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ECONOMIC DEVELOPMENT AND INNOVATION (EDI) OFFICE CONDITIONS OF SERVICE: STANDARD OPERATING PROCEDURES

Table of Contents

FOREWORD

For over fifty years, Lakehead University and its predecessors have been at the forefront of discovery and dissemination of new knowledge. Although much of this knowledge has been disseminated for the public's use and benefit, Lakehead had relatively little involvement in the commercialization of its research. This changed when Lakehead University created the Economic Development and Innovation Office ("EDI Office", formerly the Innovation Management Office) in 2000 and formally decided to work towards commercializing intellectual property developed by Lakehead researchers.

Lakehead's collective agreement with its faculty gives ownership of patent rights and some copyright to faculty, with a requirement to share income from certain intellectual property with the University if the Lakehead University Faculty Association (LUFA) member chooses to commercialize. Lakehead University's Intellectual Property Policy was adopted by Priorities and Planning Group (**PPG**) in November 2007. This policy extends most of the rights and obligations of LUFA Faculty members to the rest of the University community, with the added requirement that non-LUFA members disclose inventions to the University to enable a dialogue to commence.

The Economic Development and Innovation Office (EDI Office) exists to carry out the following functions:

- Industry Research Partnerships: assist Lakehead researchers in finding and building relationships with industry to partner on research projects. Additionally, assist industry that are interested in carrying out research with the University to connect with suitable Lakehead researchers. Industry is broadly defined as small and medium-sized enterprises (SMEs), large industry, not-for-profit corporations and all levels of government.
- Intellectual Property Management and Licensing: evaluate newly disclosed inventions and other intellectual property. Where appropriate, assist with the effective transfer of Lakehead innovations to the private sector where these discoveries can be developed for public use and benefit, through licensing or start-up/spin-off companies.
- Start-Up Company Development: Where appropriate (i.e. when a suitable existing licensee cannot be located or when it makes sense from an economic development point of view), support the creation and implementation of new student-owned or faculty-owned start-up companies based on commercializing University intellectual property.
- Economic Development: support the activities of the President's Advisory Council on Economic Development, assist in the implementation of various economic development initiatives, collect and report on metrics of success, work with local and regional municipalities and First Nations to support business retention, expansion and attraction and an active participant in the regional entrepreneur eco-system.
- Special Projects and Initiatives: Projects that utilize the unique set of skills possessed by EDI Office staff, are assigned to the EDI Office or that primarily fall within the realm of Economic Development and Innovation.

To assist in carrying out these functions, the EDI Office has developed standard operating practices consistent with its responsibility to the public, the University, and its faculty, staff and students. The following summary of practices for intellectual property management and

licensing, industry research partnerships, and start-up company development is intended as a guide to Lakehead researchers and employees in understanding how the EDI Office carries out its functions.

Guiding Principles

Innovation Management and commercialization are by-products, not the purpose, of the University's academic missions of education, research, and dissemination of knowledge. The following minimum principles guide the University's licensing mission:

- All technology licensing activities must conform to University policies on conflict of interest and conflict of commitment. When conflicts arise, the University's academic mission must take precedence;
- No agreement may unreasonably delay or restrict publication of research results or otherwise prohibit the dissemination of knowledge, without the express written consent of all involved researchers;
- Any research project that delays or restricts publication of research results (or otherwise prohibits the dissemination of knowledge) must be carried out without the involvement of graduate students, to ensure that graduate students can complete their programs and graduate from the University;
- All license agreements must provide for fair and equitable return to all parties and minimize institutional liability.

EDI Office Standard Operating Procedures and Timelines

The EDI Office has implemented standard operating procedures and service standards that set out various guidelines for engaging the EDI Office and specifies approximate timelines for service provision. Additionally, a summary of these guidelines can be found at https://www.lakeheadu.ca/research-and-innovation/economic-development.

I. Industry Research Partnerships

The EDI Office is the first point of contact for researchers, industry, and other external parties who wish to establish an industry-academic research partnership, or a research contract or agreement between university researchers and a government or non-profit organization. Researchers often have significant external relationships to draw on when starting to engage in collaborative research, however in those circumstances where connections do not exist, the EDI Office assists in connecting researchers and industry. The EDI Office is also the place to start for industry that are looking for university research expertise.

