INNOVATION TO COMMERCIALIZATION

A guide to protecting your Intellectual Property

BLG
Borden Ladner Gervais

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What is Intellectual Property?

Intellectual property (IP) refers to creations of the mind: inventions, literary and artistic works, and symbols, names, images and designs used in commerce.

Intellectual property is divided into two categories: Industrial property, which includes inventions (patents), trademarks, industrial designs and geographic indications of source; and copyright, which includes literary and artistic works such as novels, poems and plays, films, musical works, artistic works such as drawings, paintings, photographs and sculptures, and architectural designs. Rights related to copyright include those of performing artists in their performances, producers of phonograms in their recordings and those of broadcasters in their radio and television programs.

Source: World Intellectual Property Organization

“Before everything else, getting ready is the secret of success.”

Alexander Graham Bell

Introduction

At Borden Ladner Gervais LLP (BLG), we are excited by new ideas. We also understand that nurturing an idea and developing it into a viable business opportunity can be a daunting task. How do you translate your discovery into dollars?

A strong foundation for your company is absolutely crucial. In many cases, that foundation is your company's Intellectual Property (IP). Your IP must be effectively protected from the outset to adequately support a clear path to commercialization.

We have developed this reference guide to provide a basic introduction to patents and commercialization. Whether it serves as an introduction to the subjects or simply reinforces your current knowledge, we hope that it will assist innovators on the path from innovation to commercialization in bringing products and services to market for the benefit of Canada.

We are here to help. BLG has offices in Calgary, Montréal, Ottawa, Toronto and Vancouver.

Expert advice is closer than you think.

Contact Us: info@blg.com

Patents

What is a patent and what does it do?

A patent is an IP right granted by a country to the patent holder for a specific period of time. It gives the patent holder the exclusive right to prevent others from making, using, offering for sale, selling or importing articles covered by the invention *without the patent holder's permission.* In exchange for this exclusive right granted by a country, the patent holder must disclose the invention to the public.

What a patent does *not* do is grant the right to make, use, offer for sale, sell or import the patented article. The patent holder must comply with laws that affect the manufacture, advertising, use and sale of the patented article (for example, the *Food and Drugs Act* and its regulations may apply to a biotechnology invention).

A patent only offers protection in the country in which it is obtained. Therefore, an Applicant should obtain a patent in every country where a substantial market exists for the patented article (including articles developed from a patented process).

> **"The patent system added the fuel of interest to the fire of genuis."**
> ***Abraham Lincoln***

What criteria must my invention meet to be patentable?

Invention

Each country has its own laws governing what is patentable. In Canada, an invention is defined as "any new and useful art, process,

machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter." In the United States, whoever "invents or discovers any new and useful process, machine, manufacture or composition of matter" or any improvement thereof is entitled to a patent. In Europe "any invention which [is] susceptible of industrial application" is patentable unless a specific exclusion is noted. Each country continues to clarify the limits of the law regarding what is, and is not, patentable.For example, the Canadian courts and the *Canadian Patent Act* have established the following criteria:

- the subject matter must relate to a useful art as distinct from a fine art;
- the inventor must adequately describe the subject matter so it is operable, controllable and reproducible;
- the subject matter must have practical application in industry, trade or commerce; and
- the subject matter must be more than a mere scientific principle or abstract theorem.

The terms "art," "process," "machine," "manufacture" and "composition of matter" are not defined in the *Patent Act* and are used as generally understood. Although this seems to include anything and everything, the Canadian courts and sections of the *Patent Act* exclude specific subject matter from being patentable. For example, a patent cannot be granted for software. Business methods may be patentable according to a ruling of the Federal Court in the Amazon[1] decision. The court held that there are three important elements in the test for whether subject matter falls within the definition of an "art": i) it must have a practical application, ii) it must be a new and inventive method of applying skill or knowledge, iii) it must have a commercially useful result. Methods of medical treatment are also

[1] Amazon.com, Inc. v. The Attorney General of Canada, and The Commissioner of Patents (2010), 2010 FC 1011.

not patentable. Canadian courts do not allow patents for higher life forms, including plants and animals. The Supreme Court of Canada ruled accordingly in the Harvard Mouse decision.[2] However, a subsequent decision allowed claims to a plant cell to be enforceable against an infringer possessing an entire plant.[3] This decision gives inventors of new higher life forms some protection.

The law continues to evolve. In particular, caution needs to be taken when attempting to patent diagnostic methods, methods of medical treatment, higher life forms, business methods and computer programs. The laws on these subjects vary depending upon the country, and the specific limitations can be subtle. Often commercially valuable patents can be designed with use of the appropriate wording. Therefore it is very helpful to consult a patent agent on these matters.

> **"Research serves to make building stones out of stumbling blocks."**
> ***Arthur Little***

Novelty/Disclosure

In many countries an invention must not have been disclosed anywhere in the world before the initial patent application is filed (not necessarily in Canada) or the invention will not be patentable. Disclosure means any form of public disclosure including journal articles, published patent applications, abstracts, conference proceedings, trade pamphlets, magazine articles, theses, PowerPoint presentations, oral disclosures and trade-show viewings.

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[2] Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45, 2002 SCC 76.
[3] Percy Scmeiser.

In Canada, an exception exists where the novelty of the invention will not be destroyed if the inventor, or someone acquiring knowledge directly or indirectly from the inventor, makes the information public within one year before the patent application is filed. Inventors should pay particular attention to journals or conference materials that post material on the Internet before the print versions are published. The earliest public disclosure date will prevail. The USA, Mexico and Australia offer a similar grace period.

> **"The most exciting phrase to hear in science, the one that heralds new discoveries, is not 'Eureka!' but 'That's funny...'"**
>
> ***'Doc' Edgerton***

As noted, many countries do not allow grace periods, meaning that, if the invention is disclosed anywhere in the world before the initial application is filed (not necessarily in any one of those countries), it will not qualify for protection in all of those countries. For this reason, inventors are strongly advised not to disclose their invention before filing appropriate patent applications.

