHEREAS, [University] desires to have the PATENT RIGHTS developed and commercialized to benefit the public and is willing to grant a license hereunder; and

WHEREAS, COMPANY has represented to [University], to induce [University] to enter into this Agreement, that COMPANY shall commit itself to a thorough, vigorous and diligent program of exploiting the PATENT RIGHTS so that public utilization shall result therefrom; and

WHEREAS, COMPANY desires to obtain a license under the PATENT RIGHTS upon the terms and conditions hereinafter set forth; and

NOW, THEREFORE, [University] and COMPANY hereby agree as follows:

1. DEFINITIONS

1.1 "AFFILIATE" shall mean any legal entity (including, but not limited to, a corporation, partnership, or limited liability company) that is controlled by COMPANY. For the purposes of this definition, the term "control" means (i) beneficial ownership of at least fifty percent (50%) of the voting securities of a corporation or other business organization with voting securities or (ii) a fifty percent (50%) or greater interest in the net assets or profits of a partnership or other business organization without voting securities.

1.2 "COVERED" shall mean, with respect to a given product, process, method or service, that a claim of the PATENT RIGHTS would (absent a license thereunder or ownership thereof) be infringed by the making, using, selling, offering for sale, importation or other exploitation of such product, process, method or service. With respect to a claim of a pending patent application, "infringed" refers to activity that would infringe or be covered by a claim of the PATENT RIGHTS if it were contained in an issued patent.

1.3 "FIELD" shall mean [insert Field of Use].

1.4 "LICENSED PRODUCT" shall mean any product that, in whole or in part:

(a) is COVERED by one or more issued, unexpired claims or pending claims of the PATENT RIGHTS; or

(b) is manufactured by using a LICENSED PROCESS or that, when used, practices a LICENSED PROCESS.

1.5 "LICENSED PROCESS" shall mean any process that, in whole or in part:

(a) is COVERED by one or more issued, unexpired claims or pending claims of the PATENT RIGHTS; or

(b) which uses a LICENSED PRODUCT.

1.6 "NET SALES" shall mean the gross amount billed by COMPANY and, as applicable, its AFFILIATES, SUBLICENSEES, agents or distributors, for LICENSED PRODUCTS and LICENSED PROCESSES, less the following:

(a) customary trade, quantity, or cash discounts to the extent actually allowed and taken;

(b) amounts repaid or credited by reason of rejection or return;

(c) to the extent separately stated on purchase orders, invoices, or other documents of sale, any taxes or other governmental charges levied on the production, sale, transportation, delivery, or use of a LICENSED PRODUCT or LICENSED PROCESS which is paid by or on behalf of COMPANY; and

(d) to the extent separately stated on invoices, outbound transportation costs prepaid or allowed and costs of insurance in transit.

No deductions shall be made for commissions paid to individuals whether they be with independent sales agencies or regularly employed by COMPANY and on its payroll, or for cost of collections. NET SALES shall occur on the date of billing for a LICENSED PRODUCT or LICENSED PROCESS. If a LICENSED PRODUCT or a LICENSED PROCESS is distributed at a discounted price that is substantially lower than the customary price charged by COMPANY, or distributed for non-monetary consideration (whether or not at a discount), NET SALES shall be calculated based on the non-discounted amount of the LICENSED PRODUCT or LICENSED PROCESS charged to an independent third party during the same REPORTING PERIOD or, in the absence of such sales, on the fair market value of the LICENSED PRODUCT or LICENSED PROCESS.

Non-monetary consideration shall not be accepted by COMPANY or any SUBLICENSEE for any LICENSED PRODUCTS or LICENSED PROCESSES without the prior written consent of [University].

1.7 “PATENT CHALLENGE” shall mean a legal or administrative challenge to the validity, patentability, scope, or enforceability of any of the PATENT RIGHTS (as defined below) or otherwise opposing any of the PATENT RIGHTS.

1.8 “PATENT RIGHTS” shall mean:

(a) the United States and international patents listed on Appendix A;

(b) the United States and international patent applications and/or provisional applications listed on Appendix A and the resulting patents;

(c) any patent applications resulting from the provisional applications listed on Appendix A, and any divisionals, continuations, continuation-in-part applications, and continued prosecution applications (and their relevant international equivalents) of the patent applications listed on Appendix A and of such patent applications that result from the provisional applications listed on Appendix A, to the extent the claims are directed to subject matter specifically described in the patent applications listed on Appendix A, and the resulting patents;

(d) any patents resulting from reissues, reexaminations, or extensions (and their relevant international equivalents) of the patents described in (a), (b), and (c) above; and

(e) international (non-United States) patent applications and provisional applications filed after the EFFECTIVE DATE and the relevant international equivalents to divisionals, continuations, continuation-in-part applications and continued prosecution applications of the patent applications to the extent the claims are directed to subject matter specifically described in the patents or patent applications referred to in (a), (b), (c), and (d) above, and the resulting patents.

1.9 "REPORTING PERIOD" shall begin on the first day of each calendar quarter and end on the last day of such calendar quarter.

1.10 "SUBLICENSE INCOME" shall mean payments received as consideration for any sublicense granted pursuant to this Agreement, including without limitation license fees, milestone payments and bonus payments, license maintenance fees, and other payments, but specifically excluding royalties on NET SALES payable under [insert appropriate Section number].

1.11 "SUBLICENSEE" shall mean any entity that has been granted a sublicense of the rights granted to COMPANY under Section 2.1 of this Agreement. For clarity, a sublicense shall include, without limitation: (i) any right granted, license given or agreement entered into by COMPANY to or with another person or entity, under or with respect to or permitting any use of the PATENT RIGHTS or otherwise granting rights to such person or entity pursuant to this Agreement; (ii) any option or other right granted by COMPANY to any other person or entity to negotiate for or receive any of the rights described under clause (i); or (iii) any standstill or similar obligation undertaken by COMPANY toward another person or entity not to grant any of the rights described in clause (i) or (ii) to any third party, in each case regardless of whether such grant of rights, license given or agreement entered into is referred to or is described as a sublicense.

1.12 "TERM" shall mean the term of this Agreement, which shall commence on the EFFECTIVE DATE and shall remain in effect until the expiration or abandonment of all issued patents and filed patent applications within the PATENT RIGHTS, unless earlier terminated in accordance with the provisions of this Agreement.

1.13 "TERRITORY" shall mean [insert territory or "world-wide"].

2. GRANT OF RIGHTS

2.1 License Grants. Subject to the terms of this Agreement, [University] hereby grants to COMPANY for the TERM an exclusive (subject to 2.4, below) equity and royalty-bearing license under the PATENT RIGHTS to develop, make, have made, use, sell, offer to sell, lease, and import LICENSED PRODUCTS in the FIELD in the TERRITORY and to develop and perform LICENSED PROCESSES in the FIELD in the TERRITORY.

2.2 Sublicenses. So long as COMPANY remains the exclusive licensee of the PATENT RIGHTS in the FIELD, COMPANY shall have the right to grant sublicenses of its rights under Section 2.1. COMPANY shall not extend this right to its SUBLICENSEES. COMPANY shall incorporate terms and conditions into its sublicense agreements sufficient to enable COMPANY to comply with this Agreement. COMPANY shall also include provisions in all sublicenses to provide that in the event that SUBLICENSEE brings a PATENT CHALLENGE against [University] or assists another party in bringing a PATENT CHALLENGE against [University] (except as required under a court order or subpoena) then COMPANY may terminate the sublicense. Non-monetary consideration shall not be accepted by COMPANY for any sublicense hereunder without the prior written consent of [University]. COMPANY shall promptly furnish [University] with a copy of each executed sublicense and any amendments thereto and, also, shall report each executed sublicense and relevant amendment to [University] as required under Section 5.1. Upon termination of this Agreement for any reason, any SUBLICENSEE not then in default shall have the right to seek a license from [University]. [University] agrees to negotiate such licenses in good faith under reasonable terms and conditions. For the avoidance of doubt, in the event that any rights granted to COMPANY under this Agreement become nonexclusive, the exclusivity of any such sublicense shall expire.

2.3 U.S. Manufacturing. COMPANY agrees to comply with the applicable requirements of 35 U.S.C. §204 "Preference for United States Industry", as amended, or any successor statutes or regulations.

2.4 Retained Rights.

(a) Research and Educational Use. [University] retains the right on behalf of itself and all other non-profit research institutions to practice under the PATENT RIGHTS for research, teaching, and educational purposes.

(b) Federal Government. COMPANY acknowledges that the U.S. federal government retains a royalty-free, non-exclusive, non-transferable license to practice any government-funded invention claimed in any PATENT RIGHTS as set forth in 35 U.S.C. §§201–211, and the regulations promulgated thereunder, as amended, or any successor statutes or regulations.

(c) Sponsor Rights. The invention underlying the PATENT RIGHTS was based on research supported by _____________ (the "SPONSOR"). COMPANY acknowledges that SPONSOR has been granted a non-exclusive, non-transferable, royalty-free license to practice any invention claimed in the PATENT RIGHTS for internal research purposes.

2.5 No Additional Rights. Nothing in this Agreement shall be construed to confer any rights upon COMPANY by implication, estoppel, or otherwise as to any technology, patent, or other rights of [University] or any other entity other than the PATENT RIGHTS, regardless of whether such technology or patent rights shall be dominant or subordinate to any PATENT RIGHTS.