To assist in this role, we participate in various commercialization related economic development initiatives, and invest time in developing and sustaining local, regional, and global networks. Such networks are also crucial to the support of several aspects of IP commercialization, including

invention evaluation, locating suitable licensees, developing commercialization strategies, determining appropriate compensation, start-up company development (i.e. raising financing, attracting experienced management), and supporting industry-sponsored research activities.

Once potential research partners and a research project have been identified, the EDI Office also negotiates and drafts industry-sponsored research and related contracts for Lakehead University. To assist in this role, Lakehead has developed sample research collaboration contracts that address standard areas such as intellectual property, results sharing, publication, and graduate student involvement. We also have an experienced Registered Technology Transfer Professional (RTTP) on staff to fast-track contract negotiations, and are open to considering industry partners contract templates in addition to our own.

Researchers wishing to engage in industry sponsored research must provide sufficient information to the EDI Office to allow suitable industry participants to be sourced, and contracts to be drafted and reviewed. At a minimum, researchers should provide a budget, project title and synopsis, and other information listed in "Schedule A" to the University's standard draft research contract.

II. Intellectual Property

It is widely believed that Intellectual Property ("IP") is the wave of the future, and one of the most valuable natural resources of the new millennium. Knowledge and innovation are fueling today's economy, and that of the future. It is therefore vital that everyone engaged in the research and the creation of intellectual property know of the different forms of Intellectual Property, and the rights, benefits, restrictions, and responsibilities that attach to each type.

Intellectual Property consists of the expression of ideas. IP may exist in many forms, including artistic works, literary works, inventions, discoveries, processes, knowledge, data sets, data bases, audio visual and computer material or equivalent circuitry, biotechnology and genetic engineering products (including plant cultivars and germ plasma), computer software, circuit board schematics, and any other item, knowledge, thought, or product of research.

Intellectual Property can be protected in several different ways, depending upon the type or form in which the IP exists. For example, a traditional invention may be protected by a patent application; an artistic work by a copyright registration, trademark, or industrial design registration; an idea for a new circuit by integrated circuit topography legislation, and plant varieties by plant breeder's legislation.

An example of the use of different forms of IP protection can assist the reader in understanding the differences between them. Consider a bottle of Coca-cola® pop. The written material on the label is protected by copyright, the shape of the bottle is protected by industrial design, the name is protected by a trademark, and the method of capping the bottle is protected by a patent. The recipe for the beverage would most likely be protected by a trade secret.

The owner of IP may grant rights in the IP to others, either through a transfer of part or all of their ownership interest in the IP (called an "assignment"), or by giving permission to others to use or otherwise deal with the IP (called a "license"). Licenses may be either exclusive (where the person receiving the license is the only one that can use the IP) or non-exclusive (where the grantor retains the right to license the IP to another person). The EDI Office is available to assist the University community with the transfer of intellectual property and to understand the different types of protection.

III. Reporting New Discoveries

Lakehead's faculty (except LUFA members), staff, and graduate students and other members of the University community have an obligation to report new intellectual property developed with University support to the EDI Office. LUFA members are encouraged to report new IP developed with University support. University support is defined as financial or other support, regardless of origin, that is used in the discovery or development of intellectual property and is provided through University channels. The Lakehead University Intellectual Property Policy can be found here: https://www.lakeheadu.ca/research-and-innovation/innovation/researchers.

LUFA members are required to provide the University notice within three months of filing a patent application on their own, pursuant to Article 38.01.03 of the Collective Agreement. The notice should include an assertion of whether or not it refers to an invention, improvement, design or development made with the extraordinary support of the Board. This notice should be forwarded to the EDI Office's attention.

According to the LUFA Collective Agreement, copyright to the following types of works shall belong to the LUFA member who prepared such works and may be assigned or retained by them:

- books, articles, and similar printed material written or prepared by a member;
- painting, sculpture, music, and similar works of art created by a member;
- lectures delivered by a member;
- audio and video recordings or digitally encoded representations;
- photographs, film, and other similar recordings for which the content was created by a member; and
- computer programs developed, improved, or written by a member.

These rights may be signed away by LUFA members in various contractual instruments, and caution should therefore be exercised prior to signing legal agreements. Distance education materials are treated differently under the LUFA Collective Agreement. According to the *Copyright Act* of Canada, any other copyright matter developed by an employee of Lakehead University in the course of employment is owned by the University.