For Canadian patent applications, the grace period for the public disclosure covers one year back from the filing date in Canada. Therefore, when an inventor makes a public disclosure anywhere in the world, the inventor must file a patent application in the Canadian Patent Office within one year of that disclosure so that the invention may still be considered novel. If the inventor files the patent application after the grace period has expired, the disclosure counts as prior art.[4]

[4] See section on Prior Art in this document.

If the inventor must disclose all or some elements of an invention during business negotiations, he or she must protect the confidentiality of that information by having the recipient sign a confidentiality agreement (also called a non-disclosure agreement) beforehand. A confidential disclosure (preferably supported by a signed agreement) does not destroy the novelty of an invention. However, there is always a possibility that the recipient will disclose the confidential information, accidentally or otherwise.

In Canada, selling a product that incorporates an invention does not constitute public disclosure if the product cannot be "reverse-engineered" to reveal the invention. If the sale of the product does not reveal or disclose the invention to the public, then a subsequent patent directed to that invention could still be granted to the inventor.[5]

Inventive Ingenuity/Obviousness

For subject matter to be inventive, it must not be obvious. A determination of what is obvious is undertaken by each national patent office. In most cases, it must be more than a mere workshop improvement. If someone with general knowledge in the subject matter can "discover" the invention, the invention is considered obvious and therefore non-patentable. In addition, the combination of known elements may make the subject matter obvious.[6] Keep in mind, however, that everything appears obvious in hindsight. It is therefore helpful to consult a patent agent to determine whether the subject matter would be considered obvious.

"There's a way to do it better – find it."
Thomas Edison

[5] *Baker Petrolite Corp. v. Canwell-Enviro Industries Limited* (2001), 13 C.P.R. (4th) 193 (F.C.T.D.).
[6] *KSR International v. Teleflex Inc.* 550 U.S.(2007)

As with novelty, many countries do not allow for a one year grace period, but in Canada if the inventor makes a public disclosure anywhere in the world, and so long as the Canadian patent application is filed within one year of that disclosure, the disclosure will not apply against the Canadian patent application and make the invention obvious.

Like novelty, the one-year grace period only applies if the inventor, or someone acquiring knowledge directly or indirectly from the inventor, discloses the information. A disclosure by any other person will count as prior art.[7]

Utility

To qualify as an invention, the subject matter must have utility. Utility is generally assessed on a claim-by-claim basis. In Canada, if an invention does not do what the claim says it will do, the application is rejected. The inventor must carefully consider the claims stated in an application to avoid claiming any subject matter that does not work as described. Any such claim would be considered invalid. In some cases, the subject matter does not have the sufficient or substantial utility required for patentability. Expressed sequence tags (ESTs), for example are not considered to meet the utility requirement under many laws.[8]

> **“Anything that won’t sell, I don’t want to invent. Its sale is proof of utility, and utility is success.”**
> ***Thomas Edison***

[7] See section on Prior Art in this document.

[8] *In re Fisher,* 421 F.3d at 1374, 76 USPQ2d at 12; Trilateral Project B3b *“Comparative study on biotechnology patent practices Theme: Patentability of DNA fragments”.*

What do I need to understand about Patent Laws?

Each country has a set of laws relating to the protection of patents in that country. For example the current patent law in the USA is set out in Title 35 of the United States Code. The current Canadian patent law is set out in the *Patent Act*.[9] On October 1, 1989, amendments were made that changed the system from first-to-invent to a first-to-file. The Act was amended again, effective January 1, 1994, to comply with the North American Free Trade Agreement. As a result of these amendments, and in response to the use of the first-to-file system, more amendments were made, effective October 1, 1996. Because of the changes over the years, it is important to refer to the relevant version of the Act and to the appropriate transitional rules.

As noted earlier, a patent application must be filed in each country for which patent protection is desired. Each country applies its own laws to determine whether the invention is patentable, and will ultimately issue a patent, if appropriate. Filing in each desired country is clearly a costly endeavor, and it is often desirable to delay many of these costs for as long as possible.

The Patent Co-operation Treaty (PCT) is a multi-lateral treaty that provides an administrative procedure to allow for the filing of a single international patent application, for all countries which are a party to the treaty.[10] The filing of a PCT application allows the Applicant (inventor(s)/owner(s)) to express the intention to have national patent applications filed in the indicated countries, but permits the deferral of the cost of translations and national filing fees for at least 20 months from the first date on which a patent application on the subject matter has been filed.

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[9] R.S.C. 1985, c. P-4 as amended.

[10] At last count 142 countries are members of the PCT.

Review of the merits of the application can often be delayed even further. Most jurisdictions permit national filing to be deferred for at least 30 months.[11]

First-to-invent

In Canada, before October 1989, the rights to an invention were determined by the date of the invention. If two inventors filed applications containing the same subject matter, a patent for the overlapping subject matter would be granted to the inventor proving the earlier date of invention. The USA is one of the few jurisdictions still operating under this first-to-invent system.

Patents issued in Canada before October 1989 were granted a term of 17 years from their date of issue. Amendments that came into effect on July 12, 2001 extended this term to the longer of 17 years from the date of issue or 20 years from the date the application was filed. This extension applies only to patents that were filed before October 1, 1989 and in good standing as of July 12, 2001. A patent that expired before July 12, 2001 cannot be revived to benefit from the extension.

> **“They thought I was crazy, absolutely mad.”**
>
> ***Barbara McClintock*** *on the initial response of the National Academy of Sciences to her (later Nobel prize-winning) theory that proposed that genes could “jump” to new locations on a chromosome.*

First-to-file

Almost all countries (except the USA as noted) operate on a first-to-file basis. This means that the exclusive rights granted in each country are given to the first person to file a patent application on

[11] Further information on national and regional phase deadline s under the PCT may be found at: http://www.wipo.int/pct/en/texts/time_limits.html

the subject matter. Luckily, it is not necessary to race to each patent office in the world to demonstrate first filing. Rather, in accordance with the Paris Convention, the filing of a "priority" patent application in any Paris Convention member country[12] will be considered as the first filing date (or "priority date") in each Paris Convention member country, if certain criteria are met. In particular, a patent application can "claim priority" to an earlier-filed application that described the same invention, so long as the later application is filed no more than 12 months after the earlier-filed application and the subject matter in the earlier-filed application fully supports the claims in the later application. When properly and timely filed, the later application enjoys the benefit of an earlier "priority date" or "claim date" that corresponds to the filing date of the earlier application. Where two or more inventors claim the same subject matter in separate applications, the inventor having the earliest claim date is entitled to a patent for the overlapping subject matter.