3. COMPANY DILIGENCE OBLIGATIONS

3.1 Diligence Requirements. COMPANY shall use diligent efforts to develop LICENSED PRODUCTS or LICENSED PROCESSES and to introduce LICENSED PRODUCTS or LICENSED PROCESSES into the commercial market; thereafter, COMPANY shall make LICENSED PRODUCTS or LICENSED PROCESSES reasonably available to the public. Specifically, COMPANY shall fulfill the following obligations:

(a) Within _____ months after the EFFECTIVE DATE, COMPANY shall furnish [University] with a written research and development plan describing the major tasks to be achieved in order to bring to market a LICENSED PRODUCT or a LICENSED PROCESS, specifying the number of staff and other resources to be devoted to such commercialization effort.

(b) Within sixty (60) days after the end of each calendar year, COMPANY shall furnish [University] with a written report (consistent with Section 5.1) on the progress of its efforts during the immediately preceding calendar year to develop and commercialize LICENSED PRODUCTS or LICENSED PROCESSES, with specific reference to the diligence obligations required under this Section 3.1. The report shall also contain a discussion of intended efforts and sales projections for the year in which the report is submitted.

(c) [OPTIONAL]COMPANY shall develop a working model on or before __________, 201___, and permit an in-plant inspection by [University] on or before __________, 201___, and thereafter permit in-plant inspections by [University] at regular intervals with at least ______ (   ) months between each such inspection.

(d) [OPTIONAL] COMPANY shall raise at least __________ Dollars ($____________) by ________, 201___ from the sale of COMPANY's equity securities for its own account.

(e) [OPTIONAL]In the aggregate, COMPANY shall raise at least __________ Dollars ($______) by ________, 201__ from the sale of Company's equity securities for its own account.

(f) [OPTIONAL]COMPANY shall fund no less than ________ Dollars ($_________) of research toward the development of LICENSED PRODUCTS and/or LICENSED PROCESSES in each calendar year (pro-rated for partial years) beginning in 201____ and ending with the first commercial sale of a LICENSED PRODUCT or a first commercial performance of a LICENSED PROCESS.

(g) [OPTIONAL] COMPANY shall enter into at least one (1) partnership agreement for development and commercialization of LICENSED PRODUCTS or LICENSED PROCESSES on or before __________, 201___.

(h) [OPTIONAL]COMPANY shall make a first commercial sale of a LICENSED PRODUCT and/or a first commercial performance of a

LICENSED PROCESS on or before ________, 201___ and shall notify [University] in writing within thirty (30) days of such first commercial sale or first performance.

(i) [OPTIONAL]COMPANY shall make NET SALES according to the following schedule:

_____		$_________;
_____		$_________;
_____	and each year thereafter	$_________.

(j) [OPTIONAL]COMPANY shall sell the following numbers of LICENSED PRODUCTS according to the following schedule:

201___		_________ units;
201___		_________ units;
201___	and each year thereafter	_________ units.

3.2 Material Breach, Right to Cure. In the event that [University] determines that COMPANY has failed to fulfill any of its obligations under this Section 3.1, then [University] may treat such failure as a material breach in accordance with Section 12.3(b).

4. ROYALTIES AND PAYMENT TERMS

4.1 Consideration for Grant of Rights.

(a) License Issue Fee and Patent Cost Reimbursement. COMPANY shall pay to [University], within thirty (30) days of invoicing, a license issue fee of [ ]dollars ($#) and, in accordance with Section 6.3, shall reimburse [University] for its actual expenses incurred as of the EFFECTIVE DATE in connection with obtaining the PATENT RIGHTS. These payments are nonrefundable.

(b) License Maintenance Fees. COMPANY shall pay to [University] the following license maintenance fees on the dates set forth below:

[January 1, year]	[dollar amount]
[January 1, year]	[dollar amount]
[and each January 1 of every year thereafter]	[dollar amount]

This annual license maintenance fee is nonrefundable; however, the license maintenance fee may be credited to running royalties subsequently due on NET SALES earned during the same calendar year, if any. License maintenance fees paid in excess of running royalties due in such calendar year shall not be creditable to amounts due for future years.

(c) Running Royalties. COMPANY shall pay to [University] a running royalty of [number] percent (#%) of NET SALES [OPTIONAL: "whether sold by LICENSEE or any SUBLICENSEE"] Running royalties shall be payable for each REPORTING PERIOD and shall be due to [University] within sixty (60) days of the end of each REPORTING PERIOD.

(d) Milestone Payments. COMPANY shall pay to [University] the amounts set forth below upon the achievement by COMPANY or its SUBLICENSEES of certain milestone events as described below.

Milestone Event	Payment
______________________________	$#
______________________________	$#
______________________________	$#

COMPANY shall notify [University] within thirty (30) days of the achievement of any of the above milestones by COMPANY or its SUBLICENSEES, such notice to specifically identify the payment obligation. Payments will be due in respect of the achievement of the milestone events in the tables above for each LICENSED PRODUCT. Such amounts shall be payable for each REPORTING PERIOD, shall be both non-creditable and non-refundable, and shall be due to [University] within sixty (60) days of the last day of the REPORTING PERIOD.

The milestone events set forth above are intended to be successive. In the event that any milestone is reached without achieving a preceding milestone, then the amount which would have been payable on achievement of the preceding milestone shall also be payable upon achievement of the next successive milestone.

(e) Sharing of SUBLICENSE INCOME. COMPANY shall pay [University] a total of XX (XX%) of all SUBLICENSE INCOME [OPTIONAL: "excluding Running Royalties, which are to be paid in accordance with Section 4.1(c0} Such amount shall be payable for each

REPORTING PERIOD and shall be due to [University] within sixty (60) days of the end of each REPORTING PERIOD.

(f) Consequences of a PATENT CHALLENGE. In the event that: (i) COMPANY or any of its AFFILIATES brings a PATENT CHALLENGE against [University] ; or (ii) COMPANY or any of its AFFILIATES assists another party in bringing a PATENT CHALLENGE against [University] (except as required under a court order or subpoena); and [University] does not choose to exercise its rights to terminate this Agreement pursuant to Section 12.4, then all payments due under this Article 4 shall be doubled for the remainder of the TERM. In the event that such a PATENT CHALLENGE is successful, COMPANY will have no right to recoup any payments made during the period of challenge. In the event that a PATENT CHALLENGE is unsuccessful, COMPANY shall reimburse [University] for all reasonable legal fees and expenses incurred in its defense against the PATENT CHALLENGE.

(g) No Multiple Royalties. If the manufacture, use, lease, or sale of any LICENSED PRODUCT or the performance of any LICENSED PROCESS is covered by more than one of the PATENT RIGHTS, multiple royalties shall not be due.

4.2 Payments.

(a) Invoices. All invoices issued by [University] under this Agreement shall be addressed to COMPANY as follows, or as otherwise provided by COMPANY in writing to [University]:

insertcompanyname
addressline1
addressline2
addressline3
Attention to:
emailaddress

(b) Method of Payment. All payments under this Agreement shall be made payable to "[University]" and sent to the address identified on the invoice received. Each payment should reference this Agreement and identify the obligation under this Agreement that the payment satisfies. Payments shall be sent to:

[name and address of university, ATTN: [Person, Department, local address]

(c) Payments in U.S. Dollars. All payments due under this Agreement shall be drawn on a United States bank and shall be payable in United States dollars. Conversion of foreign currency to U.S. dollars shall be made at the conversion rate existing in the United States (as reported by the Federal Reserve Bank of St. Louis) on the last working day of the calendar quarter of the applicable REPORTING PERIOD. Such payments shall be without deduction of exchange, collection, or other charges, and, specifically, without deduction of withholding or similar taxes or other government imposed fees or taxes, except as permitted in the definition of NET SALES.

(d) Taxes. In the event that any payment under this Agreement is or becomes subject to any levy or tax, including, but not limited to any form of tax withholding, income tax, service tax, sales tax or VAT, by local, regional or federal government authorities, COMPANY shall (i) pay to the applicable tax authorities, whether on its own or [University]'s behalf, such amount of levy or tax and, if applicable, penalties and interest; and (ii) promptly provide [University] with a copy of the withholding tax certificate or other tax filing documentation evidencing remittance was made. For the avoidance of doubt, any payments made by or on behalf of COMPANY pursuant to this Section 4.2(d) shall not be deducted from any amounts due to [University] under this Agreement.

(e) Late Payments. Any payments by COMPANY that are not paid on or before the date such payments are due under this Agreement shall bear interest, to the extent permitted by law, at five (5) percentage points above the Prime Rate of interest as reported by the Federal Reserve Bank of St. Louis on the last business day of the calendar quarterly reporting period to which such royalty payments relate.

5. REPORTS AND RECORDS

5.1 Progress Reports. COMPANY shall deliver progress reports to [University] annually, within sixty (60) days of the end of each calendar year, sufficient to illustrate compliance with this Agreement and specifically discussing:

(a) the progress of efforts to develop and commercialize LICENSED PRODUCTS or LICENSED PROCESSES, with specific reference to the diligence obligations set forth under Article 3;

(b) the number of sublicenses active during the applicable calendar year as well as an updated list of all sublicenses, and amendments thereto, executed during the applicable calendar year (and copies thereof to the extent not already provided);

(c) a summary of the milestones achieved, as relevant to Section 4.1(e); and

(d) COMPANY's current Certificates of Insurance, in accordance with Section 8.2.