A. Invention Disclosure

To report new Intellectual Property, an Invention Disclosure Form must be completed and submitted to the EDI Office. An Invention Disclosure provides the necessary information about

the intellectual property for evaluation by the EDI Office. Electronic copies of the form can be found here: https://www.lakeheadu.ca/research-and-innovation/forms

An Invention Disclosure for a potentially patentable invention should be submitted as soon as the inventor can describe completely how to practice the invention, but before any public disclosure, because patent laws limit available patent rights after an "enabling disclosure". Examples of public disclosures include journal articles, newspapers, newsletters, bulletins, textbooks, journals, theses, reports, letters to the editor, some oral presentations, and distribution of a paper copy of a poster at a public meeting. Basically, any dissemination of information regarding the invention that results in a loss of control of who may know about the invention is considered by patent law to be a public disclosure. The timeliness of Invention Disclosure submission is therefore very important.

The optimum time to report a discovery or invention is when it can be described in detail and there is some data which shows how the invention works. Prior to this, there is seldom sufficient information for the purpose of patent filing. In Canada, a patent must be filed within one year of public disclosure, whereas most other countries require filing before any disclosure. Publication of an abstract, paper, or oral presentations in seminars and/or meetings prior to submitting a patent application usually results in the loss of foreign patent rights. **While patent filings can be done rapidly once all requisite information is available and funds to pay the patent agent have been secured, several weeks' notice of pending disclosure is best for thorough protection.**

Works covered by copyright differ from those protected by patent in that copyright vests immediately upon original works of authorship being fixed in a tangible medium. No time bar exists regarding disclosure. Other types of IP protection (i.e. industrial designs, plant breeder rights) have different rules, and will be considered on a case-by-case basis.

B. Evaluation of Invention Disclosure

Upon receipt of the Invention Disclosure, the EDI Office will review it for completeness. Incomplete Invention Disclosures will be returned to the investigator. The EDI Office will gladly answer questions and provide guidance on how to complete an Invention Disclosure. Once the Invention Disclosure is complete, including provision of all supporting documentation and execution of the option by Lakehead inventors of their rights, title, and interest in the invention to the University, the Invention Disclosure will begin to be evaluated by the EDI Office.

For administrative efficiency, the EDI Office communicates through a lead inventor identified in the Invention Disclosure.

The EDI Office strives to manage its intellectual property portfolio in the best interest of the University, the inventors, and for the public benefit. The EDI Office evaluates reported Intellectual Property and inventions for:

- commercial potential and likelihood of licensing,
- encumbrances and other issues that may complicate patenting and licensing efforts, and
- strength of patent or other IP protection.

It typically takes at least four to eight weeks from the time the EDI Office receives a **completed** Invention Disclosure for full evaluation of the reported invention. During the evaluation period, EDI Office staff will meet with the inventor to learn more about the invention and discuss marketing and licensing strategy. However, some inventions are sent to external review, such as various Centres of Excellence for Commercialization and Research (**CECR**) that have been set up by the Government of Canada. CECRs require sometimes at least 90 days to review invention disclosures. In addition, some research grants and contracts require inventors and the University to give notice to external parties of invention disclosures. Depending on these requirements, invention evaluation procedures could be further delayed.

After evaluation of an Invention Disclosure, the EDI Office will decide whether to exercise its option and take title to the invention or release title to the inventors, subject to approval as applicable by any research sponsor. If the University decides to exercise its option, an assignment agreement implementing the standard EDI Office revenue sharing requirements will be implemented (see EDI Office "Conditions of Service: EDI Office Participation in Commercialization Project" available at https://www.lakeheadu.ca/research-and-innovation/innovation/researchers/knowledge-transfer/commercialization. If the University exercises its option and takes title to the invention, the EDI Office will manage the process of patent or other IP protection as appropriate, and begin the processes of marketing and licensing. In such cases, the University pays all (or a portion of) patent, copyright, and licensing costs; some costs may be shared with the inventor(s). Whenever possible, these costs are recouped through license agreements.

