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PATENT PROTECTION IN CANADA

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With the second-largest biotechnology industry in the world, Canada represents a valid alternative to the US with regards to patent protection. But there are some important differences between the two regimes, as Katie Wang and Dr Victoria Carrington explain.

Why file in Canada?

Many have traditionally viewed the US as the main jurisdiction for patent protection in North America, and Canada as an after-thought. It is important to note, however, that Canada has the second-largest biotechnology industry in the world. Furthermore, because of the close geographical proximity, many US companies deal extensively with Canadian importers and suppliers.

In fact, Canada is a logical route for importation into the US market. If a product is not protected by a Canadian patent, it can be manufactured in Canada and sold to customers elsewhere. Having patent rights in the country that is the source of supply enables one to stop infringement at its source. It is easier to enforce a valid Canadian patent in Canada than to bring a successful action against a party situated in Canada for inducing infringement of a US patent.

Patent system differences

Patent laws in the US and Canada have evolved along parallel lines. However, there remain fundamental differences between the two systems.

Patentable subject matter

Higher/lower life form

In January 2009, the Canadian Patent Office (CPO) issued new biotechnology examination guidelines. Pursuant to these guidelines, the distinction between lower and higher life forms is whether the life form is unicellular (lower) or multicellular (higher). The CPO takes the position that animals at any stage of development are not statutory matter: fertilised eggs and totipotent stem cells (which have the inherent ability to develop into animals) are higher life forms, whereas embryonic, multipotent and pluripotent stem cells, which do not have the inherent ability to develop into an animal, are lower life forms.

Specifically, the CPO considers lower life forms to include microscopic algae; unicellular fungi (including moulds and yeasts); bacteria; protozoa; viruses; transformed cell lines; hybridomas; and embryonic, pluripotent and multipotent stem cells; and higher life forms to include animals, plants, seeds, mushrooms, fertilised eggs and totipotent stem cells.

Plants

In contrast to plant patents in the US, in Canada, plant varieties that are distinct, uniform and stable may be protected under the Plant Breeders' Rights Act.

Method of medical treatment

In Canada, a method that provides a practical therapeutic benefit to a subject, even if not as its primary or intended purpose, is considered to be a "method of medical treatment" and is not patentable. For example, surgical, medical, dental and physiotherapeutic methods of treatment are considered to be non-statutory matter. However, they may be redrafted into an allowable "use" format. For example, medical use claims such as "use of an effective amount of compound X for treatment of disease Y in a subject in need thereof" or "use of compound X in the manufacture of a medicament for treatment of disease Y" are found to be allowable.

Filing requirements

First-to-file system

Compared to the US first-to-invent system, Canada has a first-to-file system.

Small/large entity

In Canada, filing and prosecution fees depend on the applicant's entity status. Generally speaking, a small entity in Canada must employ fewer than 50 employees, and must not have transferred and licensed, nor be under any obligation to transfer or license, any rights to the invention to any person or entity, other than a university; whereas in the US, a small entity must have fewer than 500 employees under similar conditions.

No power of attorney requirement

In Canada, it is not necessary to have a power of attorney signed by the inventors, as is required in the US.

Declaration of entitlement

Under the new legislation that came into force in Canada on June 2, 2007, an applicant who is not the inventor will now be required, either in the petition or in a separate document, to declare, as of the filing date, the basis on which it claims entitlement to file the application; for example, *inter alia*, by virtue of having been the employer of the inventor or in accordance with an assignment by the inventor in favour of the applicant, etc.

No excess claim fees

In contrast to the US and European Patent Office practices, there are no excess claim fees in Canada.

Late PCT national phase entry

In Canada, if the 30-month PCT (Patent Cooperation Treaty) national phase entry deadline has lapsed, there is a 12-month grace period, i.e. an applicant may enter the national phase in Canada 42 months from the earliest priority date for the PCT application. The additional government fee for filing a "late" national entry is a nominal C$200 ($161). This delayed option can be quite useful when the applicant needs more time to decide whether to enter Canada for strategic or budgetary considerations.

