Regulations Amending the Patent Rules

Statutory Authority

Patent Act

Sponsoring Department

Department of Industry

REGULATORY IMPACT ANALYSIS STATEMENT

Description

The purpose of this minor, technical amendment is to:

- eliminate the possible ambiguity which currently exists in respect of paragraphs 62(1)(b) and (c) of the *Patent Rules* concerning the requirement to submit sequence listings; and
- ensure that patent applicants who make use of the Patent Cooperation Treaty (PCT) to obtain patent protection in Canada for biotechnology-related inventions are not subjected to the automatic abandonment of their patent application and the potential loss of patent rights.

The PCT is a multilateral treaty which helps obtain protection for inventions where such protection is sought, i.e., in any or all of the 123 PCT Contracting States, including Canada. The PCT provides for the filing of one "international" application, with effect in several States, instead of filing several separate national patent applications. While the PCT does not eliminate the necessity of prosecuting the application in the national phase under the jurisdiction of national offices, it does facilitate such prosecution.

Applicants who have filed a patent application under the PCT, and subsequently enter the national phase in Canada, are required to provide to the Canadian Intellectual Property Office (CIPO) certain information, generally within six months from the date the application is received in Canada. For certain biotechnology-related inventions, the required information includes, in some instances, a sequence listing in both paper and computer-readable format.

Clients of CIPO, particularly those specializing in biotechnology, have expressed concern over the potential loss of patent rights arising from the possible ambiguity in interpreting paragraphs 62(1)(b) and (c) of the *Patent Rules* which pertain to the requirement to submit the sequence listing. This is particularly problematic in situations where both CIPO and patent applicants become aware of non-compliance with the requirement to submit a sequence listing in both paper and computer-readable format after the aforementioned six-month period has expired. Such non-compliance could be argued to result in the abandonment of the patent application and the potential loss of patent rights.

In order to address this concern it is proposed to simply delete the requirement to submit to CIPO a sequence listing upon initially entering the national phase in Canada. The substantive

requirement for the applicant to submit this information would still remain but be initiated through a patent examiner's requisition at a later point in the patent examination process. The deletion of the requirement at the early stage in the process ensures that patent applicants who do not comply with the requirement to provide a sequence listing, will not automatically lose their patent rights without first receiving a notification and being given the opportunity to comply within a prescribed period of time. This approach is consistent with the practice of most foreign intellectual property offices.

Alternatives

In order to clarify the existing regulatory requirement, as well as to harmonize CIPO's approach with foreign patent offices, there is no alternative but to amend the Canadian *Patent Rules*.

Benefits and Costs

Applicants utilizing the PCT system to file patent applications in Canada will benefit from the elimination of ambiguous regulations which have the potential to result in a loss of patent rights. Once paragraphs 62(1)(b) and (c) of the *Patent Rules* are repealed, patent applicants will profit from a more user-friendly, fair and flexible patent system.

No financial costs to applicants are associated with this amendment, nor are there any environmental effects.

Consultation

Consultations have been held with the Intellectual Property Institute of Canada (IPIC), which represents over 90 percent of all registered patent agents in Canada. There has been unanimous support for the proposed amendment.

Compliance and Enforcement

As the proposed amendment only repeals certain existing regulations, no compliance mechanism is required.

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