C. Inventor Participation

Throughout the evaluation and subsequent patenting, marketing, and licensing efforts, inventor cooperation and participation are critical for effective intellectual property management and licensing. If the inventor cannot, or will not, fully support the process, the EDI Office may, after consultation with the Vice President, Research & Innovation (VPRI), choose to inactivate the invention file. In this circumstance, title to the Intellectual Property may remain with the University and does not revert to the inventor.

D. Assignment of Rights before Filing a Patent Application

The ability to effectively protect Intellectual Property and commercialization potential are important elements in the EDI Office's decision to retain title to an invention. Whereas many inventions represent significant scientific or social advancements, not all have the commercial potential to justify the significant expense of patent protection or licensing efforts. In such cases, the EDI Office, after consultation with the inventor, might elect to waive title to its ownership interest in the invention before filing a patent application, and title would then revert back to the inventors. At the inventor's request, the EDI Office will discuss the associated rules and encumbrances for acquiring title. For example, IP rights may have been encumbered through a research contract.

E. Commercialization Plan Development (including grant applications)

After evaluation of an Invention Disclosure and the decision to take on a particular commercialization project, the EDI Office creates a commercialization plan in consultation with the inventors. The Plan includes decisions such as the suitable route for commercialization (i.e. exclusive vs. non-exclusive licenses, territorial and/or field of use licenses, start-up company creation) and modes for protecting Intellectual Property (e.g. patents, copyright, other). It may also include plans to obtain financing to implement the plan or further develop the Intellectual Property or invention to increase the chances of successful licensing. Funding mechanisms can include Northern Ontario Heritage Fund Corporation (NOHFC), FedNor, Industrial Research Assistance Program (IRAP) various proof of principle funds, and other sources. The EDI Office will need the assistance of inventors in drafting appropriate grant applications.

Several granting agencies (e.g. Canadian Institutes of Health Research (CIHR), Ontario Centres of Excellence (OCE) and Natural Sciences and Engineering Research Council (NSERC) - now require detailed commercialization plans in certain grant applications. In these circumstances, the EDI Office needs sufficient time to understand your project and custom design a commercialization plan, and does not simply rubber stamp researcher draft plans. In addition, Proof of Principal grants are generally institutional applications and are development, not research, applications. The EDI Office takes an active role in both the drafting and review of such grant applications. In addition, the EDI Office should be involved in the decision of when and whether to apply for commercialization related grants. Please involve the EDI Office as soon as you consider applying for a grant of this type.

IV. Patents & Copyright

The greatest expense in the protection of the University's Intellectual Property is the patent process. Each year the University spends tens of thousands of dollars for preparation and filing of patent applications, and maintenance fees for filed patent applications and issued patents. The cost of a patent can range from less than $5000 to more than $40,000, depending upon the complexity of the application and prosecution. A complete national and international patent portfolio on an individual invention can often exceed $300,000. With the increasing number of Invention Disclosures submitted each year, the cost of patent prosecution represents a significant expense. The EDI Office manages this expense by focusing and supporting those discoveries that have or will have commercial value, and filing patent protection only in cases where funding is available and sufficient commercial potential is evident. In addition, the EDI Office does not typically have resources to prosecute patents through the national phase, and will consider letting an invention go if a suitable licensee is not found prior to national phase.

The EDI Office emphasizes that the filing of a patent application does not mean that the University has an issued patent or the right to enforce a patent on the invention. The issuance of the patent typically takes at least 3 to 7 years from the time of first filing. Inventors must also note that issuance of a patent is not guaranteed.

A. Provisional Patent Application

One of the most effective tools for managing the patent process is the provisional patent. The University usually first files a US provisional application rather than full patent applications. A provisional patent application establishes a filing date with the United States Patent and Trademark Office ("USPTO"), provided that the statutory requirements of the patent laws are met. These requirements include a description of the invention sufficient for others to make or use the invention without further undue experimentation (methodology and results). It is the responsibility of the inventors to provide the EDI Office with the requisite written description of their invention.

Provisional patent applications must be converted to an international patent application (PCT Application) within one calendar year of the provisional filing or all rights are lost, with one exception. If the invention has **never been publicly disclosed**, the provisional patent application may be re-filed to restart the provisional year (we'll call this the "Provisional Exception").

During this one-year period the inventor can continue to develop the technology while the EDI Office begins the marketing process and seeks potential licensees.

