

# The Regulation of Life Sciences/Biotech in Canada: Frequently Asked Questions

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**Q** 1. What legislation governs the grant and protection of IP rights in relation to biotechnology/life sciences? Have there been any recent legislative developments?

**A** In the context of biotechnology/life sciences, the most important legislation governing intellectual property (IP) rights in Canada is the *Patent Act*, which governs the grant and protection of all patent rights, including those related to biotechnology. There are also regulations and legislation specifically related to biotechnology/life sciences.

The *Patented Medicines (Notice of Compliance) Regulations* under the *Patent Act*, together with that Act, creates a regime that protects patent rights for pharmaceutical patents listed on the Patent Register maintained by the Minister of Health. Amendments to these regulations came into force on October 5, 2006 and are discussed further in question 9.

The *Food and Drug Regulations* contain provisions on data exclusivity, but these regulations have been interpreted by the courts in a way that limits data protection. These regulations were also amended on October 5, 2006.

The *Plant Breeder's Rights Act* is also relevant in the life sciences field. This Act grants certain rights to breeders of new plant varieties, provided that they meet the requirements set forth in the Act.

Additional legislation governing IP rights in Canada includes the *Copyright Act* and the *Trade-marks Act*.

**Q** 2. Are there any international conventions or co-operation agreements in this area? If so, how effective are they? What problems arise in connection with international protection of intellectual property?

**A** Patents must be applied for in each country where patent protection is desired, a potentially costly process. The Patent Cooperation Treaty (PCT), to which Canada is a signatory, is administered through the World Intellectual Property Organization in Geneva. The PCT provides for the filing of a single international application that can take effect in each designated country that has signed the treaty.

Although the eventual grant and prosecution of patents is still under the authority of individual countries, the time and costs associated with filing a patent application in different countries can be deferred by filing a PCT application.

The PCT has promoted patent harmonization in different countries, but due to the complexity of the different national legislative regimes, filing patent applications internationally can still be a complex and expensive process.

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**Q** 3. Please give an overview of the types of legal issues or problems which have been raised by recent developments in biotechnology and life sciences.

**A** Recent developments in biotechnology and life sciences have afforded the public numerous health benefits. However, progress has also brought ethical controversy, and some legislative response.

An example of such progress is stem cell research. Stem cells in animals retain the ability to self renew and differentiate into other cell types. Researchers believe that stem cells can be used to repair specific tissues and grow organs. Embryonic stem cells are obtained from an early stage human embryo and are thought to have much greater developmental potential than adult stem cells. However, as these require the destruction of a human embryo, embryonic stem cell research is ethically controversial. The Canadian Patent Office issued a policy on June 20, 2006 that takes the position that “embryonic, multipotent and pluripotent stem cells, which do not have the potential to develop into an entire animal, are patentable subject matter.” However, animals at any stage of development, from fertilized eggs on, are higher life forms and are not patentable.

The Canadian Patent Office also takes the position that plants and seeds are higher life forms and therefore not patentable (further details on patentable subject matter are discussed in question 6).

The introduction of genetically modified organisms (GMOs) into our food supply has led to the novel food regulations under the *Food and Drugs Act*, which define a “novel food” to include a food derived from a plant, animal or micro-organism that has been genetically modified in such a way that the characteristics exhibited by the plant, animal or micro-organism have changed. The regulations further specify the conditions under which novel foods can be sold or marketed.

## Patents

**Q** 4. How, when, by whom and to whom must a patent application be made?

**A** A patent application must be filed with the Canadian Intellectual Property Office. The process of obtaining a patent can be complex, requiring broad knowledge of patent law and practice. It is highly recommended to hire a registered patent agent or lawyer to properly prepare and prosecute a patent application so that it can withstand future challenges to its validity—although inventors may go through the application process themselves.

The patent application consists of three components: (i) the abstract, (ii) the specification, and (iii) the drawings. The abstract is simply a brief summary of the application. The drawings are the visual representation of the substance of the invention to be considered for patent. The core of the patent application is the specification. The specification provides a clear and complete description of the invention and its usefulness, and contains the claims that define the boundaries of patent protection.

For patents filed after October 1, 1989, patent rights are granted to the first to file the patent. Therefore, it is in the interests of an inventor to file a patent application as soon as possible. However, there may

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be disadvantages to filing an application too early because further research may be required to ensure the application is complete and that the claims can be supported. Furthermore, it is important that the patent application is filed within a year of any publication or disclosure of the invention, to avoid the patent being invalid for lack of novelty and to avoid the loss of rights outside Canada.