5.2 Royalty Reports. COMPANY's obligation to submit reports under this Section 5.2 shall commence upon the earlier of: (i) the date of execution of the first sublicense agreement for any of the PATENT RIGHTS; (ii) the date of first achievement of a Milestone Event under Section 4.1(e); or (iii) a first commercial sale or performance. Thereafter, COMPANY shall deliver royalty reports to [University] within sixty (60) days of the end of each REPORTING PERIOD, containing at least the following information for the immediately preceding REPORTING PERIOD:

(a) the number of LICENSED PRODUCTS sold, leased or distributed by COMPANY, its AFFILIATES and SUBLICENSEES to independent third parties in each country, and, if applicable, the number of LICENSED PRODUCTS used by COMPANY and SUBLICENSEES in the provision of services in each country;

(b) a description of LICENSED PROCESSES performed by COMPANY and SUBLICENSEES in each country as may be pertinent to a royalty accounting hereunder;

(c) a description of the Milestone Event achieved, with reference to the payment due pursuant to Section 4.1(e);

(d) the gross price charged by COMPANY and SUB-LICENSEES for each LICENSED PRODUCT and, if applicable, the gross price charged for each LICENSED PRODUCT used to provide services in each country; and the gross price charged for each LICENSED PROCESS performed by COMPANY and SUB-LICENSEES in each country;

(e) calculation of NET SALES for the applicable REPORTING PERIOD in each country, including a listing of applicable deductions;

(f) total royalty payable on NET SALES in U.S. dollars, together with the exchange rates used for conversion; and

(g) the amount of SUBLICENSE INCOME received by COMPANY from each SUBLICENSEE and the amount due to [University] from such SUBLICENSE INCOME, including an itemized breakdown of the sources of income comprising the SUBLICENSE INCOME.

(h) If no amounts are due to [University] for any REPORTING PERIOD, the report shall so state.

5.3 Financial Statements. On or before the ninetieth (90th) day following the close of COMPANY's fiscal year, COMPANY shall provide [University] with COMPANY's financial statements for the preceding fiscal year including, at a minimum, a balance sheet and an income statement, certified by COMPANY's treasurer or chief financial officer or by an independent auditor.

5.4 Records. COMPANY and its agents, as applicable, shall keep, in accordance with generally accepted accounting principles, up-to-date, complete, true and accurate books of account in sufficient detail to permit calculation of all amounts due hereunder, including without limitation, copies of all invoices, which will be properly itemized. [University], or [University]'s appointed agents, shall have the right, at [University]'s expense, to audit all existing and relevant records for all prior periods to the extent necessary to perform an audit. COMPANY shall fully cooperate with such audit and shall permit [University], or [University]'s agents, to inspect and copy such portions of books and records that [University] deems appropriate and necessary. Books of account and supporting records shall be retained for at least seven (7) years following the later of (i) the end of the REPORTING PERIOD to which they pertain, or (ii) the end of the calendar year in which any request for an audit under this Section is made. In the event that any audit performed under this Section reveals an underpayment in excess of the lesser of (i) three percent (3%) for the audited period or any REPORTING PERIOD or (ii) Twenty Five thousand dollars ($25,000), COMPANY shall bear the full cost of such audit and shall remit any amounts due to [University] within thirty (30) days of receiving notice thereof from [University]. The parties agree that all applicable statutes of limitation and time-based defenses (including, but not limited to, estoppel and laches) shall be tolled upon any request by [University] for an audit under this Section. The parties shall cooperate in taking any actions necessary to achieve this result.

6. PATENT PROSECUTION

6.1 Responsibility for PATENT RIGHTS. [University] shall prepare, file, prosecute, and maintain all of the PATENT RIGHTS; COMPANY shall cooperate with [University] in such filing, prosecution and maintenance. [University] shall instruct its patent counsel to copy COMPANY on all patent prosecution documents relating to the PATENT RIGHTS and shall provide COMPANY a reasonable opportunity, if time permits, to review and comment on such materials. [University] shall consider in good faith any comments received from COMPANY relating to the filing, prosecution and maintenance of the PATENT RIGHTS.

6.2 International (non-United States) Filings. Appendix B is a list of countries in which patent applications corresponding to the United States patent applications listed in Appendix A shall be filed, prosecuted, and maintained. Appendix B may be amended by mutual agreement of COMPANY and [University].

6.3 Payment of Expenses. Payment of all fees and costs, including attorneys' fees, relating to the filing, prosecution and maintenance of the PATENT RIGHTS (including without limitation interferences, reexaminations and reissues) shall be the responsibility of COMPANY, whether such amounts were incurred before or after the EFFECTIVE DATE. As of [date] [date] [University] has incurred approximately $__________ for such patent-related fees and costs. COMPANY shall reimburse all amounts due pursuant to this Section within thirty (30) days of invoicing; late payments shall accrue interest pursuant to Section 4.2(e). Infringement and Patent Challenge

6.4 Notification of Infringement. COMPANY agrees to provide written notice to the other party promptly after becoming aware of any infringement of the PATENT RIGHTS in the FIELD.

6.5 Right to Prosecute Infringements.

(a) COMPANY Right to Prosecute. So long as COMPANY remains the exclusive licensee of the PATENT RIGHTS in the FIELD in the TERRITORY, COMPANY, to the extent permitted by law, shall have the right, under its own control and at its own expense, to prosecute any third party infringement of the PATENT RIGHTS in the FIELD in the

TERRITORY, subject to Sections 7.4 and 7.5. If required by law, [University] shall permit any action under this Section to be brought in its name, including being joined as a party-plaintiff, provided that COMPANY shall hold [University] harmless from, and indemnify [University] against, any costs, expenses, or liability that [University] incurs in connection with such action.

Prior to commencing any such action, COMPANY shall consult with [University] and shall consider the views of [University] regarding the advisability of the proposed action and its effect on the public interest. COMPANY shall not enter into any settlement, consent judgment, or other voluntary final disposition of any infringement action under this Section without the prior written consent of [University] .

[University]Right to Prosecute. In the event that COMPANY is unsuccessful in persuading the alleged infringer to desist or fails to have initiated an infringement action within a reasonable time after COMPANY first becomes aware of the basis for such action, [University] shall have the right, at its sole discretion, to prosecute such infringement under its sole control and at its sole expense, and any recovery obtained shall belong to [University].

6.6 Third Party Patent Challenges.

(a) In the event of a PATENT CHALLENGE by a third party, other than as set forth in Section 7.3(b), below, [UNIVERSITY] shall promptly notify COMPANY of the PATENT CHALLENGE and, at COMPANY's request, so long as COMPANY is not in default of any obligations under this Agreement, [University] may defend the PATENT RIGHTS at COMPANY's sole expense. If COMPANY does not so request, [University] shall have the right, but not the obligation, to defend the PATENT RIGHTS at its own expense. If COMPANY declines to support the expense of defending the PATENT RIGHTS, or elects to discontinue such support, [University] shall have the right to immediately terminate this Agreement with respect to the PATENT RIGHTS that are the subject of the PATENT CHALLENGE.

(b) In the event that a PATENT CHALLENGE is brought by a defendant in a suit brought by COMPANY against an alleged infringer, COMPANY shall have the first right to defend the PATENT RIGHTS, and shall hold [University] harmless from, and indemnify [University] against, any costs, expenses, or liability that [University] incurs in connection with such action. If COMPANY does not exercise this right, [University] may take over the sole defense of the action at its sole discretion and expense, and if so, (i) [University] shall have the right to immediately terminate this Agreement with respect to the PATENT RIGHT(S) that are the subject of the PATENT CHALLENGE and (ii) any recovery obtained shall belong to [University] .

6.7 Offsets. COMPANY may offset a total of fifty percent (50%) of any expenses incurred under Sections 7.2 and 7.3 against any payments due to [University] under Article 4, provided that in no event shall such payments under Article 4, when aggregated with any other offsets and credits allowed under this Agreement, be reduced by more than fifty percent (50%) in any REPORTING PERIOD.

6.8 Recovery. Any recovery obtained in an action brought by COMPANY under Sections 7.2 or 7.3 shall be distributed as follows: (i) each party shall be reimbursed for any expenses incurred in the action (including the amount of any royalty or other payments withheld from [University] as described in Section 7.4), (ii) as to ordinary damages, COMPANY shall receive an amount equal to its lost profits or a reasonable royalty on the infringing sales, or whichever measure of damages the court shall have applied, and COMPANY shall pay to [University] based upon such amount a reasonable approximation of the royalties and other amounts that COMPANY would have paid to [University] if COMPANY had sold the infringing products, processes and services rather than the infringer, and (iii) as to special or punitive damages, the parties shall share equally in any award.

6.9 Cooperation. Each party agrees to cooperate in any action under this Article which is controlled by the other party, provided that the controlling party reimburses the cooperating party promptly for any costs and expenses incurred by the cooperating party in connection with providing such assistance.

6.10 Right to Sublicense. So long as COMPANY remains the exclusive licensee of the PATENT RIGHTS in the FIELD in the TERRITORY, COMPANY shall have the sole right to sublicense any alleged infringer in the FIELD in the TERRITORY for future use of the PATENT RIGHTS in accordance with the terms and conditions of this Agreement relating to sublicenses. Any upfront fees as part of such sublicense shall be shared equally between COMPANY and [University]; other revenues to COMPANY pursuant to such sublicense shall be treated as set forth in Article 4.