B. Inventor Responsibility

If any disclosure of IP with potential commercial value to an outside party is anticipated, and the inventor wishes to go through the commercialization process, the inventor should contact the EDI Office as soon as possible BEFORE the disclosure. Even after a provisional patent application has been filed, a University Non-Disclosure Agreement should be executed with any party before disclosure if at all possible, to preserve the Provisional Exception mentioned above (the EDI Office can help with the Non-Disclosure Agreement). In addition, any other disclosures, such as publication, abstract, or oral presentation, should be discussed with the EDI Office to assure that patent protection will not be compromised.

Once a provisional application has been filed, the inventors will be asked to prepare a non-confidential description of the invention to assist the marketing effort. Without this document, marketing activities cannot proceed and the EDI Office may inactivate the file.

If research is continuing in the area of the invention, any new data should be reported to the EDI Office to determine whether a subsequent provisional patent application should be filed.

C. Converting a Provisional Patent Application to an International Patent Application

Conversion of a provisional patent application to a PCT Application is not automatic. The decision to convert depends upon a variety of factors such as other dominating patents in the area of the invention, stage of development, and whether there has been any licensing interest during the provisional year. If there is genuine license interest by the time of conversion or there is an Option Agreement that provides for reimbursement of patent cost, the provisional application will usually be converted. If there has been little or no licensing interest, the EDI Office may not

commit to the expense of patent conversion without outside funding. Conversion decisions are usually reached 30 days before the one-year conversion deadline.

Two and a half years after the initial patent filing, the patent application must be converted to national filings, or abandoned. National filing consists of filing in every specific country around the globe in which you wish to have patent protection. This sometimes requires translating a patent application to foreign languages such as Chinese or Japanese, and can involve very significant cost. If there has been little or no licensing interest since the International Conversion, the EDI Office will not likely commit to the expense of National Conversion without outside funding.

D. Choosing Intellectual Property Counsel

The EDI Office retains outside patent agents to prepare and file patent applications on behalf of the University and its inventors. Through the EDI Office, the University reserves the sole right to choose patent agents, intellectual property lawyers and law firms. The EDI Office only works with a limited number of patent agents; those that have conflicts of interest will not be engaged.

Before drafting a patent application, the selected patent agent will review any provisional patent application and other supporting documents and may meet with the inventors to discuss relevant issues. All matters of inventorship and patentability will be determined by the patent agent in consultation with the EDI Office and the inventors.

The participation and cooperation of the inventors is necessary and expected throughout the patent prosecution process. Inventors should be prepared to provide electronic copies of any abstracts, publications, etc. for ease and efficiency in drafting the patent application. Additionally, inventors must work with the patent agent as needed to provide, in a timely manner, whatever additional information/data may be required to complete the patent application.

Inventors must thoroughly review the patent application before it is filed and sign both a Declaration for Patent Application and formal assignment documents as required by relevant patent office's such as that USPTO or the Canadian Intellectual Property Office. Once an application has been filed, inventors are expected to work with the patent attorneys to respond to Office Actions and other requests from the USPTO in a timely manner. Failure to do so can result in loss of patent rights, prompting the EDI Office to inactivate the commercialization file.

E. Copyright/Trademark

Some Intellectual Property created by Lakehead faculty, such as computer software, survey instruments, assessment tools, web-based applications, films and recordings, and internet-distributed content, represent original works of authorship that are more appropriately protected by copyright rather than patent. When appropriate, copyright is easy to obtain and offers adequate protection without the expense of patenting. A copyright typically secures exclusive rights to reproduction, modification or derivative works, distribution, and public performance and display. Such rights typically last for the life of the author, plus 50 years.

Unlike patents where inventorship is key, authorship creates copyright ownership when an author is the person who physically creates the work, not the one who conceives of the idea or merely contributes to the content.

Ownership of copyright vests initially with the author. In work for hire situations, the employer is the author and the owner if the work was created within the scope of the developer's employment. Therefore, in situations where an employee of Lakehead University creates copyright matter as part of his or her job, the employee would be the author of the work but the University would be the owner. Contractors and consultants hired by the University may create copyright material. If their contract does not stipulate assignment of ownership to the University, copyright remains with the contractor, and rights to use and commercialize the work by the University will be limited.

To preserve intellectual property rights, proper work for hire agreements must be executed with independent contractors. The EDI Office can help identify the appropriate Lakehead agreement to use.