**Q** 5. Please summarise the requirements which must be satisfied in order for an application to be granted.

**A** For a patent to be granted, the prescribed application fee must be paid, and the application filed by the inventor or the inventor's legal representative. The application must contain an abstract and a specification of the invention.

In addition to these procedural requirements, a number of legal requirements must be satisfied. The *Patent Act* defines an invention as "any new and useful art, process, machine, manufacture or composition of matter..." Therefore, for a patent application to be granted for an invention, it must be both new and useful. To be considered new, an invention must not have been disclosed to the public anywhere in the world. However, the Act grants the inventor a one-year grace period during which the inventor can disclose the invention before filing a Canadian patent application without this counting as public disclosure. In addition, the Act specifies that an invention must not be obvious.

**Q** 6. What kinds of issue typically arise in relation to the question of patentability of subject matter? How have those issues been resolved?

**A** The scope of what constitutes patentable subject matter is especially relevant to biotechnology patents, and has been addressed by the Supreme Court of Canada (SCC). In a decision dealing with the patentability of an invention for a genetically modified mouse, the SCC held that higher life forms, which include plants, seeds, and animals, are not patentable because they are not a "manufacture" or a "composition of matter" within the meaning of "invention" in the *Patent Act*. However, the SCC did affirm that lower life forms such as bacteria, fungi, cells in culture, transformed cell lines and hybridomas are patentable.

In the case of *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)* an application was filed to obtain a patent for a new soybean variety. The Patent Office rejected the application on the basis that the new plant variety could not constitute an "invention" and this decision was affirmed by the Federal Court of Appeal. The SCC dismissed the appeal on the basis that disclosure was insufficient and therefore did not consider whether the new soybean variety could be regarded as an invention within the meaning of the *Patent Act*. However the Patent Office has applied the Federal Court of Appeal decision since that time to reject claims directed to plants and seeds.

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The patentability of higher life forms was revisited by the Supreme Court of Canada in *Schmeiser v. Monsanto*, which dealt with the patentability of modified canola. In that case the subject matter at issue was canola seeds containing patented genes and cells that would be resistant to certain herbicides, such as “Roundup.” The treated seeds were marketed as “Roundup Ready Canola.” The majority noted that the patent claimed the gene and the cell in the Roundup Ready Canola, as opposed to the plant, and subsequently concluded that the patent was valid; the gene and the cells need not be in isolated form to qualify for patent protection. Consistent with this decision, the Patent Office now permits claims to cells as long as the description does not define “cells” to include plants, animals or tissue.

**Q** 7. What difficulties may be raised by the requirement of proving utility in this particular context? What practical strategies can be adopted to surmount this hurdle?

**A** One of the key aspects of proving utility in the biotechnology context is the doctrine of sound prediction. The doctrine applies where utility can be predicted before actual testing, thereby allowing a patent to be obtained on the basis of “sound prediction.” Three criteria must be met for a patent to be granted on this basis. First, there must be factual basis for the prediction. Second, the inventor must have, on the date of the patent application, a sound line of reasoning from which the result can be inferred. Finally, there must be proper disclosure, although it is not necessary to provide a theory of the reason why the invention works. The date for determination whether an invention was soundly predicted is the Canadian filing date of the patent application. The Supreme Court of Canada in *Apotex Inc. v. Wellcome Foundation Ltd.* (the AZT case), explained that the soundness of a prediction is a question of fact and, therefore, evidence must be led about what was known about the invention on the relevant date. The Court also recognized that although bare speculation will be insufficient to comply with the requirements for sound prediction, clinical tests in humans are not necessary to establish the utility of the invention.

**Q** 8. What particular considerations must be taken into account when drafting the written description and compiling the enabling disclosure?

**A** The disclosure is what the inventor gives the public in exchange for the time-limited right to exclude other persons from practising the invention as claimed in the patent. In the disclosure the inventor explains what the invention is and how to use it. If one skilled in the art can arrive at the same results only through chance or further experiments, the patent will be void for insufficiency under section 27(3) of the *Patent Act*.

The duty of disclosure in relation to pharmaceutical and biotechnological subject matter presents special difficulties. In *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, the Supreme Court of Canada held that the deposit of seeds with U.S. and Canadian government agencies was insufficient to comply with the duty of disclosure. This decision caused concern in the biotechnological community.