7. INDEMNIFICATION AND INSURANCE

7.1 Indemnification.

(a) Indemnity. COMPANY shall indemnify, defend, and hold harmless [University] and its trustees, officers, faculty, students, employees, and agents and their respective successors, heirs and assigns (the "Indemnitees"), against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses) incurred by or imposed upon any of the Indemnitees in connection with any third party claims, suits, investigations, actions, demands or judgments arising out of or related to the exercise of any right or license granted to COMPANY, its AFFILIATES, and SUB-LICENSEES under this Agreement or any breach of this Agreement by COMPANY.

(b) Procedures. The Indemnitees agree to provide COMPANY with prompt written notice of any claim, suit, action, demand, or judgment for which indemnification is sought under this Agreement. COMPANY agrees, at its own expense, to provide attorneys reasonably acceptable to [University] to defend against any such claim. The Indemnitees shall cooperate fully with COMPANY in such defense and will permit COMPANY to conduct and control such defense and the disposition of such claim, suit, or action (including all decisions relative to litigation, appeal, and settlement); provided, however, that any Indemnitee shall have the right to retain its own counsel, at the expense of COMPANY, if representation of such Indemnitee by the counsel retained by COMPANY would be inappropriate because of actual or potential differences in the interests of such Indemnitee and any other party represented by such counsel. COMPANY agrees to keep [University] informed of the progress in the defense and disposition of such claim and to consult with [University] with regard to any proposed settlement.

7.2 Insurance.

(a) Required Coverage. COMPANY shall obtain and carry in full force and effect commercial general liability insurance and, as applicable to COMPANY's performance with respect to the intellectual property received from [University] pursuant to this Agreement, professional liability insurance, which shall protect COMPANY and Indemnitees with respect to events covered by Section 8.1(a) above. Such insurance shall list [University] as an additional insured thereunder, shall be endorsed to include product liability coverage, and shall require thirty (30) days written notice to be given to [University] prior to any cancellation or material change thereof. The limits of such insurance shall not be less than One Million Dollars ($1,000,000) per occurrence with an aggregate of Two Million Dollars ($2,000,000) for bodily injury including death; One Million Dollars ($1,000,000) per occurrence with an aggregate of Two Million Dollars ($2,000,000) for property damage; and, with respect to any professional liability policy, One Million Dollars ($1,000,000) per occurrence with an aggregate of Two Million Dollars ($2,000,000) for errors and omissions. COMPANY shall provide [University] with Certificates of Insurance evidencing compliance with this Section.

(b) Option to Self-Insure. COMPANY may elect to self-insure all or part of the coverage described above if: (i) COMPANY shall be liable as a self-insurer for the risks that would have otherwise been covered by a commercial policy; (ii) COMPANY continues to earn, throughout the term of this Agreement, net income (as set forth in a certified financial statement) in excess of $100,000,000 per fiscal year (the "Net Income Requirement"); (iii) [University] shall have the right to request and receive either (x) a certified financial statement sufficient to evidence satisfaction of the Net Income Requirement or (y) a certified statement confirming that COMPANY's self-insurance program is sufficient to address the liabilities that could reasonably arise under this Agreement; and (iv) if COMPANY is unable to provide such confirmation, [University] may require that COMPANY purchase sufficient insurance.

8. NO REPRESENTATIONS OR WARRANTIES

EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, [University] MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND CONCERNING THE PATENT RIGHTS, AND HEREBY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANT-ABILITY, FITNESS FOR A

PARTICULAR PURPOSE, NON-INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF [University] OR THIRD PARTIES, VALIDITY, ENFORCEABILITY AND SCOPE OF PATENT RIGHTS, WHETHER ISSUED OR PENDING, AND THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE.

IN NO EVENT SHALL [University], ITS TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES AND AFFILIATES BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING ECONOMIC DAMAGES OR INJURY TO PROPERTY AND LOST PROFITS, REGARDLESS OF WHETHER [University] SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING.

9. ASSIGNMENT

This Agreement is personal to COMPANY. None of the rights or obligations hereunder may be assigned or transferred, whether by merger, consolidation, acquisition or other change of control, without the prior written consent of [University]. Any purported assignment or transfer in violation of the foregoing shall be null and void and of no force and effect.

10. GENERAL COMPLIANCE WITH LAWS

10.1 Compliance with Laws. COMPANY shall, and shall cause its AFFILIATES and SUBLICENSEES as necessary to, use reasonable commercial efforts to comply with all commercially material local, state, federal, and international laws and regulations relating to the development, manufacture, use, and sale of LICENSED PRODUCTS and LICENSED PROCESSES.

10.2 Registration. As required by applicable law, COMPANY shall, and shall cause its AFFILIATES and SUBLICENSEES as necessary to, register or record this Agreement with the relevant government authority. After the completion of the registration and recordation, COMPANY shall provide [University] with documentation of registration and recordation issued by the government authorities with respect to this Agreement. The costs of the registration and filing shall be borne by COMPANY.

10.3 Export Control. COMPANY shall, and shall cause its AFFILIATES and SUBLICENSEES as necessary to, comply with all United States laws and regulations controlling the export of certain commodities and technical data, including without limitation all Export Administration Regulations of the United States Department of Commerce. Among other things, these laws and regulations prohibit or require a license for the export of certain types of commodities and technical data to specified countries. COMPANY hereby gives written assurance that it will comply with, and will cause its AFFILIATES and SUBLICENSEES to comply with, all United States export control laws and regulations, that it bears sole responsibility for any violation of such laws and regulations by itself or its AFFILIATES or SUBLICENSEES, and that it will indemnify, defend, and hold [University] harmless (in accordance with Section 8.1) for the consequences of any such violation.

10.4 Use of [University] Name. COMPANY, its AFFILIATES and SUBLICENSEES shall not use the name of "University" or any variation, adaptation, or abbreviation thereof, or of any of its trustees, officers, faculty, students, employees, or agents, or any trademark owned by [University], or any terms of this Agreement in any promotional material or other public announcement or disclosure without the prior written consent of [University], which consent [University] may withhold in its sole discretion. The foregoing notwithstanding, without the consent of [University], COMPANY may make factual statements during the term of this Agreement that COMPANY has a license from [University] under one or more of the patents and/or patent applications comprising the PATENT RIGHTS in business literature. Such statements may not be used in marketing, promotion, or advertising.

10.5 Marking of LICENSED PRODUCTS. To the extent commercially feasible and consistent with prevailing business practices, COMPANY shall, and shall cause its AFFILIATES and SUBLICENSEES as necessary to, mark all LICENSED PRODUCTS that are manufactured or sold under this Agreement to notify the public and competitors that such products are patented.

11. TERMINATION

11.1 Voluntary Termination by COMPANY. COMPANY shall have the right to terminate this Agreement, for any reason, (i) upon at least six (6) months prior written notice to [University], such notice to state the date at least six (6) months in the future upon which termination is to be effective, and (ii) upon payment of all amounts due to [University] through such termination effective date.

11.2 Cessation of Business. If COMPANY ceases to carry on its business related to this Agreement, [University] shall have the right to terminate this Agreement immediately upon written notice to COMPANY.

11.3 Termination for Default.

(a) Nonpayment. In the event COMPANY fails to pay any amounts due and payable to [University] hereunder, and fails to make such payments within thirty (30) days after receiving written notice of such failure, [University] may terminate this Agreement immediately upon written notice to COMPANY.

(b) Material Breach. In the event COMPANY commits a material breach of its obligations under this Agreement, except as described in Section 12.3(a), and fails to cure that breach within sixty (60) days after receiving written notice thereof, [University] may terminate this Agreement immediately upon written notice to COMPANY.

11.4 Termination as a Consequence of PATENT CHALLENGE.

(a) By COMPANY. If COMPANY or any of its AFFILIATES brings a PATENT CHALLENGE against [University], or assists others in bringing a PATENT CHALLENGE against [University] (except as required under a court order or subpoena), then [University] may immediately terminate this Agreement.

(b) By SUBLICENSEE. If a SUBLICENSEE brings a PATENT CHALLENGE or assists another party in bringing a PATENT CHALLENGE (except as required under a court order or subpoena), then [University] may send a written demand to COMPANY to terminate such sublicense. If COMPANY fails to so terminate such sublicense within thirty (30) days after [University]'s demand, [University] may immediately terminate this Agreement.

11.5 Disputes Regarding Termination. If COMPANY disputes any termination by [University] under this Section, it must notify [University] of the nature of such dispute and the proposed manner in which to resolve the dispute within (10) days of receipt of notification of breach or notification of termination by [University], whichever is sooner. If the parties do not resolve such dispute within ten (10) days of such notification, then COMPANY shall be required to initiate the dispute resolution procedures outlined in Section 13.3 immediately. If it does not do so, COMPANY shall be considered to have waived its rights to dispute the termination.

11.6 Effect of Termination

(a) Survival. The following provisions shall survive the expiration or termination of this Agreement:

- Article 1 ("Definitions");
- Section 4.1(b) ("Equity");
- Section 5.2 ("Royalty Reports");
- Section 5.4 ("Records");
- Article 8 ("Indemnification and Insurance");
- Article 9 ("No Representations or Warranties");
- Article 11 ("General Compliance with Laws");
- Section 12.5 ("Disputes regarding Termination");
- Section 12.6 ("Effect of Termination");
- Article 13 ("Dispute Resolution"); and
- Article 14 ("Miscellaneous").

(b) Pre-termination Obligations. In no event shall termination of this Agreement release COMPANY from the obligation to pay any amounts that became due on or before the effective date of termination.