Although not required to maintain rights, affixing a copyright notice to the creative work is useful for providing notice of ownership of rights. Lakehead's copyright notice is:

> Copyright © [insert the year of first publication], Lakehead University, All Rights Reserved.

The EDI Office will consider assisting with the commercialization of copyright matter, on the same basis as patentable matter discussed above. Developers of copyrighted material to be licensed or commercialized by the University must complete an Invention Disclosure, clearly identify any elements coming from third party sources, and obtain in writing any necessary permissions for use and distribution of third-party material. Assignments and/or options must be completed prior to the EDI Office investing resources in copyright commercialization.

Occasionally, it might be advisable to protect brand names associated with Lakehead inventions or programs by the use of trademarks. In fact, in certain cases Lakehead University may apply for special trademark protection using a non-standard process that is more expensive, however less administratively-heavy than the general Canadian trademark process. The EDI Office can assist in obtaining trademark protection for inventions and programs, as applicable. Companies that license these inventions or materials and wish to use the associated trademark are provided permission by licensing the right to use the trademark in conjunction with the materials.

V. Marketing Intellectual Property

According to the Association of University Technology Managers ("AUTM"), fewer than a third of industry licensing executives acknowledge that they routinely canvas universities for new technologies. The most important source of access to university technologies is through personal contact between the company's research and development staff and university personnel. The EDI Office's marketing effort can be substantially enhanced by the inventor's knowledge of the marketplace, likely commercial applications of the invention, and specific companies that might be interested in the technology.

Once the EDI Office has decided to obtain title to an invention, the inventor may be asked to provide:

- A non-confidential marketing summary, written to be understood by a wide audience of both technical and non-technical individuals, which includes a brief description of the invention that highlights the commercial relevance of the technology and how the technology is different from any similar technologies in the marketplace;
- Keyword profile; and
- PDF files of relevant publications.

This information allows the EDI Office to market the invention through its website and other web-based technology marketing services, promote the technology through regional and national technology fairs, and provide non-confidential information to licensing inquiries.

In the event of licensing interest, a Non-Disclosure Agreement will be executed between the University and the potential licensee (the Company) so that the Company can evaluate the strengths of Lakehead's patent position, market potential, and the development needs of the technology. Inventor participation in discussions with the Company may be essential at this time. If the evaluations are favorable, the Company typically begins negotiating a licensing term sheet with the EDI Office.

Throughout these negotiations and even after a license agreement is executed, the EDI Office may continue to promote the invention. The University's technology marketing efforts can also foster industry-to-university collaborations by presenting to industry the ongoing research in our laboratories.

Industry's willingness to license and invest in technology development is largely market driven and greatly influenced by trends in the financial marketplace. The inability to identify a licensee through the EDI Office's marketing efforts is usually due to a lack of market interest. According to AUTM data, less than 15% of all inventions reported to university technology licensing offices are ultimately licensed.

VI. Licensing Process

Strategies for transferring inventions from universities to industry are based upon non-exclusive, exclusive, limited-field, or limited-territory licensing. A non-exclusive license is usually suitable for technologies, such as research tools, that would be of interest to a number of companies. Exclusive licenses are generally granted for technologies where product development requires significant effort and cost on the part of the licensee. An exclusive market position is often necessary to justify the expense. With some technologies, exclusive licensing by discrete fields of use is more appropriate because it allows parallel commercial development in multiple fields or applications. We may also consider limited territorial licensing as well, depending upon the characteristics and markets accessed by potential licensees. The EDI Office welcomes inventor participation in developing appropriate licensing strategies and in establishing certain licensing terms. However, since the University holds title to the invention and assumes the role of licensor, it has the sole liability exposure. Accordingly, negotiation of licensing terms in any agreement is

the right of the University; however, prior to any negotiation, the EDI Office will meet with the inventor to discuss licensing terms and strategy.

To determine if a potential licensee is appropriate for a particular technology, the University may require the Company to submit a brief business plan that outlines its ability and intent to develop the technology and to bring it to market. Information contained in the business plan is used to determine whether the Company is an appropriate match for the technology, field of use, or territory, and will assist in the formulation of a licensing strategy.

