

WELCOME TO
A RESEARCHER'S GUIDE TO INTELLECTUAL PROPERTY

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This CD was designed for researchers at the University of Ottawa, University of Ottawa Heart Institute and Ottawa Health Research Institute as a tool for learning about intellectual property and the patenting process. All information provided on this CD and links to any other websites are provided for informational purposes only.

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A RESEARCHER'S GUIDE TO INTELLECTUAL PROPERTY

1. Guide to Intellectual Property

1.1 Introduction to Intellectual Property

Simply stated, intellectual property is any form of knowledge or expression created with one's intellect. It includes such things as Inventions, computer software, trademarks, literary, artistic musical or visual works and even expertise or know-how.

Different types of Intellectual Property (IP) can have different forms of legal protection. For example: Inventions may be protected by a patent; while software, literary, artistic and musical works may be protected by copyright. Prior to any patenting a research discovery may require a non-disclosure or confidentiality agreement to be signed, or in the case of a biological material, there may also need to be a material transfer agreement.

The initial ownership of Intellectual Property, in most cases, resides with the creator of that Intellectual Property, but policies at the University of Ottawa, the Ottawa Health Research Institute and the University of Ottawa Heart Institute require the assignment of any invention by a researcher to the institution in exchange for the royalty revenue sharing outlined in the APUO Collective Agreement (Article 35). This provides the basis for policies at UOHI and OHRI, so that all academic researchers fall under the same revenue sharing rules at the University of Ottawa and its affiliated institutions.

1.2 Research Discovery and Inventions

Most inventions and software created at Canadian universities are based on (laboratory-based) research discoveries or research projects that are primarily sponsored by government. In such cases, there is an institutional responsibility (imposed by federal granting agencies and other research sponsors) to ensure that Intellectual Property resulting from research is utilized for the benefit of the public at large. This may require formal intellectual property protection, followed by technology transfer and commercialization (with a Canadian based company, wherever possible).

Research discoveries in all fields of academic research have the potential to be patentable. However, most patentable inventions from Canadian and US institutions result from engineering and biomedical research (see www.autm.net). Increasingly the transfer of intellectual property from academic research to the local community

is becoming an important role for an academic institution. Furthermore this provides tangible examples of local economic development, and a return to the taxpayer on its investment in academic research.

1.3 What is the Benefit to Me, the Inventor(s), if my Invention is Commercialized?

The Inventor(s) will not only enjoy royalty revenues, but will receive satisfaction from knowing that their invention has benefited the public at large, and has contributed to the economic development of the region and the Institute.

2. Patents

2.1 What is a Patent?

First and foremost a patent is a legal document, developed for commercial purposes. A patent is granted by the government of a country (after application, disclosure and review) that gives the owner the right to exclude others from making, using or selling an invention for a limited period of time. This requires complete disclosure of an invention, initially on a confidential basis to the patent office, which later is published as a public document. In Canada, and most other countries, a patent provides protection for 20 years from the original date of application.

A provisional patent may be filed first, as it allows the researcher to get immediate protection over the invention disclosed in the provisional application. A full application must be filed within a year of filing the provisional. Your technology transfer or business development office will advise you on the best course of action.

2.2 What is Patentable?

Products, processes, machines, manufactures or composition of matter, or any new and useful improvement of these, such as new uses of known compounds, are patentable. However, scientific theorems or principles, and methods of doing business are not patentable. Software can be patented if it can meet the three criteria listed below, however, it is difficult to meet the novelty requirement and software patents are not very common.

An invention must be shown to have three major features **to be considered patentable**;

- The Invention must be **novel**;

- The Invention must **have utility**; and

- The Invention must **not be obvious** (to a person skilled in the field)

For most inventions, the third criterion can be the most difficult. For academic researchers, novelty (as defined by the patent office) can be the most difficult, as

researchers may publish or present their results prior to filing a patent application. Novelty requires that no previous public disclosure of the Invention has been made (by the inventor or others), anywhere in the world. In Canada and the U.S. a one-year grace period is provided to inventors that have made their invention public, but such a grace period is not available in Europe.