For example, since October 1, 1989, when Canada converted to a first-to-file system, the filing date serves as the "claim date" to determine priority among competing claims to an invention.

As a member of the Paris Convention, as well as NAFTA and WTO agreements, Canada will grant an earlier claim date if:

- an application was filed in a country that is a member of one of these agreements[13],
- an application was filed in Canada within one year after the earliest filed application, and
- the Applicant claimed priority from the filing date of the earlier filed application. Such an earlier filing date is referred to as the priority date or "claim date."

[12] At last count 173 countries are members of the Paris Convention.

[13] At least one of the Applicants must be a resident or citizen of a country that is a signatory to these agreements.

It is important to note that each claim in a Canadian patent application has a claim date. Therefore, several priority applications may be relied on to support different claims of an application, provided that the Canadian application is filed within one year from the earliest application. A claim may derive its claim date from any of these priority applications, not necessarily the earliest one. Where several priority applications are relied on, claims in the Canadian application may have different claim dates from each other. This may be significant when determining novelty and obviousness of the claimed subject matter, particularly when relevant prior art is published between the earliest filing of the priority application and the Canadian application.

> **"Intellectual growth should commence at birth and cease only at death."**
> ***Albert Einstein***

Publication of Patent Applications

Patent applications are published or "laid open" to the public 18 months after the earlier of the filing date or priority date. There is a limited exception in the United States. An Applicant can request that the application not be published if the invention disclosed has not, and will not, be the subject of an application filed in any other country or under any multilateral agreement.

> **"In questions of science the authority of a thousand is not worth the humble reasoning of a single individual."**
> ***Galileo Galilei***

Term of Patent Protection

The term for patents filed under the first-to-file system is 20 years from the date of filing. There is currently no mechanism for obtaining an extension of the patent term in Canada although the United States does have some patent term extension provisions (for example for pre-market regulatory review).

How and where do I file my patent applications?

Patent agents are fully trained to draw up the complex legal documents that make up a patent application. Inventors are strongly advised not to do it themselves. Patent agents are also better placed to handle the many deadlines and steps in the process from application to issuance. In particular, Canadian patent agents are often qualified to file Canadian, U.S. and PCT patent applications and, in conjunction with the Applicant, can assist in designing a strategy which helps preserve rights in each of the countries where the Applicant wishes to have the protection, while minimizing costs.

> **"A journey of a thousand miles begins with a single step."**
>
> ***Lao Tse***

How do I get the ball rolling for a Canadian Patent Application?

Under the Canadian *Patent Act,* the Applicant has two options for filing a Canadian Patent Application. The Applicant can either file directly in Canada, or can file a Canadian national phase patent after the filing of a PCT application designating Canada as one of the countries in which patent protection is sought.

For purposes of filing an application directly in Canada, the Applicant need only file the minimally required documents to obtain a filing date. For all applications filed after October 1, 1996, the minimum requirements are:

- a written statement that a patent is being sought;
- a document in English or French that describes the invention;
- the name of the Applicant (which may be the inventor, or his or her university or research institution depending on the arrangements between the inventor and his or her institution);
- the address of the Applicant or his, her or its patent agent; and
- the application fee.

A Canadian national phase application of a PCT application must be filed in Canada within the later of (i) 30-months from the priority date or (ii) 42 months from the priority date with the payment of an additional late fee. For filing a Canadian national phase application, the minimum requirements are:

- a copy of the international application, if it has not been published
- a translation of the international application, if the published application is not in English or French
- the basic national phase application fee.

For the purposes of the national phase application, the filing date of the application in Canada, once filed, is deemed to be the same as the filing date of the PCT application.

On receiving the document through either route, the Canadian Patent Office reviews the form of the document rather than its substance or merit. When only the minimum requirements are met, the application is considered “incomplete.” No new subject matter may be added to a Canadian incomplete application that is not already fully described or supported by the incomplete application at the time of its Canadian filing.

The Canadian incomplete application is not a parallel process to the United States provisional patent application. For example, unlike the United States provisional patent application, the 20-year patent term in Canada begins on the date the incomplete application is filed (or is deemed to be filed), not when it is completed.

Some useful terminology to remember:
A "claim" is what the inventor says the invention will do. A "patent specification" is a detailed description of the invention, followed by a set of claims.

> **"Innovation distinguishes a leader and a follower."**
> ***Steve Jobs***

How many inventions may I claim in one patent?

A patent is granted for one invention only, although a patent that includes more than one invention is not invalidated for that reason alone.[14] Under the Patent Rules, an application may include more than one invention if the subject matter forms, by design or operation, a "single general inventive concept." The Canadian Patent Office considers the following combinations to be acceptable in the same application:

- a product and a process for making a product;
- a product and a use of the product;
- a product, a process for making the product and a use of the product;
- a process and an apparatus designed to carry out the process;

[14] See the section on Divisional Applications in this document.

- a product, a process for making the product and an apparatus designed to carry out the process; and
- a product, a process for making the product, an apparatus designed to carry out the process and a use of the product.

An application may include claims to a final product and to an intermediate product used to directly manufacture the final product – but only if the two are similar enough that one was clearly designed to prepare the other. The intermediate product may have the same use as the final product, but it must not have other uses.

On the other hand, a "single general inventive concept" may not be present if an application includes (1) a claim to compound A, (2) a claim to compound B and (3) a claim to the combination of A and B. Claims (1) and (3) may be in the same application, or (2) and (3). However, claims (1) and (2) are directed to different substances and, therefore, lack unity. Such claims may be divided into one or more divisional applications.[15]

What if I have too many inventions in one patent?

Divisional Applications

In Canada, Applicants may file a divisional application based on its "parent" application at any time before the parent application issues to patent. The parent application can, itself, be a divisional application. Much like a family tree, if an application is divided more than once, the first divisional application may be a parent to a later one. Therefore, Applicants may still file divisional applications even though the original application has issued to patent, as long as at least one divisional application is pending that describes all the inventions.