A. Term Sheet

The basic financial terms and conditions under which the University and the Company are willing to enter into a license agreement are summarized in a formal, although non-binding, term sheet that must be agreed upon before a license agreement can be drafted. Many factors contribute to the value of a technology, including both variables intrinsic to the technology (e.g., stage of development as disclosed to the EDI Office) and extrinsic (e.g., patent enforceability, competitive markets). An exclusive University license agreement commands fair and equitable compensation by balancing the risk with the reward of a Company's efforts to bring a technology to market. Typical financial considerations include:

- Licensing fee payable within 30 days of agreement execution;
- Reimbursement of past patent costs and an obligation for payment of all future patent costs;
- Payment of minimum annual royalties beginning on the first anniversary of the license agreement;
- Royalties on the sale of licensed products and services;
- Sublicensing proceeds if the Company further licenses Lakehead's technology to a third party; and
- Equity or other compensation, as appropriate, on a case-by-case basis.

Reaching agreement on basic financial terms and conditions for a term sheet commonly requires multiple rounds of negotiation and can take several months. The resultant final term sheet serves as the basis for the EDI Office's drafting of a comprehensive license agreement.

B. License Agreement

All license agreements must protect the mission of the University by ensuring that inventors retain rights to continue research in the licensed field, publish freely, and disseminate tangible research materials related to the invention to other academic researchers. In addition, the University requires that all licensees agree to appropriate indemnity and insurance obligations. In order to ensure these retained rights and protect the interest of the University, the EDI Office uses a standard agreement format and usually prepares the first agreement draft. Company and University interests and objectives are seldom totally aligned, and reaching fair and equitable compromises can be both lengthy and challenging. Whereas the University always enters into such negotiations with the desire to reach mutually acceptable licensing terms, no compromise can be made on matters of academic freedom and institutional liability.

A license agreement defines the structure of a long-term relationship between the University and the Company. In a simple non-exclusive license, the relationship may be limited to a one-time delivery of materials and/or payment of royalties. In exclusive licenses, this relationship is more extensive and often involves ongoing collaborations via sponsored research and consultation between the inventor and the Company.

Although the inventors are not a party to University license agreements, all persons receiving income distributions under a license agreement will be required to review the agreement and sign an acknowledgment agreeing to abide by the terms of the agreement and to any proportional royalty distribution among multiple inventors.

C. Option & Inter-Institutional Agreements

Option: Since a licensing arrangement can represent a significant long-term investment, most companies will undertake a thorough investigation of the patent and market potential and/or evaluate the University's rights and materials before entering into licensing negotiations. In some instances, a Company will request an option to the technology. During this evaluation time period, the University cannot license to another party. Unlike a license agreement, which has a typical life span of 10 to 20 years, option agreements last for only a few months (usually less than six). Because the Company is not granted rights through this vehicle, compensation for an option agreement is usually limited to a modest option fee and/or reimbursement of any patent costs incurred during the option period.

Inter-Institutional: Collaborations with investigators at other universities often result in jointly owned inventions. An Inter-Institutional Agreement creates a relationship by which Lakehead and another university can consolidate their licensing efforts and share the costs and revenues associated with the patenting and licensing of a joint invention. Although such agreements can be complex, requiring considerable negotiation time, they add value to the University's technology by ensuring potential licensees the ability to obtain exclusive rights.

D. Non-Disclosure Agreement

Before an inventor shares confidential and/or unprotected information with a researcher at another institution or a potential licensee, a Non-Disclosure Agreement (NDA) should be executed between the University and the outside parties. The NDA provides the necessary protections for confidential disclosure and limits use of the information by the receiving party. The University prefers to limit the "flow" of confidential information to a one-way direction, either from the University to the other party or from the other party to the University (unilateral). In some cases, it is necessary to have both parties disclose information. The EDI Office will also consider NDAs from external parties, and will review them to ensure that certain minimum requirements are met prior to signing.

The NDA must be signed by the inventor, an authorized representative of the University, and an authorized representative of the other party. A copy of the fully-executed NDA should be returned to the EDI Office before the exchange of any information.

E. Assignment of Rights

Before investing significant time and other resources into a commercialization matter, the EDI Office will require ownership of the Intellectual Property to be either assigned or optioned to the University. The decision of whether or not to take title rests with the EDI Office upon consultation with the VPRI. Many factors are considered when making this decision. When it is determined that it is not in the best interest of the University to pursue or continue to support patent protection on inventions, the EDI Office can release or waive title to the invention to the inventors. The decision to release or waive title is solely the decision of the University, but it is made in consultation with the inventors.