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The *Patent Act* responded to this concern by providing that a deposit of biological material can be considered to comply with the sufficiency requirements of the Act. In addition, the *Patent Rules* contain detailed provisions relating to deposits of biological material and nucleotide and amino acid sequence listing.

**Q** 9. What particular considerations are raised by generic drugs? Please explain the compromise embodied in the Patented Medicine (Notice of Compliance) Regulations.

**A** In Canada the interface between the patent and regulatory legislative schemes with respect to brand name and generic drugs is governed by the *Patented Medicines (Notice of Compliance) Regulations*, enacted under the *Patent Act* in 1993. The regulations create a scheme similar to that in the United States, whereby the ability of generic manufacturers to obtain a notice of compliance (NOC) for a drug that might infringe the patent held by a brand name drug manufacturer is restricted. Under the *Canadian Food and Drugs Act* and *Food and Drug Regulations*, an NOC must be issued to market a drug in Canada. To receive an NOC, an innovator must establish the safety and effectiveness of the drug through experimentation and clinical trials. A generic drug company is permitted to rely on the safety and efficacy data submitted by the innovator if bioequivalence can be established.

Like in the United States, an innovator-manufacturer obtaining an NOC for a drug must submit a list of the patents for listing on the Patent Register maintained by Health Canada. A generic drug company that seeks a notice of compliance for a drug and makes a comparison to one that is on the Patent Register must notify the patent owner. The patent owner can then apply to the court for an order prohibiting the Minister of Health and Welfare from issuing an NOC to the generic. If the order is issued, the generic drug company cannot market its product for the duration of the patent's life. Once court proceedings have been initiated, the Minister is not allowed to issue an NOC until the parties reach agreement, the listed patents expire, the court renders a decision or a period of 24 months elapses, whichever comes first. In this way the rights of the patent owner against the generic drug company are strengthened. The *Patented Medicines (Notice of Compliance) Regulations* also provide some advantage to the generic drug company, which no longer needs to manufacture and market before "taking a run at" a patent.

On October 5, 2006 amendments to the *Patented Medicines (Notice of Compliance) Regulations* came into force. One of the implications of these amendments is that the ability of the innovator drug company to list patents on the Patent Register has been restricted; only patents that meet the current timing, eligibility and relevance requirements set out in section 4 of the regulations are entitled to be added to the register and to the concurrent protection of the 24-month stay. Furthermore, a generic manufacturer is not required to address patents that are added to the register after the filing date of its regulatory submission for an NOC. As Health Canada may not grant an NOC until every patent on the register relating to the medicine at issue has been addressed, these amendments have strengthened the rights of the generic manufacturers against the innovator drug companies.

The new patent listing eligibility requirements do not apply to patent lists submitted before June 17, 2006.

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**Q** 10. Are there any exceptions to patent infringement that are applicable in the biotechnology context?

**A** Exceptions to infringement that are applicable in the biotechnology context include that under a section of the *Patent Act* that permits the use or sale of a patented invention for “uses reasonably related to the development and submission of information required under any law of Canada, a province, or any other country that regulates the manufacture, construction, use or sale of any product.” The Federal Court recently considered this provision in *Merck & Co. v. Apotex Inc.* The Court found that the exception extends to all uses of patented compounds reasonably related to the regulatory process, whether or not the research was ultimately used for that purpose. In addition, the common law “fair dealing” exception to patent infringement provides that an experimental use of a patented invention for a bona fide experiment is not an infringement. Research and development material has been found to fall within this common law exception.

**Q** 11. What remedies are there for infringement of a patent? How effective are these?

**A** When a patent is infringed, the patentee may elect to claim damages or an account of profits, but not both. In addition, the court may order an injunction and delivering up of the offending goods. Damages can take the form of a reasonable royalty or may consist of the patentee’s lost profits if the patentee is making, using or selling the patented invention.

If the patentee elects to claim an account of profits, the award may be restricted to the profits made from the defendant’s use of the patented features that exceed the profits from its use of the next-best non-patented features.

The quantum of these damages may be difficult to ascertain.

**Q** 12. How is a patent renewed? What requirements must be satisfied?

**A** An applicant and patentee must pay maintenance fees to the Canadian Intellectual Property Office to maintain patents and patent applications in good standing.