[15] See the section on Divisional Applications in this document.

If the Canadian Patent Office insists that the application be divided on the basis of unity of invention[16], any attack for "double patenting" will fail because the Patent Examiner requested the division (referred to as filing a divisional application "involuntarily"). However, a divisional application filed "voluntarily" by the Applicant may be open to a double-patenting attack. Applicants are strongly advised not to "voluntarily" file divisional applications.

What else do I need to do to complete the application?

The Applicant must file the following additional documents with the Canadian Patent Office within 15 months from the earlier of the earliest claimed priority date and the Canadian filing date:

- the petition;
- an abstract of the invention;
- claim(s) to the invention;
- any drawing mentioned in the description;
- a biological deposit (e.g. microorganism) number, if applicable; and
- a sequence listing (i.e. novel nucleotide or peptide sequence(s)), if applicable.

The patent specification must describe the invention and its operation in such full and exact terms that anybody experienced in the subject matter (referred to as a "person skilled in the art") can make, construct or use the invention. The entire patent specification must state the novel and inventive features of the invention, and it must end with a claim defining the subject matter. If the patent specification is not detailed enough, one or more claims may be found invalid.

Prior to allowance, the Applicant must file a statement explaining how the Applicant is entitled to the invention. The Applicant cannot add new

[16] See section above.

subject matter to the application once it has been filed. This includes new features in the invention, more data, recent developments or a more precise description.

What is the Canadian Intellectual Property Office (CIPO)?

CIPO is responsible for administering and processing the IP in Canada. Its areas of activity include:

- Patents: new inventions (process, machine, manufacture, composition of matter) or any new and useful improvement of an existing invention;
- Trade-marks: words, symbols and/or designs used to distinguish goods or services;
- Copyright: protection for artistic, dramatic, musical or literary works (including computer programs), and performance, sound recording and communication signal;
- Industrial design: the visual features of shape, configuration, pattern or ornament applied to a finished article of manufacture;
- Integrated circuit topographies: the three-dimensional configurations of electronic circuits in integrated circuit products or layout designs.

“Without the playing with fantasy no creative work has ever yet come to birth. The debt we owe to the play of imagination is incalculable.”

Carl Jung

What is the Canadian Patent Office?

The Patent branch within CIPO is commonly referred to as the Canadian Patent Office.

When will the Patent Office examine my application?

The Canadian Patent Office does not automatically examine applications. The Applicant has to file a request for examination and pay a fee within five years after the Canadian filing date. For divisional applications, the deadline is the same as for the parent application or, if that has passed, within six months after the divisional application has been filed. Once a request for examination and the appropriate fee have been submitted, an Examiner will review the application on its merits. If the Examiner finds one or more defects arising from non-compliance with the Patent Act or Patent Rules, the Examiner will issue an "Examiner's Report" (also referred to as an Office Action) to the Applicant, requesting argument and/or amendments to the application. However, if no defects are found on the patent application, the Examiner will issue a Notice of Allowance, which initiates the patent granting process.

Expedited examination (Special Order) may be requested at any time upon payment of the required government fee. This typically results in issuance of an Office Action within about four months.

The Patent Prosecution Highway (PPH) also allows Applicants to request expedited examination at no additional cost in certain cases in which the claims of a corresponding foreign application have been deemed allowable during examination. Currently, the Canadian Patent Office has PPH pilot programs in place with the U.S., Denmark, Germany, Japan, Korea, Finland, and Spain.[17] To

[17] Futher information on the PPH may be found at: http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr02160.html

request entry into the PPH, examination of the Canadian application must be requested, but must not yet have commenced.

What fees do I pay and when?

An Applicant must pay the patent filing fee, the patent maintenance fees and, if the patent issues, the patent issuance fee to the Canadian Patent Office.

Maintenance Fees

For all applications filed after October 1, 1989, the Applicant must pay annual maintenance fees to maintain the application in good standing. The first maintenance fee is due on the second anniversary of the filing date and is payable every year until the patent expires. An Applicant may pay the maintenance fees up to one year after the due date as long as an additional late payment fee is also paid. If the Canadian Patent Office does not receive such fees within the one-year grace period, the patent will lapse. A lapsed patent cannot be revived.

What happens if I forget deadlines and payments?

If the Applicant does not reply to requests from the Canadian Patent Office, the application will be considered abandoned – for example, if the Applicant does not request an examination by the deadline.

If the Applicant has corrected all deficiencies, including paying all outstanding amounts, within one year after the date of abandonment, the application will be reinstated. If an application has been abandoned for more than one reason, dates of abandonment run from each failure, not simply from the earliest. This is why Applicants must pay multiple reinstatement fees to restore an application to good standing. For example, if an Applicant does not request

examination within the time limit, the application becomes abandoned. If the Applicant does not also pay the maintenance fee, the application is abandoned for that reason also. To fully reinstate the application, the Applicant must request examination, pay the examination fee, request reinstatement from failure to pay the examination fee, pay a first reinstatement fee, pay the outstanding maintenance fee, request reinstatement from the failure to pay the maintenance fee and pay a second reinstatement fee.

There's a mistake in my application. Am I in trouble?

If the Applicant has been diligent and not willfully misled the Canadian Patent Office, the patent will be assumed valid. However, this only applies to omissions or additions. The courts have been inconsistent in applying this provision. For example, leaving out the names of some inventors was not enough to void a patent[18] because the failure was not false or misleading. The courts also did not void the patent in a case[19] where none of the correct inventors was named. Although the omission was false and misleading, it was not done willfully in order to mislead.

On the other hand, a patent may be void if the application contains untrue allegations, regardless of whether or not the allegation was made willfully.

New data isn't in the application. How do I deal with that?

The Applicant may include new subject matter in a new Canadian application that may claim priority from the earlier Canadian application if it is filed within one year after the earlier application.

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[18] *Apotex Inc. v. Wellcome Foundation Ltd.* (1998), 79 C.P.R. (3d) 193, at 264 (F.C.T.D.), aff'd. (2000), 10 C.P.R. (4th) 65 (F.C.A.).