The decision to waive title usually occurs either after the Invention Review is completed, or after a period of marketing with no commercial interest. Upon mutual agreement, the EDI Office will prepare an Assignment Agreement that covers the release of rights from the University to the faculty inventors. This agreement conveys all title to the invention to the inventors and relieves the University of any future rights or obligations to the technology.

In those instances, where the University has invested in marketing and patent filings, the Assignment Agreement may contain provisions for recouping such expenses and a small ongoing royalty if the technology is ultimately licensed, following the provisions set out in the LUFA Collective Agreement.

VII. University Start-Up Companies

As part of its mission to commercialize University innovations, the EDI Office will consider licensing requests from University inventors wanting to start new companies with technologies they have created. Although not obligated to do so, the EDI Office is willing to license technology to a start-up company, provided that the inventors demonstrate a clear commitment and ability to develop the licensed technology, and a clear business case to support ongoing operations of the start-up. Start-ups are encouraged to locate in Northwestern Ontario or Simcoe County to assist with the creation of local and regional employment.

A business plan should be developed prior to the decision to launch a start-up company, to ensure that the company will be financially feasible. It is recommended that the inventor/founder seek outside advice and guidance regarding the development of their business plan, although some assistance can be provided by the EDI Office. The plan should include:

- Description of Business
- Lakehead Technology to be Licensed
- Expected Target Market for Product or Service
- Principal Competition/Market Barriers
- Projected Product Development Timeline
- Management Structure (including faculty/inventor participation)
- Capital Needs and Resources (five-year expense/income projections)
- Equity Distribution

- University resources needed

The EDI Office can assist with several aspects of start-up company creation and organization. The University will consider assisting in circumstances where it can obtain an equity position in the start-up.

Start-up companies require a significant amount of time and resources to create and nurture. In fact, in the technology transfer profession, one start-up is considered to be the equivalent of ten licensing files. The EDI Office will therefore only be able to participate in a limited number of start-ups, and will do so when a suitable commercial promise exists. The EDI Office will also share the names and contact information of local corporate lawyers who are willing to work with Lakehead start-up companies at a discounted, pre-arranged rate.

VIII. Material Transfer Agreements

A significant portion of intellectual property created by Lakehead faculty consists of tangible research materials such as new compounds and formulations and biological research materials such as cell lines and genetic constructs. The abundance of these research materials developed and produced through research efforts of Lakehead scientists by virtue of their prominence, uniqueness, and utility, make up a significant and valuable portion of Lakehead's intellectual property portfolio. As part of the University's obligation to share such research materials with other academic researchers throughout the world, the EDI Office can assist with Material Transfer Agreements to protect the researcher and University interest in their tangible research materials.

When University researchers want to share patented or unpatented tangible properties with their colleagues at non-profit institutions for research purposes, the materials should be transferred under a Material Transfer Agreement (MTA). MTAs are binding legal agreements between the provider of research material and the recipient, which set forth the conditions of transfer and use, protect proprietary interest in the material, and restrict distribution. Most important, the MTA requires the recipient to indemnify the provider from any liability arising from use of the material. Executing an MTA also helps preserve the faculty and University's intellectual property rights while recording the transfer of the invention to another party.

When faculty wish to obtain research material from other non-profit institutions or commercial sources, the provider will usually require that the faculty and University sign their MTA before transfer of the material. MTAs from other academic institutions are all quite similar to those from Lakehead and seldom impose any reach-through rights. However, material transfers from commercial sources often impose unacceptable encumbrances and reach-through rights on any discoveries made with the research materials.

Most MTAs can be processed quickly, but delays can occur when the MTAs contain terms that are contrary to University policy or standard expected terms. This is often the case with MTAs provided by companies for use of their research materials. Delays of several weeks or even months are common when the EDI Office must negotiate with the other party for acceptable terms.

CLOSING

This document is provided as a summary of the current practices of the University's EDI Office and as a guide through the processes involved in managing the University's intellectual property. As government regulations and industry standards change, the University and the EDI Office will review and update these practices. Updates to this document will be available through the EDI Office's website.

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