

CA – CANADA

Canadian Intellectual Property Office

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1. Requirements for Deposit

Where an invention cannot be enabled in the absence of access to a biological material, the deposit of the biological material is necessary unless the required material is publicly known and reliably available to the person skilled in the art. A biological material is considered to be reliably available if it can be obtained commercially or can be reproducibly prepared or isolated from available materials using established procedures and without undue experimentation. In the case of plant seeds, a seed is considered to be reliably available where it enables one to obtain, in a reproducible manner, a homogeneous population of plants that are identical to the plant of the invention.

Where a specification in a patent application filed in Canada, or in a Canadian patent issued on the basis of such an application, refers to a deposit of biological material, the deposit of the biological material is considered to be in accordance with the Patent Act and Patent Rules if the deposit meets the following requirements:

- the deposit has been made by the applicant or their predecessor in title with an international depositary authority;

(Patent Rules, Paragraph 93(1)(a))

- the applicant, before the day on which the patent application becomes open to public inspection, informs the Commissioner of Patents of the name of the international depositary authority and the accession number given by the international depositary authority to the deposit; and

(Patent Rules, Paragraph 93(1)(b))

- the name of the international depositary authority, the date of the deposit, and the accession number given by the international depositary authority to the deposit have been included in the description of the patent application.

(Patent Rules, Paragraph 93(1)(c), and Section 94)

In the case of an international application that has become a PCT national phase application and that is published by WIPO on or before its national phase entry date, the requirements to inform the Commissioner of the name of the international depositary authority and the accession number given by the international depositary authority is considered to be met only if said information was furnished in accordance with the requirements of the Patent Cooperation Treaty before the day on which the international application is published.

(Patent Rules, Subsection 93(1.1))

Where a specification refers to a deposit of biological material, an examiner may by notice requisition the applicant to amend the description to include the date of that deposit if it is not already included in the description.

(Patent Rules, Section 94)

2. Time of Deposit

The deposit of the biological material must be made with an international depositary authority on or before the filing date of the patent application.

(Patent Rules, Paragraph 93(1)(a))

In the case where a sample of the biological material is transferred to a substitute authority under Rule 5 of the Regulations under the Budapest Treaty, the applicant or patentee must inform the Commissioner of Patents of the accession number given to the new deposit by that authority not later than

- (i) In respect of an applicant for a patent other than a PCT national phase application, three months after the day on which the authority issues a receipt, and
- (ii) In respect of a PCT national phase application, the later of three months after the day on which the authority issues a receipt and three months after the national phase entry of that application.

(Patent Rules, Paragraph 93(1)(d))

In the case where the depositor is notified under Article 4 of the Budapest Treaty of the inability of the IDA to furnish samples, a new deposit must be made within three months after the date on which the depositor received the notification in accordance with that article.

(Patent Rules, Paragraph 93(1)(e))

In the case where a new deposit of the biological material is made with another IDA under Article 4(1)(b)(i) or (ii) of the Budapest Treaty, the applicant or patentee must inform the Commissioner of Patents of the accession number given to the new deposit by that authority not later than

- (i) In respect of an applicant for a patent other than a PCT national phase application, three months after the day on which the authority issues a receipt, and

(ii) In respect of a PCT national phase application, the later of three months after the day on which the authority issues a receipt and three months after the national phase entry of that application.

(Patent Rules, Paragraph 93(1)(f))

3. Duration of Storage

A deposited biological material shall be stored for a period of at least five years after the most recent request for the furnishing of a sample of the deposited biological material, and for a period of at least 30 years after the date of the deposit.

(Budapest Treaty Regulations, Rule 9.1)

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

Where the applicant wishes that, until either a patent has been issued on the basis of the application, or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn, a sample of the deposited biological material be furnished only to an independent expert nominated by the Commissioner, when:

- for national phase applications, before the patent application is open to public inspection, the applicant may file a notice of request to furnish samples to an independent expert with the Commissioner of Patents; and
- for PCT applications, before completion of technical preparations for publication of the international application the applicant must inform the International Bureau accordingly by a written statement, wherein such statement must be separate from the description and claims of the international application and must preferably be made on Form PCT/RO/134, referred to in Section 209 of the Administrative Instructions under the PCT.

(Patent Rules, Section 95)

The Intellectual Property Office publishes on the website of the Canadian Intellectual Property Office a form for making a request for the furnishing of a sample of the deposit (available in the Manual of Patent Office Practice Chapter 23.11 Appendix 2).

(Patent Rules, Subsection 97(1))

Where the specification in a Canadian patent or in a patent application filed in Canada that is open to public inspection refers to a deposit of biological material by the applicant, and where a person files with the Commissioner of Patents a request made on the form referred to in Subsection 97(1), the Commissioner makes the certification referred to in Rule 11.3(a) of the Regulations under the Budapest Treaty in respect of that person and sends a copy of the request, together with the certification, to the person who filed the request.

(Patent Rules, Subsections 97(2) and (3))

In the case of a patent that has been issued, or an application that has been refused, withdrawn or deemed abandoned and beyond the period of reinstatement, the request for a sample of the deposited material may be made directly to the IDA without the need to provide a request form certified by the Commissioner of Patents unless the IDA specifically requires that a certified request form be submitted. The request should include evidence that the patent has been issued or that the patent application has been refused, withdrawn or deemed to be abandoned and beyond the period of reinstatement, e.g., a copy of the cover page of the Canadian patent indicating that the patent has issued or information from the Canadian Patent Database indicating the status of the patent application, as the case may be. Should a certified request form be required, the requester must fill and send the request form to the Patent Office for certification.

(ii) Restrictions Concerning the Furnishing of Samples

Until either a patent has been issued on the basis of the patent application or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn, the Commissioner of Patents does not make the certification referred to in subsection 97(2) in respect of a person unless the Commissioner has received an undertaking by that person to the applicant:

- not to make any sample of biological material furnished by the international depositary authority or any culture derived from such sample available to any other person before either a patent is issued on the basis of the application or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn; and
- to use the sample of biological material furnished by the international depositary authority and any culture derived from such sample only for the purpose of experiments that relate to the subject-matter of the application until either a patent is issued on the basis of the application or the application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn.

(Patent Rules, Subsection 97(2))

Where a request has been filed with the Commissioner of Patents pursuant to subsection 95(1) in respect of a patent application, the Commissioner, upon request of any person that an independent expert be nominated and with the agreement of the applicant, nominates, within a reasonable time, a person as an independent expert for the purposes of that application.

(Patent Rules, Subsection 96(1))

If no agreement can be reached on the nomination of an independent expert within a reasonable time after the request is made, the notice of the applicant referred to in subsection 95 is deemed never to have been filed.

(Patent Rules, Subsection 96(2))

Where a request has been filed with the Commissioner of Patents pursuant to section 95 in respect of a patent application, until a patent is issued on the basis of the application or the

application is refused, or is abandoned and no longer subject to reinstatement, or is withdrawn, a request for the furnishing of a sample of deposited biological material pursuant to subsection 97(2) may only be submitted by an independent expert nominated by the Commissioner in accordance with section 96.

(Patent Rules, Subsection 98(1))

Where the Commissioner of Patents makes a certification pursuant to subsection 97(2) in respect of an independent expert nominated by the Commissioner, a copy of the request, together with the certification, is sent to the applicant and to the person who requested the nomination of the independent expert.

(Patent Rules, Subsection 98(2))