[19] *671905 Alberta Inc. v. Q'Max Solutions Inc.* (2003) 27 C.P.R. (4th) 385.

The Applicant may file an incomplete application as early as possible after an invention has been made to obtain the earliest possible filing date for the disclosed subject matter. The Applicant may include improvements, alterations or additional data in a later application, which then requests priority over the earlier one.

This practice allows the Applicant to retain an early claim date for the subject matter disclosed in the first application while receiving a later claim date for the new subject matter. The Applicant has the option of proceeding with both applications or only with the second one. Applicants may make an unlimited number of priority claims. Claiming internal priority (i.e. priority to a previously filed Canadian application) is similar to making a priority claim on the basis of an application filed abroad. Once the one-year period after the earlier application has expired, internal priority may no longer be claimed. The patent term for the later application is calculated as 20 years from its filing date.

"I do not 'get' ideas; ideas get me."
Robertson Davies

What could somebody do to challenge my patent?

Prior Art

A third party may file prior art with the Canadian Patent Office that the third party believes may affect the patentability of any claim in an application. Prior art includes patents, published patent applications and printed publications such as journal or newspaper articles and

advertisements that describe the subject matter of the claim in question. The publication (or publicly available) date of any of the publications should preferably appear on the face of the documents. The third party must state the claim against which it believes the prior art is relevant and explain its relevance in writing. The third party does not have to pay any filing fee.

The third party will receive an acknowledgement from the Examiner that the prior art will become part of the Canadian Patent Office file and will not receive any further communication from the Canadian Patent Office. It is up to the third party to monitor the application to determine whether any steps have been taken by the Examiner.

Once the prior art becomes part of the Canadian Patent Office's file, the Examiner will review the prior art and decide if it is relevant to the claims in the application. If relevant, the Examiner will issue an Office Action to the Applicant on that basis. If not relevant, the Examiner will take no further action.

"To raise new questions, new possibilities, to regard old questions from a new angle, requires creative imagination and marks real advance."
Albert Einstein

The third party is not limited to one filing of prior art.The third party may file further submissions against an application, including additional prior art in response to the Examiner's decision that the previous prior art was not relevant. Throughout this process, the third party may remain anonymous.

Should the third party decide to challenge the validity of a patent that issues from the application, the Federal Court may defer to the Examiner's decision concerning the prior art. Because the Canadian Patent Office is a specialized tribunal that has already considered the prior art, the Federal Court may be reluctant to overturn the decision.

Re-examination

A third party may ask the Canadian Patent Office to re-examine any claim of a patent issued from applications filed after October 1, 1989. The third party may launch a re-examination by filing a Request for Re-examination along with prior art and the requisite fee. The Request for Re-examination must state the relevance of the prior art and explain how it applies to the claim(s) being re-examined.

When a third party requests a re-examination, the Canadian Patent Office will send a copy of the request to the patent holder. The Canadian Patent Office will set up a Re-examination Board made up of at least three people, at least two of whom must be employees of the Patent Office. The Board has three months to decide whether the Request for Re-examination raises a question of patentability. The re-examination process takes place between a Re-examination Board and the patent holder.

If the Board decides that the Request for Re-examination raises a substantial new question affecting the patentability of a claim, it will notify the patent holder of this decision and the reasons behind it. The patent holder has three months to reply. Once the Board has received this reply, or after the time limit has expired, it will re-examine the claim at issue. The re-examination proceedings must be completed within 12 months of receiving the patent holder's reply.

When the re-examination is over, the Board will issue a certificate that is attached to the patent and becomes part of it. The certificate does one of the following:

- cancels any claim of the patent determined to be unpatentable;
- confirms that any claim of the patent is patentable; or
- incorporates into the patent any proposed amendment or new claim determined to be patentable.

The patent holder may appeal the Board's decision to the Federal Court within three months from the date of the certificate's issuance. The third party however has no right of appeal.

If someone buys a patented article, what are the purchaser's rights?

A person who buys a patented article also buys an implied licence to use the invention underlying it, to repair the article if it breaks and to modify the article as needed, unless specific notice of a more limited use is provided to the customer. However, even if no notice of limitations are provided, these rights are limited to the specific units of the patented article purchased.

What about improvements to my patented invention?

If the improvement is new and non-obvious, the inventor may patent it as an independent invention.

However, the inventor of the improvement does not gain any rights to the original invention if it was not his to begin with. If he wants to make, use, or sell an improvement that somehow contains the original invention, he will need a licence from the owner of the original invention. Similarly, anyone licensing the patent for the improvement will also need a licence from the owner of the original invention. Conversely, the owner of the original invention does not gain any rights to the improvement of the other person.

Improvement patents often form the basis for cross-licensing arrangements where the patent owner of the original invention and the patent owner of the improvement both have the right to exploit the original and the improved invention.

> **“If the facts don’t fit the theory, change the facts.”**
> ***Albert Einstein***

Does my invention have to show a patent mark?

Preferably, yes. Markings on articles, such as “patented” (sometimes accompanied by a patent number) or “patent pending,” indicate the status of a patent. Markings should only appear when the statement is true. Making false claims is against the law in most countries.

Articles patented in Canada no longer have to be marked as such. That said, marking may be important if articles are exported to jurisdictions with laws that require patent marking or make it beneficial for remedies if the patent is infringed. In any event, marking is a good practice and may help deter infringement.

My patent has been infringed! What can I do?

The patent owner may apply to the court for an injunction requiring the infringer to cease the infringing activities. If the infringement is proven, the patent owner may be entitled to an injunction against the infringer as well as monetary damages or a percentage of the profits attributable to sales of the infringed article. In nearly all cases, the infringer will defend by attacking the validity of the patent.

“We try to keep tabs on our intellectual property, but sometimes it’s difficult to make sure infringement isn’t happening. When it does, it’s your work that’s at stake, and you have to do what you can to protect it.”

Jill Stelfox

Commercialization

What is it all about?

The process of commercialization – moving a technology or discovery from the lab into the market – has many social and economic benefits, such as the social good that comes out of making a technology accessible by the public or the creation of spin-off companies that provide jobs and wealth.