Most countries, including Canada, operate under a "first-to-file" patent system (i.e. if multiple applications for the same invention are filed, the patent will be granted to the first applicant to file a patent application). The United States operates on a "first-to-invent" system, (i.e. the patent is granted to the person able to prove the earliest date of invention, regardless of the date of filing).

2.3 What May Prevent Obtaining a Patent?

For example, if filing for a patent in the US, the following would prevent the inventor(s) from obtaining it:

- Before he/she made the invention, it was known or used by others in the U.S. or was patented or described in a printed publication in the U.S. or a foreign country.
- The invention was patented or described in a printed publication in the U.S. or a foreign country, or was in public use or on sale in the U.S. more than one year before the date of filing a U.S. patent application.
- The applicant for patent has abandoned the invention.
- He/she did not invent the subject matter sought to be patented, that is, it was invented by another person who was not indicated as an inventor.
- Before the applicant made the invention, it was made in the U.S. by another who had filed for an application and had not abandoned, suppressed or concealed it.
- The invention is not obvious in view of one or more prior publications.
- The scope of the claims are broader than what was disclosed in the application.
- The invention lacks a specific, credible and substantial utility.
- The subject matter is non-statutory - for example, cloning of humans. Additionally, methods of medical treatment, or animals and plants are not patentable in Canada; in Europe diagnostic and therapeutic methods of medical treatment are not patentable.

2.4 What is Public Disclosure?

Any previous public disclosure may void the right to patent. Public disclosure refers to any public presentations, abstracts or publication of the research discovery has been made. It is important to note that grant applications can also be considered a public disclosure. To be certain, contact the Technology Transfer/Business Development office as soon as you believe you have an invention that may be patentable.

It is the relationship between the parties that determines whether the disclosure is public or made in confidence. The disclosure is legally confidential if, the recipient personally understands and accepts a duty to keep the information confidential. A disclosure to an academic colleague may or may not be considered confidential depending on the understanding between the parties. Any printed publication in a newspaper, scientific journal or other written form available on an unrestricted basis is a public disclosure, as is an oral presentation at a public meeting. Published pre-prints or abstracts of (a) papers for a scientific meeting or (b) degree theses are also considered public disclosures. A non-disclosure agreement (NDA) can be used to ensure confidentiality and protect the IP (Talk to your Technology Transfer/Business Development Office to arrange for this).

2.5 Effect of a Publication on Patent Rights

An application must be filed in Canada or the U.S. within one year of a disclosure (anywhere in the world) made by the inventor. However, a disclosure prior to filing the application by the inventor or other person is a bar to filing the application in most other countries.

A publication, anywhere in the world, that is published prior to the priority date of the application and that describes the invention is an immediate bar to a patent in most foreign countries. In foreign countries which adhere to an International Convention on priority, a publication which describes an invention is not a bar to a patent provided that the publication appeared after the filing date of the priority application, for example a U.S. or Canadian patent application on the invention and provided that the foreign patent application is filed within one year of the priority filing date.

2.6 I Think My Invention is Patentable, Now What?

If you think your invention may be patentable (novel, has utility and not obvious) contact your Technology Transfer Office immediately. Be aware that publication may impact any opportunity to patent. You will be asked to complete an invention disclosure form so that the intellectual property assessment process can begin.

3. Intellectual Property Assessment Process

Once a researcher or clinician-scientist feels that he/she has made an invention, contact your Technology Transfer/Business Development office. They will assist you in completing an invention disclosure form that will initiate the formal institutional intellectual property assessment process/review of your invention.

There are 5 components in the invention assessment process as follows:

- Invention Disclosure Process: Review Novelty, Inventors, Publication Timelines, Funding Sources
- Patentability Assessment: Patent Search/Opinion
- Commercial Assessment: Marketability, Partners
- Research/Service Assessment: Impact on Research Funding
- Financial Assessment: Patent Funding Source/Recovery

3.1 Invention Disclosure Process

What is involved in the Invention Disclosure Process?