12. DISPUTE RESOLUTION

12.1 Mandatory Procedures. The parties agree that any dispute arising out of or relating to this Agreement shall be resolved solely by means of the procedures set forth in this Article, and that such procedures constitute legally binding obligations that are an essential provision of this

Agreement. If either party fails to observe the pro-cedures of this Article, as may be modified by their written agreement, the other party may bring an action for specific performance of these procedures in any court of competent jurisdiction.

12.2 Equitable Remedies. Although the procedures specified in this Article are the sole and exclusive procedures for the resolution of disputes arising out of or relating to this Agreement, either party may seek a preliminary injunction or other provisional equitable relief if, in its reasonable judgment, such action is necessary to avoid irreparable harm to itself or to preserve its rights under this Agreement.

12.3 Dispute Resolution Procedures.

(a) Mediation. In the event of any dispute arising out of or relating to this Agreement, either party may initiate mediation upon written notice to the other party ("Notice Date") pursuant to Section 14.1, whereupon both parties shall be obligated to engage in a mediation proceeding. The mediation shall commence within forty-five (45) days of the Notice Date. The mediation shall be conducted by a single mediator in [City, State]. The party requesting mediation shall designate two (2) or more nominees for mediator in its notice. The other party may accept one of the nominees or may designate its own nominees by notice addressed to the American Arbitration Association (AAA) and copied to the requesting party. If within fifteen (15) days following the request for mediation, the parties have not selected a mutually acceptable mediator, a mediator shall be appointed by the AAA according to the Commercial Mediation Rules. The mediator shall attempt to facilitate a negotiated settlement of the dispute, but shall have no authority to impose any settlement terms on the parties. The expenses of the mediation shall be borne equally by the parties, but each party shall be responsible for its own counsel fees and expenses.

(b) Trial Without Jury. If the dispute is not resolved by mediation within forty-five (45) days after commencement of mediation, each party shall have the right to pursue any other remedies legally available to resolve the dispute, provided, however, that the parties expressly waive any right to a jury trial in any legal proceeding under this Article.

12.4 Performance to Continue. Each party shall continue to perform its undisputed obligations under this Agreement pending final resolution of any dispute arising out of or relating to this Agreement; provided, however, that a party may suspend performance of its undisputed obligations during any period in which the other party fails or refuses to perform its undisputed obligations. Nothing in this Article is intended to relieve COMPANY from its obligation to make undisputed payments pursuant to Articles 4 and 6 of this Agreement.

12.5 Statute of Limitations. The parties agree that all applicable statutes of limitation and time-based defenses (including, but not limited to, estoppel and laches) shall be tolled while the procedures set forth in this Article are pending. The parties shall cooperate in taking any actions necessary to achieve this result.

13. MISCELLANEOUS

13.1 Notice. Any notices required or permitted under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be sent by hand, recognized national overnight courier, confirmed facsimile transmission, confirmed electronic mail, or registered or certified mail, postage prepaid, return receipt requested, to the following addresses or facsimile numbers of the parties:

If to [University] : ____________________

____

____

Attention: ____________________
Tel: ____________________
Fax: ____________________

If to COMPANY:

____

____

____

Attention: ____________________
Tel: ____________________
Fax: ____________________

All notices under this Agreement shall be deemed effective upon receipt. A party may change its contact information immediately upon written notice to the other party in the manner provided in this Section.

13.2 Governing Law/Jurisdiction. This Agreement and all disputes arising out of or related to this Agreement, or the performance, enforcement, breach or termination hereof, and any remedies relating thereto, shall be construed, governed, interpreted and applied in accordance with the laws of the [state], U.S.A., without regard to conflict of laws principles, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted. The state and federal courts having jurisdiction over [city, state], USA, provide the exclusive forum for any PATENT CHALLENGE and/or any court action between the parties relating to this Agreement. COMPANY submits to the jurisdiction of such courts and waives any claim that such court lacks jurisdiction over COMPANY or its AFFILIATES or constitutes an inconvenient or improper forum.

13.3 Force Majeure. Neither party will be responsible for delays resulting from causes beyond the reasonable control of such party, including without limitation fire, explosion, flood, war, strike, or riot, provided that the nonperforming party uses commercially reasonable efforts to avoid or remove such causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever such causes are removed.

13.4 Amendment and Waiver. This Agreement may be amended, supplemented, or otherwise modified only by means of a written instrument signed by both parties. Any waiver of any rights or failure to act in a specific instance shall relate only to such instance and shall not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar.

13.5 Severability. In the event that any provision of this Agreement shall be held invalid or unenforceable for any reason, such invalidity or unenforceability shall not affect any other provision of this Agreement, and the parties shall negotiate in good faith to modify the Agreement to preserve (to the extent possible) their original intent. If the parties fail to reach a modified agreement within thirty (30) days after the relevant provision is held invalid or unenforceable, then the dispute shall be resolved in accordance with the procedures set forth in Article 13. While the dispute is pending resolution, this Agreement shall be construed as if such provision were deleted by agreement of the parties.

13.6 Binding Effect. This Agreement shall be binding upon and inure to the benefit of the parties and their respective permitted successors and assigns.

13.7 Headings. All headings are for convenience only and shall not affect the meaning of any provision of this Agreement.

13.8 Entire Agreement. This Agreement constitutes the entire agreement between the parties with respect to its subject matter and supersedes all prior agreements or understandings between the parties relating to its subject matter.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

[Legal Name of University]		[Legal Name of Company]	
By:	____________________	By:	____________________
Name:	____________________	Name:	____________________
Title:	____________________	Title:	____________________

APPENDIX A

List of Patent Applications and Patents

APPENDIX B

List of Countries (excluding United States) for which PATENT RIGHTS Applications Will Be Filed, Prosecuted and Maintained

APPENDIX C

Annex 4.1(b)(iv) Anti-Dilution Protection After Funding Threshold[1]

1. Adjustments for Certain Dilutive Issuances.

(a) Definitions. For purposes of this Section 1, the following definitions shall apply:

(i) "Additional Shares of Common Stock" shall mean all shares of Common Stock issued (or, pursuant to Section 1(b) below, deemed to be issued) by the COMPANY after the Threshold Date, other than (1) the following shares of Common Stock and (2) shares of Common Stock deemed issued pursuant to the following Options and Convertible Securities (clauses (1) and (2), collectively, "Exempted Securities"):

(A) shares of Common Stock issued pursuant to the terms of this Section 1;

(B) shares of Common Stock, Options or Convertible Securities issued by reason of a dividend, stock split, split-up or other distribution on all then outstanding shares of Common Stock; or

(C) shares of Common Stock or Convertible Securities actually issued upon the exercise of Options or shares of Common Stock actually issued upon the conversion or exchange of Convertible Securities, in each case provided such issuance is pursuant to the terms of such Option or Convertible Security.

ii) "Convertible Securities" shall mean any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for Common Stock, but excluding Options.

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1 Draft Note: The provisions of this Annex are intended to provide customary broad-based weighted-average anti-dilution protection and are based on the anti-dilution provisions contained in the model legal documents published by the National Venture Capital Association (NVCA). The principal component in this Annex that is not contained in the NVCA model is Section 1(d) of this Annex, which provides for the issuance of additional common stock to give effect to anti-dilution adjustments (unlike the NVCA form, which is premised solely on an adjustment of the conversion ratio of convertible preferred stock).

(iii) "Options" shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities.

(iv) "Share Price" shall mean the Threshold Share Price, subject to adjustment following the Threshold Date as provided in this Section 1.

(v) "Threshold Date" shall mean the date of the Funding Threshold.

(vi) "Threshold Share Price" shall mean the fair market value per share of the Common Stock as of the Threshold Date, as determined in good faith by the Board of Directors of the COMPANY by the reasonable application of a reasonable valuation method in accordance with the provisions of Treasury Regulation §1.409A-1(b)(iv)(B), subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar re-capitalization with respect to the Common Stock occurring after the Threshold Date. On or as soon as reasonably practicable following the Threshold Date, the COMPANY shall give written notice to each Shareholder of the Threshold Share Price as determined in accordance with the foregoing, together with reasonable supporting details. Upon the reasonable request of a Shareholder, the COMPANY shall afford such Shareholder a reasonable opportunity to consult with management of the COMPANY in connection with the determination of the Threshold Share Price, whether prior to or after such determination has been made.

(vii) "Threshold Shares" shall mean, with respect to each Shareholder, the number of shares of Common Stock held by such Shareholder as of the Threshold Date, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock occurring after the Threshold Date.

(b) Deemed Issue of Additional Shares of Common Stock.

(i) If the COMPANY at any time or from time to time after the Threshold Date shall issue any Options or Convertible Securities (excluding Options or Convertible Securities which are themselves Exempted Securities) or shall fix a record date for the determination of holders of any class of securities entitled to receive any such Options or Convertible Securities, then the maximum number of shares of Common Stock (as set forth in the instrument relating thereto, assuming the satisfaction of any conditions to exercisability, convertibility or exchangeability but without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or, in the case of Convertible Securities and Options therefor, the conversion or exchange of such Convertible Securities, shall be deemed to be Additional Shares of Common Stock issued as of the time of such issue or, in case such a record date shall have been fixed, as of the close of business on such record date.