Companies that recognize the value of their IP, build upon it and extract the value from it, are in a much better position to compete nationally and internationally than those that do not. The real value in any IP lies in recognizing:

- its uniqueness and structuring an agreement that appropriately recognizes it;
- its competitive strength in national and international markets;
- its importance in the strategic plan of the current and potential owners; and
- the ability of the current and potential owners to develop it, commercialize it (including navigating the regulatory hurdles), recover their costs and make a profit from it.

Did you know…

One hour before Alexander Graham Bell registered his patent for the telephone in 1876, Elisha Gray patented his design. After years of litigation, the patent went to Bell.

Licenses

What is a licence agreement?

Licensing is when a patent owner gives someone else permission (a licence) to use the owner's invention, usually for commercial exploitation, subject to any restrictions that the owner may impose. Without that permission, the patent owner's legal rights will be infringed.

Is a licence the same thing as a contract?

Yes. As in other contracts, each party to the contract gives something of value to the other party in the contract. In the case of a licence, the patent owner (the licensor) gives the other party (licensee) a right to use his property (for example, a patented invention) in return for a one-time payment, milestone payments (an amount due when certain events happen) and/or royalties (a percentage of the proceeds from the sale of products or services that use the licensed property) or anything else of value, such as shares in the licensee's company.

As a licensor, does the invention still belong to me?

Yes. The licensor grants the licensee the right to use – but not to own – the invention and related IP rights. The licensor retains ownership and control (in the form of a contract) over the licensed invention. A licence is therefore not a transfer, sale or assignment of ownership in the invention.

Are there different types of licences?

Yes. A licensor may grant licences to some or all of the licensor's exclusive rights.

- An exclusive licence allows only one licensee to use the invention and related IP rights. The licensor may not use the property and related IP rights while the exclusive licence is in effect.
- A sole licence allows both the licensor and one licensee to use the invention and related IP rights.
- A non-exclusive licence allows an unlimited number of licensees, together with the licensor, to use the invention and related IP rights.

Can I restrict a licence?

A licence may be restricted or limited in a number of ways, for example:

- the number of users;[20]
- time (one year, ten years, etc.);
- geography (for example, limiting the territory of the licence to one country);
- use (manufacturing, research and development, testing, marketing, distribution or sale – or all of them);
- therapeutic area, indication, disease or condition (such as bovine spongiform encephalopathy, chronic wasting disease, Creutzfeldt-Jakob disease);
- route of administration (injection, topical, oral…); or
- subpopulation (age, ethnicity, genetic predispositions, etc.).

My licence has been breached. What can I do?

If the licensee does not meet one or more of the main conditions of the licence, the licensor usually has the right to terminate the licence and regain full rights to the invention.

[20] See above section.

Breaching a licence is the same as breaching any other contract. A licensor may require the licensee to fulfill the licensee's obligations, to pay monetary damages, to stop a particular activity (where the licensee has used the property beyond the scope of the licence), or to turn over any profits earned as a result of the breach.

Can I simply sell my IP?

What is an assignment (or purchase and sale) agreement?

If the owner no longer wishes to own, control or maintain the IP rights, it may try to sell them. An assignment is a purchase and sale transaction. As a one-off, one-time event, the purchaser usually has no ongoing obligations to the seller (unless the purchaser wishes to pay the purchase price or other consideration over time, or perhaps to adjust the purchase price depending on whether certain projected events occur such as patent registration, governmental approvals, and realization of revenue projections). The seller's ongoing obligations to the purchaser may include guaranteeing the performance of the invention for a fixed period of time and protecting the purchaser from third party lawsuits concerning the invention sold.

What should I watch out for?

Assignments are one-off, one-time events, which means that they do not usually give the seller and purchaser an opportunity to undo or amend the transaction unless the terms of the assignment explicitly allow this to occur and describe the circumstances under which this may occur. Therefore, it is important for the seller and purchaser to know as much as possible about the value of the invention so that the seller does not undervalue it and the purchaser does not pay too much for it or assume too many risks associated with it. Some factors to consider include the scope, patent term, territorial protection and

competitive strength of the invention, the amount of time, effort, resources and infrastructure required to bring the invention to market (including acquisition of third party technologies if necessary), and each party's ability to carry out the commercialization.

What if I can't pinpoint the value of my invention?

Where the value of the invention is difficult to determine, it may still be possible for the seller and the purchaser to structure the assignment so that the seller and the purchaser can both share in the risks and rewards. For example, they may structure the compensation so that the purchaser pays the seller a fixed sum when the assignment is signed, and additional sum(s) in later years (fixed or indefinite) based on how the invention actually performed in the market. Both parties will have to establish objective criteria against which the invention's performance can be measured so that the amount of the additional sum(s) payable by the purchaser can be determined accordingly.

> **"The man with a new idea is a crank until the idea succeeds."**
> ***Mark Twain***

I'm not ready to sell or license my IP. Are there other arrangements for me?

What is a research and development agreement?

If the owner is not ready to license or sell the invention, particularly if the value of the invention can be better determined or enhanced through confirmatory or exploratory research and development, the owner may wish to enter into research and development arrangements. Research and development are common activities

undertaken in the field of life sciences, whether for the purpose of exploring a new indication, dosage range, formulation or manufacturing process, or making improvements to existing intellectual property.

What should I include in my research and development agreement?

Where researchers from multiple parties (e.g. the owner, universities, teaching hospitals and other research institutions) are going to carry out the research and development activity, the terms of the agreement should, at a minimum, address:

- what has to be done, by whom and when;
- what background information or knowledge will each
- contribute (to separate what each one already knows from what will be learned from conducting the research and development activity);
- who will own the data, results and any IP arising from the research and development activity; and
- who can use the data, results and any IP generated.

What is an option agreement?

When the owner and the potential licensee or purchaser of the invention are not ready to enter into a license or an assignment agreement but the owner is nevertheless willing to give the potential licensee or purchaser an opportunity (usually an exclusive opportunity) to obtain a licence or assignment at a later date if certain requirements have been met (e.g. preconditions), the parties may enter into an option agreement to temporarily reserve for the potential licensee or purchaser (known as the “option holder”) the rights to the invention.