Prosecution

Delayed examination

In Canada, the examination of a patent application is not automatic. An applicant does not have to request examination until five years from the filing date, during which time, it can further assess whether the application is worth pursuing. If patent protection is desirable but further R&D is required, a first filing can be sought, and additional subject matter can be disclosed and claimed through subsequent filings. If these filings are done within a year of the initial filing, the subject matters can be combined into one convention application with multiple priorities. In the rapidly evolved biotechnology areas, a cost-effective approach is to file a series of closely related applications in Canada and later combine them for the purposes of filing convention applications in the US or elsewhere.

Accelerated examination

An applicant interested in seeking speedy prosecution may wish to file an accelerated examination request. The request, along with the payment of the standard C$500 fee, is usually granted automatically, provided the application is open to public inspection (if not, the applicant can request early publication) and a statement that failure to advance the prosecution of the application will prejudice the applicant's rights. The request can be filed at any time and the procedure can be seen as a mere formality. This is in contrast to the considerably more onerous requirements for accelerated examination in the US.

Accelerated examination by patent prosecution highway (PPH)

A one-year PPH pilot programme between Canada and the US was launched on January 28, 2008 and has been extended to January 28, 2011. Under this scheme, if at least one claim has been found allowable by the US Patent and Trademark Office (USPTO), an accelerated examination can be requested at the CPO, and vice versa.

During the pilot, the CPO will process requests for advance prosecution free of charge. Regular fees for requesting examination will continue to apply. The scheme provides useful strategic options for applicants who wish for speedy prosecution in both countries. For example, by first filing an accelerated examination on a Canadian patent application, an applicant may be able to receive a first office action, and possibly allowance, within a year of such a filing. Accelerated examination on the corresponding US application may be requested, under the PPH at the USPTO, as soon as the Canadian application is allowed. In this manner, applicants may avoid the onerous and expensive accelerated examination requirements in the US to obtain speedy allowance on the US application.

> "IN CANADA, A METHOD THAT PROVIDES A PRACTICAL THERAPEUTIC BENEFIT TO A SUBJECT, EVEN IF NOT AS ITS PRIMARY OR INTENDED PURPOSE, IS CONSIDERED TO BE A 'METHOD OF MEDICAL TREATMENT' AND NOT PATENTABLE."

Filing of prior art

In contrast to the US practice, there is no "duty of candour" requirement in Canada. The applicant is only obligated to respond to specific requests from the examiner. During prosecution, the examiner is entitled to request details regarding the prosecution of the corresponding foreign applications (i.e. prior art cited, state of opposition proceedings, etc.). When such a request is made, the applicant is obligated to file a complete and truthful reply.

No Continuation-in-Part practice

In the US, an applicant may file a 'Continuation-in-Part' patent application, which introduces new matter to the pending application. In Canada, the applicant must file a new patent application if it wishes to add new subject matter.

After grant

No patent term adjustment

In Canada, there is no patent term adjustment. The patent term is 20 years from the filing date.

Maintenance fees

In contrast to the US, where maintenance fees are due three and a half , seven and a half, and 11 and a half years after the date of issuance of the patent, maintenance fees are due in Canada on an annual basis beginning on the second anniversary of the filing date.

No file wrapper estoppels

In construing the claims of a patent, the courts in Canada are limited to considering the patent and cannot consider any extrinsic evidence. For example, the courts may not consider any submissions made by the patentee during the prosecution of the application. This is in contrast with the US doctrine of 'file wrapper estoppels', where a patentee is estopped from taking a position with respect to the scope of the claims that is contrary to the one taken during prosecution. The fact that the doctrine of file wrapper estoppel does not apply in Canada provides a distinct advantage for patentees if the patent is subsequently litigated.

Based on the foregoing, it is evident that patent protection in Canada may play an important role in the IP management of any life sciences company with a global vision. Furthermore, the difference between the US and Canadian patent systems warrants that patent protection in Canada requires its own strategies.

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