For patents filed before October 1, 1989, the term of patent protection is 17 years from the date of the patent grant. For those filed on or after October 1, 1989, the term is 20 years from the date of filing. The patent cannot be renewed.

Unlike other countries, Canada does not permit an extension of the patent term to account for delays in obtaining regulatory approval of drugs or to account for delays in patent prosecution.

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**Q** 13. What considerations of competition law must be taken into account when settling patent litigation?

**A** The interface between patent and competition law is less developed in Canada than in the United States. Canadian competition law is governed by the *Competition Act*. Section 45 of the Act states that it is an offence to agree with another person to unduly restrain competition. Although in the past, the Federal Court of Appeal has held that this prohibition does not encompass a patentee's exercise of rights granted under the *Patent Act*, a court decision indicates that anti-competitive agreements in the context of patent rights may not continue to be completely insulated from scrutiny. In *Eli Lilly and Co. v. Apotex Inc.*, Apotex successfully appealed a decision that granted summary judgment to Eli Lilly and struck paragraphs from Apotex's defence and counterclaim alleging that a licensing agreement between Eli Lilly and Shionogi created a monopoly, and therefore unduly lessened competition. In allowing the appeal, the Federal Court of Appeal concluded that the assignment of a patent may unduly lessen competition contrary to section 45 of the *Competition Act*, despite the fact that the assignment of a patent is a right granted under the *Patent Act*. This case may pave the way for further use of competition law to challenge agreements made pursuant to patent rights.

**Q** 14. What moral and ethical issues have been raised by patenting of life forms and pharmaceuticals? How have the courts grappled with such issues?

**A** The Patent Office does not address the ethical aspects of patenting life forms and pharmaceuticals. Rather, controversial patents are challenged as to whether they constitute patentable subject matter as explained in the answer to question 6. In *Harvard College v. Canada (Commissioner of Patents) (Harvard Mouse Case)*, the Supreme Court of Canada unanimously held that the Commissioner has no discretion to refuse a patent on the basis of public policy considerations independent of any express provision in the *Patent Act*. The *Harvard Mouse* decision turned exclusively on the interpretation of the term "manufacture" or "composition of matter" in the definition of "invention" of the Act, and not on the ethics of patenting higher life forms. Similarly, the Federal Court of Appeal in *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)* held that a plant was not an invention because it was not a "manufacture" or "composition of matter" in the definition of "invention" of the Act. Ethical issues involved in patenting life forms and pharmaceuticals are therefore addressed through legislation and regulation, rather their patentability.

**Q** 15. What have been the most important recent cases on biotechnical patents, and what is their significance?

**A** The most significant recent cases on biotechnological patents dealt with the patentable subject matter. The patentability of higher life forms was considered by the Supreme Court of Canada in 2002 in the *Harvard Mouse Case*, in which the Commissioner's decision not to grant a patent to a genetically

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modified mouse was challenged by Harvard College. The Supreme Court of Canada confirmed the position taken by the Patent Office: lower life forms were patentable, but higher life forms were not.

Canada's position as the only Western country to refuse to grant patents to higher life forms was somewhat mitigated by the Supreme Court's decision in *Monsanto Canada Inc. v. Schmeiser*. In that case, the Supreme Court of Canada upheld Monsanto's claim for patent infringement. In doing so, the Court considered the validity of Monsanto's patent over a gene that causes Canola seeds to become resistant to the herbicide Roundup. The patent was upheld because it did not claim the whole plant, but rather the genes that gave the canola its herbicide-resistant qualities and plant cells containing those genes. Consistent with the decision, the Patent Office now permits claims to cells as long as the description does not define "cells" to include plants, animals or tissue.

The decision of the Supreme Court of Canada in *AstraZeneca Canada Inc. v. Canada (Minister of Health)* may have significant implications for innovator drug companies. The decision suggests that generic manufacturers may no longer be required to address every patent listed on the Patent Register in respect of a particular drug but only those patents that are relevant to the product cited as the Canadian reference product. While it is important to note that this case was decided under the regulations as they existed before the October 5, 2006 amendments, the Court's narrow construction of the *Patented Medicines (Notice of Compliance) Regulations* may be potentially problematic for innovator pharmaceutical companies.

## Trademarks



16. How effective are trademarks as a form of protection of intellectual property in the life science context?



Trademarks protect a company's brand name and symbols, and are therefore essential in effectively promoting a company's product and services by distinguishing them. A trademark can represent not only the products and services sold but also the reputation, experience and expertise of the business.