In exchange for temporarily reserving the rights to the invention for the option holder, the owner usually requires the option holder to pay a fee (known as the “option fee”).

The time period in which the rights to the invention are reserved is known as the “option period”.

What kind of preconditions could there be?

Examples of a few preconditions are:

- The owner receiving the patent or other governmental approval for the invention (to justify the licence fee or the purchase price);
- the option holder having the requisite funds, scientific, clinical or management personnel and/or facilities to carry out commercialization activities effectively; and/or
- the option holder being satisfied with results of tests that confirm the value of the invention or its market demand.

The owner and the option holder must also negotiate when the option commences, how long the option period lasts, how much is the option fee, and what preconditions must the option holder meet before the owner will enter into a license or assignment agreement with the option holder to give the option holder more long-term or permanent rights to the invention.

Can I commercialize my invention through a spin-off company?

Creating a company is a life changing commitment, and inventors must weigh the risks and benefits associated with being a founder or co-founder of a spin-off company.

“To turn really interesting ideas and fledgling technologies into a company that can continue to innovate for years, it requires a lot of disciplines.”
Steve Jobs

What is a spin-off company?

A spin-off company is a separate, commercial legal entity. The spin-off company may:

- license an invention developed at the university or parent company;
- provide funding to the university or parent company to develop an invention that the company will later license from the university or parent company; or
- provide a service through university-derived or parent company-derived expertise.

How do I know if it is the right time to launch a spin-off company?

The decision to launch a spin-off company may happen immediately or many years after the invention has been developed. Typically, companies created around software or information technology (IT) are launched sooner because of fewer business and regulatory hurdles. Life sciences companies, on the other hand, usually require greater infrastructure and resources to develop their technologies and overcome regulatory hurdles.

Timing is influenced by a number of factors, including:

- the innovativeness of the invention;
- the value of the invention, scientifically and commercially;
- the nature and scope of the intellectual property protection;
- the need for complementary and/or enabling technologies;
- the existence of competing technologies;
- the time and money needed to protect and commercialize the invention;
- the commitment of the inventors and other founders to the commercialization process;
- potential strategic partners to advance development and commercialization of the invention; and
- the existence of potential investors of the company.

Am I better off launching a spin-off company or licensing my invention to an existing company?

Inventors will need to consider many factors, some of which may be unique to their universities and own circumstances, before making that decision. The following are some of the factors that are critical to spin-off company formation:

- the invention fulfills an umet need;
- there is a global market for the invention;
- a champion (entrepreneur or self-starter who had succeeded in similar enterprises) is present;
- a strong management team is available to lead the company;
- a credible business plan is in place;
- adequate funding is available for the early stages;
- future funding are likely to be forthcoming;
- infrastructure and other resources are readily accessible; and
- strong support from the university or parent company.

> **"Often you have to rely on intuition."**
> ***Bill Gates***

Where can I find money to support my spin-off?

There are various sources of funding for setting up a company and its business. In the early phases, the funding is often obtained from credit lines and friends and family. Angel investors may also play a role. Angel investors are individuals who provide financial backing to very early-stage businesses or business concepts or for the development of prototypes. Often these individuals look for a higher rate of return than would be required by more traditional lenders and investors such as banks. Angel investors also look to play an active role in the management of the company.

As a spin-off company ramps-up, more funds will be required to finance technology development and the hiring of an experienced management team. Typically, that is where venture capital plays a role. Venture capital generally comes from a group of wealthy investors, investment banks and other financial institutions that pool their investments to fund new, growth businesses. Some venture capital companies provide funding to businesses in the early stages, but most do not. Of those that do, they tend to invest in companies only if the companies have an experienced management team and can prove the claims they make about their technology and the market potential. If funds are provided, venture capitalists will usually require a say in company decisions, as well as equity (e.g. shares) in the company.

Did you know…

In 1834, Charles Babbage designed the Analytical Engine, the precursor of the computer. He was unable to obtain funding for it from the government, who thought it would be worthless.

Are there other commercialization issues that I should know about?

What does Canada's *Food and Drugs Act* do?

The federal *Food and Drugs Act* and its regulations govern the advertising and sale of all food, drugs, cosmetics and medical devices in Canada – wherever they are manufactured. Its regulatory regime is complex and changes frequently.

How do I know if my invention fits into the "New Drug" category?

A "new" drug is one that contains or consists of a substance that has not been sold in Canada for enough time and in enough amount to

check the safety and effectiveness of that substance as a drug. A new drug can also be a combination of two or more drugs that has not been sold in that combination, or in the proportion in which those drugs are combined, for enough time and in enough amount to check the safety an effectiveness of that combination and proportion. It can also be a new use (including dosage, route of administration or duration of action) of a drug that has not been sold for that use in Canada for enough time and in enough amount to check the safety and effectiveness of that use.

Any new drug that is manufactured, advertised or sold for the purpose of diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or its symptoms, or for the purpose of restoring, correcting or modifying organic functions, in humans or animals, will need to comply with the *Food and Drugs Act*.

Do I need a product licence and/or a facility licence for a new drug?

In general, no person may advertise, import or sell a drug unless Health Canada has issued a product licence; and no person may manufacture, package, label or import a new drug without having first obtained a facility licence (an establishment licence) from Health Canada.

Product licences

To apply for a product licence for a new drug, the manufacturer must provide Health Canada with information that will allow it to assess the new drug's safety and effectiveness. Information to be provided includes the type and amount of medicinal and non-medical ingredients; animal and clinical tests conducted to establish safety; tests applied to control the new drug's potency, purity, and stability; the plant and equipment used in the manufacture, preparation, and packaging of the new drug; the quality control

measures used in the manufacturing, preparation and packaging of the new drug, and substantial evidence of the new drug's clinical effectiveness determined from clinical trials performed in Canada and abroad.

Facility licences

To apply for a facility (establishment) licence, the manufacturer, importer, distributor, and wholesaler must provide Health Canada with information on their respective activities that will allow it to assess whether they are applying proper quality control and assurance procedures (good manufacturing practices) – even if the drug is manufactured abroad.