This process involves providing a description of the invention to your technology transfer/business development office. The market potential of the invention will be assessed. Since patenting and commercialization of technologies is a costly endeavour, the invention must have a potential market that would prove to attract investment, research or licensing opportunities. This will depend on the potential market for the product, the likely technological success of developing it, and the status of the area of the technology (i.e. state of the economy, investor interest in the area of the technology and the competitive environment). In addition the invention disclosure process involves an assessment to identify inventors, and to determine if publication timelines and funding sources may impact the possibility for patentability. **If you have a possible invention be sure to talk with your Technology Transfer/Business Development office before publishing, as PUBLICATION MAY ELIMINATE THE POSSIBILITY FOR PATENTING.*

Why is My Lab Notebook Important to this Process?

An inventor(s) lab notebook is a record of activity, and can prove the date of invention and disclosure if proper lab book procedure is followed (i.e. a permanently bound lab book is used; each page is dated and signed by both the inventor and a witness; pages are not torn out of the lab book; pictures and data printouts are securely fixed in the lab book). If these procedures are followed, the date of invention may be determined as the latter of the date that both the inventor and witness signed. Otherwise, the filing date of the application in the U.S. may be considered the date of invention. Most countries, except the United States, operate under a "first-to-file" patent system. This means that if two or more applications for a patent for the same invention have been filed, the patent may be granted to the first applicant. The United States grants patents to the first to invent (not the first to file) so evidence of the date of invention is of the utmost importance, especially since the US, being the largest market, is most often the first choice of country to patent an invention in.

Who are the Inventors?

An inventor is a person who has had an original idea or otherwise contributed intellectual input to the invention and who has placed the idea in a format that can be followed by one of skill, for example, writing the idea out, along with appropriate methods described. Inventorship is determined by what is claimed. A patent application may be filed naming one or more inventors. A person who works under the direction of another and does not contribute any original thought to the claimed invention, i.e., "works as a technician" under direction from the inventor to confirm an invention, need not be named as an inventor.

Professional collaborators may or may not contribute to the inventive concept being claimed and great care should be taken in deciding who should be named as an inventor. It is important to understand that inventorship is a legal matter, not a collegial matter - not all co-authors of a publication are necessarily co-inventors (However, this does not limit the acknowledgement of collaborators not deemed to be co-inventors through a sharing of any net proceeds from the invention. A sharing agreement should be put in place and lodged with the Invention Disclosure Form). As a starting point in assessing inventors, consider all potential persons involved in the research project (staff, students, colleagues, etc.) and then eliminate those that did not contribute original thought to the invention. Inventorship will be formally reviewed as part of the Invention Disclosure.

3.2 Patentability Assessment Process

Once an invention is disclosed to your Technology Transfer/Business Development Office, and it has potential for filling a market need, or for attracting investment, research or licensing opportunities, a patentability assessment process will be carried out. This is the process to determine if the invention is patentable. The invention will be assessed to see if it meets the patentability criteria. In other words, to see if the invention is novel, has utility, and is non-obvious to someone skilled in the art. An opinion may be solicited from a patent agent/lawyer. It is important to note that patenting, in and of itself, is not a useful goal. Further assessments of commercial, financial and market potential therefore also play a role in the decision to patent an invention or not.

3.3 Commercial Assessment

Upon first review, the invention must be shown to have some commercial value, or else the investment in patenting will not be returned. To enhance technology transfer and economic development, there must be a potential market for the patent.

3.4 Research / Service Assessment

This refers to the potential to attract research funding, as a result of a patent. Since it is the primary goal of the Institute to carry out research, such an impact would support the filing of a patent.

3.5 Financial Assessment

A financial assessment is performed to determine whether the patent will bring in at least enough money to cover the cost of patenting. Otherwise, it would not make sense to patent the invention.