(ii) If the terms of any Option or Convertible Security, the issuance of which resulted in an adjustment to the Share Price pursuant to the terms of Section 1(c) below are revised as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security to provide for either (1) any increase or decrease in the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any such Option or Convertible Security or (2) any increase or decrease in the consideration payable to the COMPANY upon such exercise, conversion or exchange, then, effective upon such increase or decrease becoming effective, the Share Price computed upon the original issue of such Option or Convertible Security (or upon the occurrence of a record date with respect thereto) shall be readjusted to such Share Price as would have obtained had such revised terms been in effect upon the original date of issuance of such Option or Convertible Security. Notwithstanding the foregoing, no readjustment pursuant to this clause (ii) shall have the effect of increasing the Share Price to an amount which exceeds the lower of (A) the Share Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (B) the Share Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date.

(iii) If the terms of any Option or Convertible Security (excluding Options or Convertible Securities which are themselves Exempted Securities), the issuance of which did not result in an adjustment to the Share Price pursuant to the terms of Section 1(c) (either because the consideration per share (determined pursuant to Section 1(e)) of the Additional Shares of Common Stock subject thereto was equal to or greater than the Share Price then in effect, or because such Option or Convertible Security was issued on or before the Threshold Date), are revised after the Threshold Date as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security to provide for either (1) any increase in the number of shares of Common Stock issuable upon the exercise, conversion or exchange of any such Option or Convertible Security or (2) any decrease in the consideration payable to the COMPANY upon such exercise, conversion or exchange, then such Option or Convertible Security, as so amended or adjusted, and the Additional Shares of Common Stock subject thereto (determined in the manner provided in Section 1(b)(i)) shall be deemed to have been issued effective upon such increase or decrease becoming effective.

(iv) Upon the expiration or termination of any unexercised Option or unconverted or unexchanged Convertible Security (or portion thereof) which resulted (either upon its original issuance or upon a revision of its terms) in an adjustment to the Share Price pursuant to the terms of Section 1(c), the Share Price shall be read-justed to such Share Price as would have obtained had such Option or Convertible Security (or portion thereof) never been issued.

(v) If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the COMPANY upon such exercise, conversion and/or exchange, is calculable at the time such Option or Convertible Security is issued or amended but is subject to adjustment based upon subsequent events, any adjustment to the Share Price provided for in this Section 1(b) shall be effected at the time of such issuance or amendment based on such number of shares or amount of consideration without regard to any provisions for subsequent adjustments (and any subsequent adjustments shall be treated as provided in clauses (ii) and (iii) of this Section 1(b)). If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the COMPANY upon such exercise, conversion and/or exchange, cannot be calculated at all at the time such Option or Convertible Security is issued or amended, any adjustment to the Share Price that would result under the terms of this Section 1(b) at the time of such issuance or amendment shall instead be effected at the time such number of shares and/or amount of consideration is first calculable (even if subject to subsequent adjustments), assuming for purposes of calculating such adjustment to the Share Price that such issuance or amendment took place at the time such calculation can first be made.

(c) Adjustment of Share Price Upon Issuance of Additional Shares of Common Stock. In the event the COMPANY shall at any time after the Threshold Date issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Section 1(b)), without consideration or for a consideration per share less than the Share Price in effect immediately prior to such issue, then the Share Price shall be reduced, concurrently with such issue of Additional Shares of Common Stock, to a price (calculated to the nearest one-hundredth of a cent) determined in accordance with the following formula:

$$P_2 = P_1 * (A + B)\ \tilde{}\ (A + C).$$

For purposes of the foregoing formula, the following definitions shall apply:

(i) “P_2” shall mean the Share Price in effect immediately after such issue of Additional Shares of Common Stock;

(ii) “P_1” shall mean the Share Price in effect immediately prior to such issue of Additional Shares of Common Stock;

(iii) “A” shall mean the number of shares of Common Stock outstanding immediately prior to such issue of Additional Shares of Common Stock (treating for this purpose as outstanding all shares of Common Stock issuable upon exercise of Options outstanding immediately prior to such issue or upon conversion or exchange of Convertible Securities outstanding (assuming exercise of any outstanding Options therefor) immediately prior to such issue);

(iv) “B” shall mean the number of shares of Common Stock that would have been issued if such Additional Shares of Common Stock had been issued at a price per share equal to P_1 (determined by dividing the aggregate consideration received by the COMPANY in respect of such issue by P_1); and

(v) “C” shall mean the number of such Additional Shares of Common Stock issued in such transaction.

(d) Issuance of Anti-Dilution Shares Upon Adjustment of Share Price. In the event of any adjustment of the Share Price pursuant to this Section 1, then the COMPANY shall issue to each Shareholder, concurrently with such adjustment of the Share Price, a number of shares of Common Stock, rounded up to the nearest whole number of shares (any such shares issued pursuant to this Section 1(d), "Anti-Dilution Shares") determined in accordance with the following formula (it being understood, for avoidance of doubt, that no such issuance shall be required unless the following formula results in a positive number):

$$S_3 = S_1 * (TSP \div SP) - S_1 - S_2.$$

For purposes of the foregoing formula, the following definitions shall apply:

(i) "S_3" shall mean the number of new Anti-Dilution Shares to be issued to such Shareholder;

(ii) "S_1" shall mean the Threshold Shares of such Share-holder;

(iii) "S_1" shall mean the aggregate number of Anti-Dilution Shares, if any, issued to such Shareholder as determined immediately prior to such issue of new Anti-Dilution Shares (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock);

(iv) "TSP" shall mean the Threshold Share Price; and

(v) "SP" shall mean the Share Price then in effect (after giving effect to the adjustment thereto giving rise to this calculation under Section 1(d)).

(e) Determination of Consideration. For purposes of this Section 1, the consideration received by the COMPANY for the issue of any Additional Shares of Common Stock shall be computed as follows:

(i) Cash and Property: Such consideration shall:

(A) insofar as it consists of cash, be computed at the aggregate amount of cash received by the COMPANY, excluding amounts paid or payable for accrued interest;

(B) insofar as it consists of property other than cash, be computed at the fair market value thereof at the time of such issue, as determined in good faith by the Board of Directors of the COMPANY; and

(C) in the event Additional Shares of Common Stock are issued together with other shares or securities or other assets of the COMPANY for consideration which covers both, be the proportion of such consideration so received, computed as provided in (A) and (B) above, as determined in good faith by the Board of Directors of the COMPANY.

(ii) Options and Convertible Securities. The consideration per share received by the COMPANY for Additional Shares of Common Stock deemed to have been issued pursuant to Section 1(b), relating to Options and Convertible Securities, shall be determined by dividing:

(A) the total amount, if any, received or receivable by the COMPANY as consideration for the issue of such Options or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the COMPANY upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities, by

(B) the maximum number of shares of Common Stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities.

(f) Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment of the Share Price pursuant to this Section 1, the COMPANY at its expense shall, as promptly as reasonably practicable, compute such adjustment or readjustment in accordance with the terms hereof and furnish to each Shareholder a certificate setting forth (i) such adjustment or readjustment and showing in detail the facts upon which such adjustment or readjustment is based and (ii) the number of Anti-Dilution Shares issued or to be issued to such Shareholder as a result of such adjustment or readjustment. The COMPANY shall, as promptly as reasonably practicable after the written request at any time of any Shareholder, furnish or cause to be furnished to such holder a certificate setting forth the Share Price and the Threshold Share Price then in effect.

APPENDIX 2 SAMPLE UNIVERSITY AGREEMENT

This sample is not to be construed as legal advice; the author gives no warranty that it will be suitable for use.

[UNIVERSITY NAME]
OFFICE OF SPONSORED PROGRAMS
RESEARCH AGREEMENT

This Research Agreement ("Agreement") is made effective as of ______________ (the "Effective Date"), by and between [University Name] located at [address] and Company Name, located at ___________________ (hereinafter referred to as the "Sponsor"). Party shall mean the Sponsor or [University Name] as the context dictates, and when used in the plural, shall mean the Sponsor and [University Name].

WHEREAS, the research program contemplated by this Agreement is of mutual interest and benefit to [University Name] and to the Sponsor, and will further the instructional and research objectives of [University Name] in a manner consistent with its status as a non-profit, tax-exempt, educational institution.

NOW, THEREFORE, the Parties hereto agree as follows:

1. **STATEMENT OF WORK**. [University Name] agrees to use reasonable efforts to perform the research program as described in Attachment A (the "Research") to this Agreement.

2. **PRINCIPAL INVESTIGATOR**. The Research will be supervised by _____________the "Principal Investigator". If, for any reason, __________ is unable to continue to serve as Principal Investigator and a successor reasonably acceptable to both [University Name] and the Sponsor is not available, this Agreement shall be terminated as provided in Article 6.

3. **PERIOD OF PERFORMANCE**. The Research shall be conducted during the period commencing _____________ (the "Start Date") and, unless earlier terminated in accordance with this Agreement, ending _____________ (the "Completion Date"). The Completion Date may be modified or extended only by mutual written agreement of the Parties.

4. **REIMBURSEMENT OF COSTS**. In consideration of the foregoing, the Sponsor shall reimburse [University Name] for all direct and F&A (Facilities & Administrative or indirect) costs incurred in the performance of the Research, including business class fares for international travel of faculty and staff. Total reimbursements shall not exceed the total estimated project cost of $_______ without written authorization from the Sponsor.

5. **PAYMENT**. Payment(s) shall be made to [University Name] by the Sponsor in advance in U.S. dollars, excluding taxes or impost of any kind, as follows:
   $ due
   Information for payment(s) by wire transfer appears in Attachment B to this Agreement.