Examples of strong trademarks in the life sciences sector include AMGEN, EPOGEN, the Bayer cross, BIOGEN, LIPITOR, 3TC.



17. What remedies lie for infringement of a trademark?



When proceedings are brought under the *Trade-Marks Act*, "the court may make any order that it considers appropriate in the circumstances, including an order providing for relief by way of injunction and the recovery of damages or profits and for the destruction, exportation or other disposition of any offending wares, packages, labels and advertising...." In common law proceedings similar relief may be granted, including damages for loss or goodwill.

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## Trade secret licences/non-disclosure agreements

**Q** 18. What are the advantages and disadvantages of trade secret licences/non disclosure agreements? What is their main application?

**A** In some situations a trade secret or non-disclosure agreement may afford better protection for intellectual property than a patent. Although a competitor cannot make or sell the patented invention, the information in the patent disclosure is made public when the patent application is published (18 months after the filing date). There is a risk that competitors can use the information to develop a superior product or process. In addition, a trade secret may provide an alternative type of protection in view of the relatively short lifetime of an inventor's exclusivity through a patent, especially in life sciences where the regulatory authorities may not approve the product until years after the patent application is filed. In life sciences, trade secrets are often used to protect new ways to manufacture the product.

One of the most successful examples of this business strategy is that of The Coca-Cola Company. Reluctant to disclose its secret formula, Coca-Cola has chosen not to use patent protection for the beverage, opting instead to protect its formula as a trade secret.

However, a trade secret is valuable only as long as the information can be kept from the public. Hence, patent protection is preferable for any product that can be reverse-engineered once publicly marketed. When a patent is the preferred route to intellectual property protection, it must be part of a comprehensive business plan that enables a company to meet market demand and gain a sustainable competitive advantage in the environment in which the company operates.

**Q** 19. What practical strategies can be adopted to protect a trade secret?

**A** As with any secret, the key to keeping a trade secret is to lock it up tightly. Strategies for maintaining secrecy include using confidentiality and non-disclosure agreements; disclosing the trade secret to very few persons; disclosing only part of the secret to some persons and other parts of the secret to other persons; ensuring that information relating to the secret is difficult to steal; attempting to ensure that information about the secret is not stored on computers or other electronic devices or in files that can be readily accessed or stolen; and using security procedures, Internet firewalls and passwords to limit access. However, protection against insider theft is also required. Toward this end, limiting access to confidential information and having those with confidential knowledge educated on their obligations of confidentiality, including having them sign non-disclosure agreements, can help protect a trade secret.

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## General

**Q** 20. What practical steps can a company take to maximise the value of its intellectual property? What considerations need to be taken into account in formulating a patents strategy?

**A** A company can take a number of steps to maximize the value of its intellectual property. An audit of a company's intellectual property assets can help identify the current IP rights of a business. Protocols and best practices can be established so that intellectual property is identified, assigned to the company and protected; then rights to the intellectual property enforced, licensed or sold.

Furthermore, the most effective means to protect a company's intellectual property must be identified, taking into account the cost and value of the protection to the company. In most cases, the major value of IP rights is in its capacity as a barrier to entry to competitors. However, these rights can also add value to a company in the form of a licensing tool. Conversely, acquiring a licence to use someone else's IP rights can be a cost-effective way to access the rights to use or sell new products, processes or technology. In addition, IP rights can be used to attract investment in a business or increase the value of a company being sold. The foregoing are all issues that must be considered in an effective intellectual property strategy.

**Q** 21. How can a company obtain worldwide patent protection?

**A** Obtaining worldwide patent protection is not possible because patent rights are granted separately in each country and some countries do not have patent laws. However, a patent application can be filed in each country with a patent system where protection is desired. Although filing under the Patent Cooperation Treaty can somewhat simplify the process of international filing, it is important to note that the local laws of the relevant country will ultimately govern.

**Q** 22. How may the involvement of universities and academic institutions affect ownership and protection of intellectual property?

**A** Many universities and academic institutions have policies requiring that the institution be assigned all rights to intellectual property developed by their employees. This can affect the IP rights of both employees involved in inventions and companies collaborating with the academic institutions. In the case of the latter, a licensing agreement is an effective way to allow the collaborator company to use an invention resulting from collaboration.

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