4. Patenting Process

4.1 What Can I Expect?

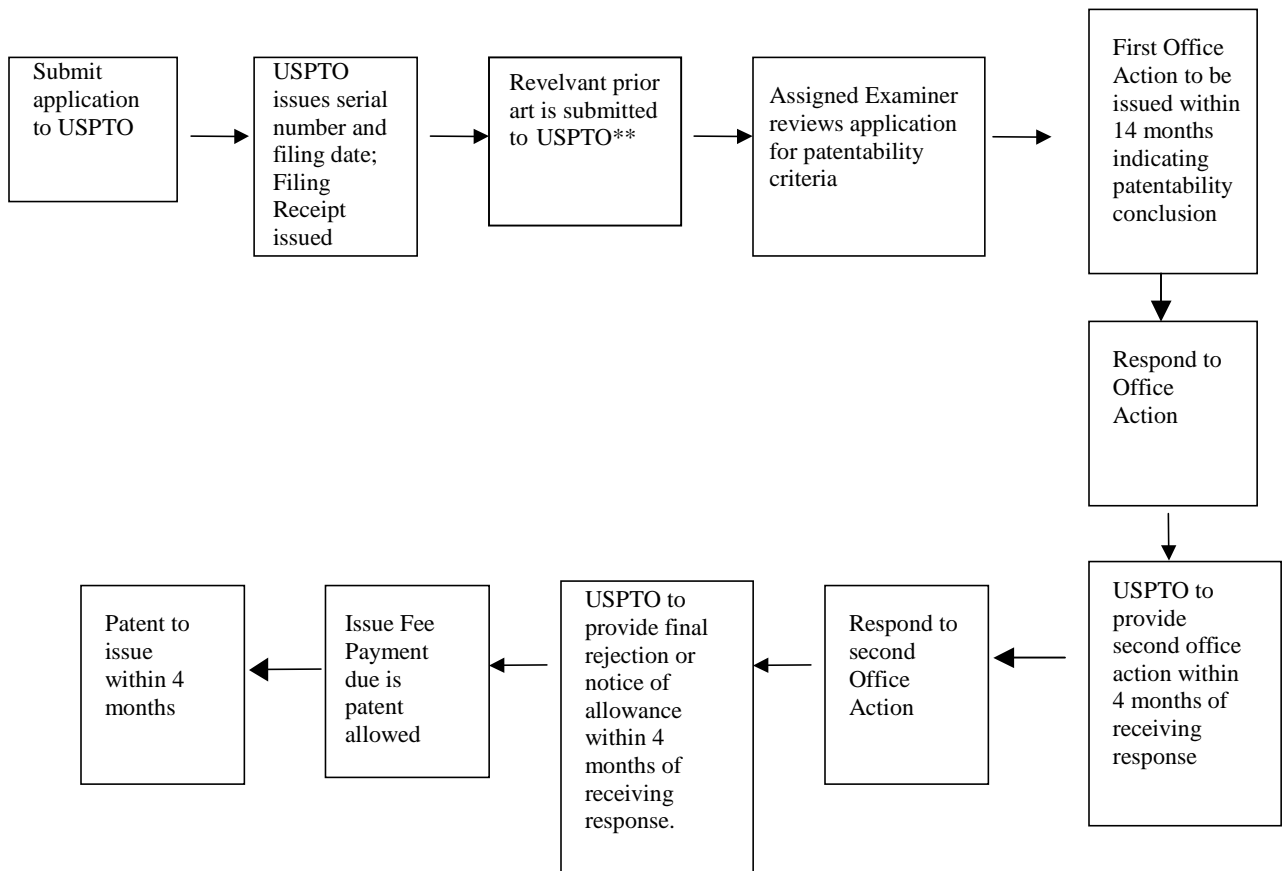
Once the decision is made to file a patent, the Inventor will need to work with a patent agent to prepare the application. The Inventor will assist in describing the Invention and in determining its' Claims. The Technology Transfer/Business Development office will assist with this process and will facilitate the process of acquiring and communicating with the patent agent.