   A final financial accounting of all costs incurred and all funds received by [University Name] hereunder, together with a check for the amount of the unexpended balance, if any, shall be submitted to the Sponsor within ninety (90) days following the Completion Date or termination of this Agreement.

6. **TERMINATION**. This Agreement may be terminated by either Party upon sixty (60) days' prior written notice to the other Party. Upon termination by either Party, [University Name] will be reimbursed as specified in Article 4 for all costs and non-cancelable commitments incurred in connection with the Research up to and including the effective date of termination, such reimbursement not to exceed the total estimated cost specified in Article 4.

7. **CONFIDENTIAL INFORMATION**. If, in the performance of the Research, the Principal Investigator and members of the [University Name] research team require and accept access to the Sponsor's "Confidential Information" (as defined in Attachment B to this Agreement), the rights and obligations of the Parties with respect to such information shall be governed by the terms and conditions set forth in Attachment B to this Agreement.

8. **RESEARCH RESULTS**. Sponsor shall have the right to use any data and research results developed in the performance of the Research, excluding inventions, tangible research property, or computer

software, whose ownership and licenses are described separately in Section [ ]. Sponsor shall keep such data and research results Confidential until [University Name] publishes the data or research results and, if appropriate, files a patent application. In no event shall Sponsor use [University Name] data in any patent application unless the patent application is jointly owned with [University Name].

9. **PUBLICATIONS**. [University Name] will be free to publish the results of the Research after providing the Sponsor with a thirty (30) day period in which to review each publication to identify patentable subject matter and to identify any inadvertent disclosure of Confidential Information. If necessary to permit the preparation and filing of U.S. patent applications, the Principal Investigator may agree to an additional review period not to exceed sixty (60) days. Any further extension will require subsequent agreement between the Sponsor and [University Name].

10. **SPONSOR INTELLECTUAL PROPERTY**. Title to any intellectual property developed by Sponsor's personnel without significant use of [University Name]-administered funds or facilities shall remain with Sponsor. Such intellectual property shall not be subject to the terms and conditions of this Agreement.

11. **JOINT INTELLECTUAL PROPERTY**.

    A. JOINT INVENTIONS. The Parties shall have joint title to (i) any invention conceived or first reduced to practice jointly by employees and/or students of [University Name] and the Sponsor's personnel in the performance of the Research and (ii) any invention conceived or first reduced to practice by the Sponsor's personnel in the performance of the Research with significant use of funds or facilities administered by [University Name] (each, a "Joint Invention"). The Sponsor shall be notified of any Joint Invention promptly after an invention disclosure is received by [University Name]'s Technology Licensing Office. [University Name] shall have the first right to file a patent application on a Joint Invention in the names of both Parties. All expenses incurred in obtaining and maintaining any patent on such Joint Invention shall be equally shared except that, if one Party declines to share in such expenses, the other Party may take over the prosecution and maintenance thereof, at its own expense, provided that title to the patent remains in the names of both Parties.

B. LICENSES. Each Party shall have the independent, unrestricted right to license to third parties any such Joint Invention without accounting to the other Party, except that the Sponsor shall be entitled to request an exclusive license to [University Name]'s interest in a Joint Invention as provided under paragraph 12.B.2 and 12.B.3 below.

C. JOINTLY DEVELOPED COPYRIGHTABLE MATERIALS. Copyrightable materials, including computer software, developed in the performance of the Research (i) jointly by employees and/or students of [University Name] and the Sponsor's personnel, or (ii) by the Sponsor's personnel with significant use of funds or facilities administered by [University Name], shall be jointly owned by both Parties, who shall each have the independent, unrestricted right to dispose of such copyrightable materials and their share of the copyrights therein as they deem appropriate, without any obligation of accounting to the other Party.

12. **UNIVERSITY INTELLECTUAL PROPERTY**.

A. [UNIVERSITY] INVENTIONS. [UNIVERSITY NAME] shall have sole title to (i) any invention conceived or first reduced to practice solely by employees and/or students of [University Name] in the performance of the Research (each an "University Invention") and (ii) any invention conceived or first reduced to practice by the Sponsor's personnel with significant use of funds or facilities administered by [University Name], if the invention is conceived or reduced to practice other than in the performance of the Research. The Sponsor shall be notified of any [University Name] Invention promptly after a disclosure is received by [University Name]'s Technology Transfer Office. [University Name] (a) may file a patent application at its own discretion or (b) shall do so at the request of the Sponsor and at the Sponsor's expense.

B. LICENSING OPTIONS. For each [University Name] Invention on which a patent application is filed by [University Name], [University Name] hereby grants the Sponsor a non-exclusive non-transferable, royalty-free license for internal research purposes. The Sponsor shall further be entitled to elect one of the following alternatives by notice in writing to [University Name] within six (6) months after [University Name]'s notification to the Sponsor that a patent application has been filed:

1. a non-exclusive, non-transferable, world-wide, royalty-free license to the Sponsor, without the right to sublicense, to make, have made, use, lease, sell and import products embodying or produced through the use of such invention, provided that the Sponsor agrees to demonstrate reasonable efforts to commercialize the technology in the public interest and reimburse [University Name] for the costs of patent prosecution and maintenance in the United States; or

2. a royalty-bearing, worldwide exclusive license (subject to third party rights, if any, and in a designated field of use, where appropriate) to the Sponsor, including the right to sublicense, below, to make, have made, use, lease, sell and import products embodying or produced through the use of such invention. This option to elect an exclusive license is subject to the negotiation of commercially reasonable license terms and conditions and conditioned upon Sponsor's agreement to reimburse [University Name] for the costs of patent prosecution and maintenance in the United States and any elected foreign country.

3. Option Extension: Provided that the Sponsor pays for patent costs in the United States in which [University Name] elects to file patents, Sponsor's option to elect an exclusive license under B 2. above shall be extended until three (3) months after the end of the Research Program. [University Name] agrees to consult with Sponsor as to which countries are elected, and [University Name] agrees to consider Sponsor's preference in good faith. Sponsor terminated this extended option at any time. Thereafter, no further patent costs shall be due unless Sponsor wishes a nonexclusive royalty-free license under the terms of B1.

If the Sponsor and [University Name] do not enter into a license agreement within three (3) months after the Sponsor's election to proceed under paragraph 12.B.1. or 12.B.2. or 12B.3 above, the

Sponsor's rights under paragraphs 12.B.1. and 12.B.2. and 12.B.3 will expire.

C. FOREIGN FILING ELECTION. If the Sponsor elects a license under 12.B.2 or 12.B.3 the Sponsor shall notify [University Name] of those foreign countries in which it desires a license in sufficient time for [University Name] to satisfy the patent law requirements of those countries. The Sponsor will reimburse [University Name] for the out-of-pocket costs, including patent filing, prosecution and maintenance fees, related to those foreign filings.

D. CONFIDENTIALITY OF INVENTION DISCLOSURES. The Sponsor shall retain all invention disclosures submitted to the Sponsor by [University Name] in confidence and use its best efforts to prevent their disclosure to third parties. The Sponsor shall be relieved of this obligation only when this information becomes publicly available through no fault of the Sponsor.

E. COPYRIGHT OWNERSHIP AND LICENSES Title to and the copyright in any copyrightable material first produced or composed in the performance of the Research solely by employees and/or students of [University Name] shall remain with [University Name].

1. For any copyrights or copyrightable material other than computer software and its documentation and/or informational databases required to be delivered in accordance with Attachment A, the Sponsor is hereby granted an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, distribute and perform all such copyrightable materials for the Sponsor's internal purposes.

2. The Sponsor shall be entitled to elect, by notice to [University Name] within six (6) months following [University Name]'s notification or delivery to the Sponsor of computer software and its documentation and/or informational databases required to be delivered to the Sponsor in accordance with Attachment A, a royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works based upon, display, and distribute to end users, such

computer software and its documentation and/or databases for internal and/or commercial purposes. If the use of the software would infringe claims of a patent application filed pursuant to paragraph 12.A. above, then the Sponsor will need to elect license rights in such patent as set forth in 12.B. above in order to elect the license contemplated by this paragraph.

F. LICENSE EFFECTIVE DATE. All licenses elected by the Sponsor pursuant to Sections B. and E. of this **Article 11** become effective as of the date the Parties sign a separate license agreement.

13. **USE OF NAMES**. The Sponsor and its affiliates shall not use the name "[University name]" or any variation, adaptation, or abbreviation thereof, or the name of any of [University Name]'s trustees, officers, faculty members, students, employees, or agents, or any trademark owned by [University Name], in any promotional material or other public announcement or disclosure without the prior written consent of [University Name] which consent [University Name] may withhold in its sole discretion.

14. **REPRESENTATIONS AND WARRANTIES**. [University Name] MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND CONCERNING THE RESEARCH OR ANY INTELLECTUAL PROPERTY RIGHTS AND HEREBY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF [University Name] OR THIRD PARTIES, CREATION, VALIDITY, ENFORCEABILITY AND SCOPE OF ANY INTELLECTUAL PROPERTY RIGHTS OR CLAIMS, WHETHER ISSUED OR PENDING, AND THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE.

    IN NO EVENT SHALL EITHER PARTY, ITS TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES, STUDENTS AND AFFILIATES, BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING ECONOMIC DAMAGES OR LOST PROFITS, REGARDLESS OF WHETHER THE PARTY WAS

ADVISED, HAD OTHER REASON TO KNOW OR IN FACT KNEW OF THE POSSIBILITY OF THE FOREGOING. THIS ARTICLE 14 SHALL SURVIVE THE EXPIRATION OR ANY EARLIER TERMINATION OF THIS AGREEMENT.