Information to be provided includes the premises where the new drug is fabricated, packaged or labeled (to see if the premises were designed, constructed and maintained to allow performance of operations under clean, sanitary and orderly conditions and prevent contamination and introduction of extraneous materials), equipment (to see if the equipment is designed, constructed and maintained to prevent contamination of one drug by another drug and by extraneous materials, including rust), personnel (to see if the personnel have the technical, academic and other training necessary to perform the duties and responsibilities allocated to them, and have undergone the necessary health examinations), sanitation program (to see the adequacy and regularity of cleaning procedures for the premises and equipment), raw material testing (to see if the testing of each lot or batch is adequate to confirm the identity of the raw materials and to assure that the quality of the drug will not be altered by raw material defects and that the raw materials will give the desired quantity or yield during the manufacturing process), manufacturing control (to see if the process is properly documented and that any deviation from the documented procedures must be described, investigated, followed-up and documented), and recall and record-retention procedures.

How does the Act handle the new medical device I invented?

Any article, instrument or apparatus (i.e. device) that has been manufactured, sold or represented to:

- diagnose, treat, mitigate or prevent a disease, disorder or abnormal physical state or its symptoms in humans or animals; or
- to restore, correct or modify a body function or the body structure of humans or animals.
- must comply with the *Food and Drugs Act.*

All devices fall under one of four categories (Class I, II, III or IV) based on their level of health risks to the patient and to the healthcare professional administering the device. Class I devices present the lowest risk.

Do I need a product licence or a facility licence for a new medical device?

In general, no person may advertise, import or sell a Class II, III or IV device unless Health Canada has issued a product licence. Class I devices do not need a product licence. No person may manufacture, package, label or import a device (including a Class I device) without having first obtained a facility licence (an establishment licence) from Health Canada.

Product licences

To apply for a product licence for a new Class II, III or IV medical device, the manufacturer must provide Health Canada with information that will allow it to assess the device's safety and effectiveness. The manufacturer must provide more information for Class III or IV devices than for Class II devices. Information to be provided includes the name and class (i.e. Class II, III or IV) of the device and whether the device is part of a system, test kit, or a larger

device grouping; the place of manufacture; a list of any national or international quality system standards (e.g. ISO standards) applied by the manufacturer to the manufacture and testing of the device; features of the device that allow the device to be used for the medical conditions, purposes and uses stated; materials used in the manufacture and packaging; the sterilization method used for devices sold in sterile condition; the manufacturing process; an analysis and evaluation of the risks; risk reduction measures; bibliography of all published reports on the use, safety and effectiveness of the device; results of clinical studies; and countries outside of Canada where the device has been sold (including the number of devices sold and a summary of any reported problems and recalls).

Facility licences

To apply for a facility (establishment) licence, the importer and distributor of the new device must provide Health Canada with information on their respective activities that will allow Health Canada to assess whether they are applying proper quality control and assurance procedures – even if the device is manufactured abroad. Manufacturers of Class I devices must also provide this information if the device is to be sold directly to a retailer or health care facility and not through a licensed importer or distributor. Information to be provided includes the premises where the importation or distribution activity is performed, the manufacturer's medical specialties and classes of devices it manufactures, and documented procedures for distribution record retention, complaint handling, recalls, storage, delivery, installation and corrective action and servicing.

What are my responsibilities to the consumer?

No drug or device may be labeled, packaged or sold in a way that is false, misleading or deceptive, or could create an untrue impression regarding its intended use, character, value, quantity, composition, merit or safety.

How can BLG help YOU?

BLG is a leader in Canadian intellectual property practice. Our professionals are responsible for over 58,000 patents, 45,000 trade-marks, and over 4,000 industrial design registrations, including applications.

We understand your technology. Our professionals have the technical and legal backgrounds necessary to understand your IP. Many of our professionals hold advanced scientific degrees, engineering degrees and graduate degrees, in fields including electronics, electrical engineering, engineering physics, chemistry, genetics, nutrition & metabolism, pharmacology, molecular biology, oncology and telecommunications. Having a considerable number of years “at the bench” and “in the field”, our scientific experts bring an insider's understanding to their IP practice.

Your idea deserves an innovative approach. We adapt quickly to your changing needs. We take an inter-disciplinary approach, working closely with professionals in other specialized areas, including tax, licensing, mergers and acquisitions, banking, capital markets, human resources, employment law and litigation.

We understand your business. Focusing on your business strategy greatly assists us in providing timely and cost effective advice and risk assessment in aspects of intellectual property matters. Involvement in the strategic development of national and worldwide intellectual property portfolios based on your marketing strategy provides the opportunity to build and maintain a strong working relationship.

We will work with you to help bring your idea to the world.

Conclusion

This document has been written for those who are relatively new to the field of IP and commercialization. We have barely skimmed the surface in order to keep this document at an introductory level – just enough to give you an idea of what you should be thinking about as your research and business develops.

Wherever you research takes you, we strongly recommend that you consult an expert. For example, work with the technology transfer office of your university or organization or seek advice from a patent agent and/or lawyer to guide you on this adventure.

“Discovery consists of seeing what everyone else has seen and thinking what nobody else has thought.”
Albert Szent-Gyorgyi

Resources

Organizations and Government

Canadian Intellectual Property Office (CIPO):
http://www.cipo.ic.gc.ca

World Intellectual Property Organization (WIPO):
http://www.wipo.int

Industry Canada:
http://www.ic.gc.ca

Industry Canada – Life Sciences Gateway:
http://www.ic.gc.ca/epic/site/lsg-pdsv.nsf/en/home

Industry Canada – Industrial Technologies Office:
http://www.ic.gc.ca/eic/site/ito-oti.nsf/eng/home

National Research Council – Industrial Research Assistance Program:
http://www.nrc-cnrc.gc.ca/eng/ibp/irap.html

Federal Partners in Technology Transfer:
http://www.fptt-pftt.gc.ca

Innovation Centre:
http://www.innovationcentre.ca

Justice Canada:
http://laws.justice.gc.ca

Patent Act:
http://laws.justice.gc.ca/en/frame/cs/P-4

Manual of Patent Office Practice:
http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr00720.html

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