The patenting process is essentially the same in most countries, but the times to issue can vary significantly. Various strategies for filing a patent application exist depending on which countries you choose to patent in, and how many countries you seek protection in. An application can be filed in individual countries, in regions, or alternatively an international patent application may be filed using the Patent Cooperation Treaty (PCT).

It should be noted that patents are only valid in a country. The PCT is a filing system - an international patent is not obtained through the PCT - the application must enter one or more countries of interest at the completion of the PCT proceedings. In Europe, a regional patenting process exists. However, this is a transient event that is completed by validating the patent in desired European countries. A European patent, is therefore only valid if it is validated (registered) in one or more countries within the EU after its issuance. International and regional patents become worthwhile if protection is sought in many countries, as the application will only be examined once (by the international or regional body), rather than by each country as would be the case if national applications were filed in each country of interest.

The Business Development Office and the patent agent will help you to determine the best strategy for your invention. As the U.S. is the largest market, and therefore most patents are filed there first (as a general rule of thumb), a flowchart outlining the filing process in the United States is below.

Example: The Process for Acquiring a U.S. Patent



→ Time from filing to issue is approximately 3 years in the U.S.

** Any publications that the inventor is aware of must be submitted to the USPTO, typically prior to examination, and throughout the examination process.

After the initial application is filed, a future application may be filed in any desired country within 12 months of the initial filing date. This future application typically claims priority to the initially filed application (The priority date is therefore the date of initial filing of a patent application). As stated above, filing a patent in individual countries tends to become very expensive, and this option is therefore less feasible if protection is sought in many countries. At this stage a European patent may be applied for, and then registered and maintained in the countries you seek protection in. If there is some uncertainty as to whether an application is to be filed within several countries, an application can be filed through the PCT thereby delaying the filing decision, and associated costs for up to 30 months from the earliest filing date. The PCT application must be filed in one or more desired countries by the end of the 30 month period. During the PCT proceedings a search is carried out that identifies any relevant prior art, and a preliminary examination of the application may also be

requested. This information is useful in determining whether or not the application is to enter other countries at the end of the PCT proceedings.

4.2 When will I get a Patent?

This will depend on the country you are patenting in, with the total time from submission to granting ranging from two to ten years. Fortunately the invention is protected from the date of publication, provided that a patent issues from the application. In the U.S. patents generally issue within 3 years, while Canadian patents on average take 4-7 years to issue. This is partially due to the number of patent examiners available in various disciplines, and whether or not examination has been requested in a timely manner. A Notice of Allowance will be received once the patent examiner determines that the patent does meet all patentability criteria, and the granted patent will be received in the Business Development Office within 3-6 months after payment of the final fee.

4.3 What are the Costs of Patenting?

The development of a patent application will usually cost between \$5,000 and \$10,000. This will be an iterative process involving the inventor(s), the Technology Transfer/Business Development Office and the patent agent. Routinely, both US and Canadian patents are filed and, in rare cases, where market demand can be demonstrated, or where external (sponsors) funds are invested, patents can be filed in other countries as well. As a guideline patenting will cost about \$10,000 per country over the life of the patent. However the US patent office is considering a significant increase in patenting costs in 2003, and this guideline may need to be revised upwards.

The Technology Transfer/Business Development office normally bears the initial cost of protecting and exploiting your invention. If it is successful in generating income, the first charge on that income is reimbursement of the costs. Thereafter, income will be divided between the Institution and the inventors. The inventor's share of net revenues (currently 80% of the first \$100,000 net revenues and 50% thereafter) will follow the latest APUO Collective Agreement. Link:
<http://www.apuo.uottawa.ca/Info/Convention/35.htm>

4.4 If I Opt to Patent, When Can I Publish?

Once a patent application is filed, the inventor can publish.