15. **NOTICES**. Any notices required to be given or which shall be given under this Agreement shall be in writing and be addressed to the Parties as shown below. Notices shall be delivered by certified or registered first class mail (air mail if not domestic) or by commercial courier service and shall be deemed to have been given or made as of the date received.

University name	Company name
Address	Address
Attention	Attention
Phone	Phone
Fax	Fax
Email	Email

16. **ASSIGNMENT**. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Neither Party may assign this Agreement without the prior written consent of the other Party, except to a successor to all or substantially all of its business and assets. Any attempted assignment in violation of this Article 16 is void.

17. **GOVERNING LAW**. The validity and interpretation of this Agreement and the legal relationship of the Parties to it shall be governed by the laws of the Commonwealth of Massachusetts and the applicable U.S. Federal law.

18. **MEDIATION**. If a dispute arises between the Parties, either Party may notify the other of its desire to mediate the dispute and the dispute shall be mediated.

    A. MEDIATOR. The mediation shall be conducted by a single mediator. The Party requesting mediation shall designate two (2) or more nominees for mediator in its notice. The other Party may accept one of the nominees or may designate its own nominees by notice addressed to the American Arbitration Association

(AAA) and copied to the requesting Party. If within, thirty (30) days following the request for mediation, the Parties have not selected a mutually acceptable mediator, a mediator shall be appointed by the AAA according to the Commercial Mediation Rules.

B. NON-BINDING EXPENSES. The mediator shall attempt to facilitate a negotiated settlement of the dispute, but shall have no authority to impose any settlement terms on the Parties. The expenses of the mediation shall be borne equally by the Parties, but each Party shall be responsible for its own counsel fees and expenses.

C. FAILED MEDIATION. If the dispute is not resolved by mediation within forty-five (45) days after commencement of mediation, each Party shall be entitled to pursue any right or other legal remedy the Party may otherwise have.

D. RIGHT TO SEEK EQUITABLE RELIEF. Notwithstanding the provisions of this Section, a Party may bring suit in a court of competent jurisdiction for equitable relief from the other Party's alleged breach of its confidentiality obligations without first mediating the issue.

19. **FORCE MAJEURE**. Neither Party shall be liable to the other for failure to perform any of its respective obligations imposed by this Agreement provided such failure shall be occasioned by fire, flood, explosion, lightning, windstorm, earthquake, subsidence of soil, governmental interference, civil commotion, riot, war, terrorism, strikes, labor disturbance, or any other cause beyond its reasonable control.

20. **EXPORT CONTROLS**. Each Party acknowledges that any information or materials provided by the other under this Agreement may be subject to U.S. export laws and regulations, including the International Traffic in Arms Regulations (ITAR, 22 CFR Chapter 1, Subchapter M, Parts 120–130), Export Administration Regulations (EAR, 15 CFR Chapter VII, Subchapter C, Parts 730–774)), and Assistance to Foreign Atomic Energy Activities (10 CFR Part 810); each Party agrees to comply with all such laws.

Because [University Name] is an institution of higher education and has many students, faculty, staff, and visitors who are foreign persons, [University Name] intends to conduct the Research as fundamental research under the export regulations, such that the results generated by [University Name] qualify as "public domain" under ITAR Parts 120.10(a)(5) and 120.11 or "publicly available under EAR Parts 734.3(b)(3) and 734.8(a, b).

Sponsor will not knowingly disclose, and will use commercially reasonable efforts to prevent disclosure to [University Name] of any information subject to ITAR controls or in the Commerce Control List (EAR Part 774 and Supplements) or 10 CFR Part 810 Restricted Data or Sensitive Nuclear Technology. If for purposes of the Research, Sponsor intends to disclose export-controlled information to [University Name], Sponsor will not disclose such information to [University Name] unless and until a plan for transfer, use, dissemination and control of the information has been approved by [University Name]'s Export Control Officer. In the event Sponsor inadvertently (i) discloses export-controlled information or (ii) breaches this Section, any deadlines contemplated by the Statement of Work will be adjusted based on the time it takes to address the disclosure.

21. **COUNTERPARTS**. This Agreement and any amendment hereto may be executed in counterparts and all such counter-parts taken together shall be deemed to constitute one and the same instrument. If this Agreement is executed in counterparts, no signatory hereto will be bound until all the Parties named below have duly executed a counterpart of this Agreement.

22. **ENTIRE AGREEMENT**. Unless otherwise specified, this Agreement and its Attachments embody the entire understanding between [University Name] and the Sponsor with respect to the Research, and any prior or contemporaneous representations, either oral or written, are hereby superseded. No amendments or changes to this Agreement, including, without limitation, changes in the statement of work, period of performance or total estimated cost, shall be effective unless made in writing and signed by authorized representatives of the Parties.

IN WITNESS WHEREOF, the Sponsor and [University Name], intending to be legally bound, have executed this Agreement as of the Effective Date by their respective duly authorized representatives.

UNIVERSITY NAME	COMPANY NAME
By	By
Name	Name
Title	Title
Date	Date

ATTACHMENT A UNIVERSITY STATEMENT OF WORK

ATTACHMENT B SPONSOR CONFIDENTIAL INFORMATION

If, in the performance of the Research, the Principal Investigator and members of the [University Name] research team designated by him/her require and accept access offered by the Sponsor to certain information that the Sponsor considers confidential, the rights and obligations of the Parties with respect to such information are as follows:

1. **CONFIDENTIAL INFORMATION**. When used in this Agreement, "Confidential Information" means confidential and proprietary information of any kind which is disclosed by the Sponsor to [University Name] that (i) prior to disclosure, is marked with a legend indicating its confidential status or (ii) is disclosed orally or visually, if the Sponsor identifies such information as confidential at the time of disclosure and, within 30 days of such disclosure, delivers to the Principal Investigator a notice summarizing the confidential information disclosed. Notwithstanding the foregoing, in no event is information Confidential Information if it (a) was in [University Name]'s possession before receipt from the Sponsor; (b) is or becomes a matter of public knowledge through no fault of [University Name]; (c) is received by [University Name] from a third party having an

apparent *bona fide* right to disclose the information without a duty of confidentiality to the Sponsor; or (d) is independently developed by [University Name] without use of the Confidential Information.

2. **LIMITATIONS ON USE**. [University Name] shall use the Confidential Information solely for the purposes of the Research. Disclosure by the Sponsor of the Confidential Information does not constitute a grant to [University Name] of any right or license to the Confidential Information except as set forth herein or in a duly executed license agreement.

3. **CARE OF CONFIDENTIAL INFORMATION**. [University Name] shall exert reasonable efforts to maintain the Confidential Information in confidence, except that [University Name] may disclose or permit disclosure of any of the Confidential Information to its directors (members of the [University Name] Corporation), officers, employees, consultants, advisors, students, subcontractors and agents, who need to know such Confidential Information in the performance of the Research and who have been advised of and have agreed to maintain the confidential nature of the Confidential Information.

   [University Name] shall be deemed to have discharged its obligations hereunder provided [University Name] has exercised the foregoing degree of care and provided further that [University Name] shall immediately, upon discovery of any disclosure not authorized hereunder, notify the Sponsor and take reasonable steps to prevent any further unauthorized disclosure or unauthorized use.

   [University Name]'s obligations of confidentiality with respect to use and non-disclosure of Confidential Information provided under this Agreement shall survive for a period of three (3) years following receipt of the information.

4. **REQUIRED DISCLOSURES**. Nothing in this Agreement shall be construed to prevent [University Name] from disclosing Confidential Information as required by law or legal process, as long as [University Name], if permitted by applicable law, promptly notifies the Sponsor of its obligation to disclose and provides reasonable cooperation to the Sponsor in any efforts to contest or limit the scope of the disclosure.

5. **RETURN OR DESTRUCTION OF CONFIDENTIAL INFORMATION**. When the Confidential Information is no longer required for the purposes of this Agreement, [University Name] shall, at the direction of the Sponsor, either destroy or return to the Sponsor all Confidential Information and shall destroy any electronic or digital manifestations of the Confidential Information, except that [University Name] may retain one copy of the Confidential Information solely for the purposes of monitoring its obligations under this Agreement.

ABOUT THE AUTHOR

Lita L. Nelsen retired in 2016 from her position as Director of the Technology Licensing Office at the Massachusetts Institute of Technology, where she had been since 1986.

Ms. Nelsen earned B.S. and M.S. degrees in Chemical Engineering from MIT and an M.S. in Management from MIT as a Sloan Fellow. Prior to joining the MIT TLO, she spent 20 years in industry, primarily in the fields of membrane separations, medical devices, and biotechnology.

Ms. Nelsen is widely published in the field of technology transfer and has been a lecturer and advisor to governments and universities in over 25 countries. She has served on many non-profit boards including the Association of University Technology Managers where she was president in 1992. She is currently a consultant and on the scientific advisory boards of Partners' Investment Fund, the Massachusetts Life Sciences Center, and two biotechnology companies that started from university inventions. She was co-founder of Praxis, the UK University Training Company (now part of Praxis Auril).

Ms. Nelsen was awarded Xconomy's Lifetime Achievement Award in Biotechnology in 2017. In 2009 the UK Government awarded her the honor of Member of the Order of the British Empire (MBE) for her work with technology transfer institutions throughout the UK.