It should be noted that a provisional patent may be filed first if it is required that the application be filed in a rush (due to a planned disclosure of the invention). [There are no real cost savings in taking this route.] However, it is strongly recommended that a full application be filed to ensure that the earliest priority date is obtained. By filing the application, this allows the researcher to get an initial filing date for the

invention disclosed in the application. If a provisional application is filed, then within a year of that filing, a full application must be filed. If a provisional or regular application was filed it may be amended and re-filed along with any new data, and further claims concerning new aspects of the invention. However, if you file either a provisional or regular patent application and then publish or present your results elsewhere, you must ensure that the published subject matter was included within the original provisional or regular application. If the published data is included in the application after the publication date, then the published data may be cited against you during examination (see above on novelty). Publication timelines and content must also, therefore, be discussed with your Technology Transfer/Business Development Office.

5. Other Forms of Intellectual Property Protection

5.1 Copyright

Copyright is the exclusive right of the creator, or subsequent copyright holder, to reproduce a work. Copyright subsists as soon as an artistic, literary or musical work or software is created, and registration at the Copyright Office is purely voluntary. It is however, advisable to put the public on notice that the creator is claiming Copyright by marking all copies of the work with a Copyright Notice. Registration of a Copyright facilitates the Copyright holder's rights in the event of a legal dispute. Copyright protection in Canada lasts for the life of the creator plus fifty (50) years. Copyright extends to other countries by virtue of treaties such as the Berne Convention and Universal Copyright Convention and the term in other countries depends on the national law.

5.2 Know - How

A researcher's know-how can often have considerable value. While it is mandatory in filing a patent application to disclose sufficient information to enable others to practice the invention, the researcher will often possess valuable confidential know-how and experience to permit commercial optimization of a process or product. Know-how can be licensed independently and a know-how license need not be restricted to the term of the related patent. Confidential information and know-how should, therefore, be clearly defined and disclosures should be covered by a written contract. Know-how, expertise, and "show-how" (a term related to the teaching of new techniques) often form the basis of the valued-added a researcher can provide to an industrial sponsor. This expertise should be included in the research contract or consulting agreement established with a commercial partner and/or industrial research sponsor.

6. How do I Contact my Technology Transfer Office?

6.1 University of Ottawa Heart Institute

Business Development Office

40, rue Ruskin Street
Ottawa, ON
K1Y4W7
Fax: (613) 761-4214

Mr. Joe Irvine, VP Business Development & Medical Affairs
Room H2-53
jjirvine@ottawaheart.ca
Tel: (613) 761-4721

Mrs. Erin Yamazaki, Business Development Officer
Room H2-47
eyamazaki@ottawaheart.ca
Tel: (613) 798-5555, ext. 13191

6.2 University of Ottawa

Technology Transfer and Business Enterprise Office

<http://www.ttbe.uottawa.ca/>

Suite 3042 - SITE

800 King Edward Avenue
Ottawa, ON
K1N 6N5
Tel: (613) 562-5399
Fax: (613) 562-5336
ttbe@uottawa.ca

6.3 Ottawa Health Research Institute

Technology Transfer and Business Development Office

<http://www.ohri.ca>

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725 Parkdale Avenue

Ottawa, Ontario
K1Y 4E9

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7. References

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This resource is primarily based on materials developed by the Canadian University Intellectual Property Group (CUIPG), a group comprising the Directors of Intellectual Property/Industrial Licensing offices at nine Canadian universities as a means to provide the Canadian University community with information on matters pertaining to Intellectual Property. Their document is available at:

<http://www.parteginnovations.com>

Additional materials consulted to prepare these materials include "A Tutorial On Technology Transfer in U.S. Colleges and Universities" which is available at

<http://www.cogr.edu/techtransfertutorial.htm> and from reference materials published by the Association of University Technology Managers (www.autm.net), as

well as John Hopkins University,

(<http://www.hopkinsmedicine.org/lbd/otl/GenInfo.html>).