HPT-167 Register of patents and CSPs.

Halsbury's Laws of Canada - Patents, Trade Secrets and Industrial Designs (2020 Reissue)

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I. Patents of Invention

13. Patented Medicines

(2) Patented Medicines (Notice of Compliance) Regulations

(c) Listing Patent

Register of patents and CSPs.

The provisions in the PM(NOC) Regulations regarding the listing of a patent on the patent register generally remain the same as in the prior PM(NOC) Regulations. The PM(NOC) Regulations provide that certificates of supplementary protection ("CSP"s) may also be listed on the patent register. The Minister must maintain a register of patents that have been submitted for addition to the register and CSPs in which any of those patents are set out.[1] In this respect, the Minister is empowered to:[2]

1. Add any patent or CSP that meets the requirements for addition to the register.
2. Refuse to add any patent or CSP that does not meet the requirements for addition to the register.
3. Delete any patent or CSP:
    a. that was added to the register due to an administrative error;
    b. that has been declared to be invalid or void;
    c. that has been declared to be ineligible for inclusion on the register (but only after the appeal period has ended or any appeals have been concluded);[3] or
    d. the deletion of which was requested by the first person.
4. Delete any patent that has expired, unless a CSP in which the patent is set out is included on the register.
5. Delete any CSP that has expired.

Deletion and addition of patent or CSP. Any patent or CSP that is listed on the patent register will be deleted 90 days after the date of cancellation of the identification number for the drug under the Food and Drug Regulations.[4] However, if a new identification number is assigned for the same drug, the Minister shall add to the patent register

the patent that was deleted.[5] No patent or CSP shall be added to the patent register until after a Notice of Compliance ("NOC") has been issued for the drug.[6] The Minister may consult with officers or employees of the Patent Office for the purpose of determining whether a patent or CSP is to be added to or deleted from the patent register.[7] However, in respect of a patent on a patent list that was submitted before June 17, 2006, the patent shall not be deleted from the patent register, unless:[8]

1. The patent has expired;
2. A court has declared that the patent is invalid or void;
3. The identification number assigned to the drug is cancelled under the Food and Drug Regulations;[9] or
4. The first person in respect of that patent list requests the Minister to delete the patent.

The Minister shall not refuse to add to the register a patent on a patent list that was submitted before June 17, 2006 solely on the basis that the patent is not relevant to the submission for an NOC to which the patent list relates.[10]

Listing a patent or CSP. Once a first person has filed a new drug submission or a supplement to a new drug submission for a drug, it can then submit to the Minister a patent list in relation to the submission or supplement for addition to the patent register.[11] The patent list may include a patent that has not expired and a CSP that has taken effect.[12]

New drug submission. With regard to a new drug submission, a patent is eligible to be added to the patent register if the patent contains:[13]

1. A claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of an NOC in respect of the submission. A patent that contains a claim for the medicinal ingredient is eligible even if the submission includes, in addition to the medicinal ingredient claimed in the patent, other medicinal ingredients.[14]
2. A claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of an NOC in respect of the submission. A patent that contains a claim for the formulation is eligible if the submission includes the non-medicinal ingredients specified in the claim, if any are specified, even if the submission contains any additional non-medicinal ingredients.[15]
3. A claim for the dosage form and the dosage form has been approved through the issuance of an NOC in respect of the submission.
4. A claim for the use of the medicinal ingredient, and the use has been approved through the issuance of an NOC in respect of the submission. A patent that contains a claim for the use of the medicinal ingredient is eligible if the submission includes the use claimed in the patent, even if: the submission includes additional medicinal ingredients, the submission includes other additional uses of the medicinal ingredient, or the use that is included in the submission requires the use of the medicinal ingredient in combination with another drug.[16]

Supplement to a new drug submission. With regard to a supplement to a new drug submission, a patent is eligible to be added to the register if:[17]

1. The supplement is for a change in formulation and the patent contains a claim for the changed formulation that has been approved through the issuance of an NOC in respect of the supplement;
2. The supplement is for a change in dosage form and the patent contains a claim for the changed dosage form that has been approved through the issuance of an NOC in respect of the supplement; or
3. The supplement is for a change in use of the medicinal ingredient and the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of an NOC in respect of the supplement.

Certificates of Supplementary Protection. CSPs are eligible to be added to the patent register if:[18]

1. The patent that is set out in the CSP is included on the patent register; and
2. The submission or supplement relates to a drug with respect to which the CSP grants rights, privileges and liberties referred to in s. 115 of the *Patent Act*.

Timing. As was the case under the PM(NOC) Regulations in force prior to September 21, 2017, a first person who submits a patent list must do so at the time the person files the new drug submission or the supplement to a new drug submission to which the patent list relates,[19] or within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date in Canada that precedes the date of filing of the submission or supplement.[20]

Footnote(s)

1 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 3(2).

2 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 3(2).

3 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 3(2.1).

4 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 3(3). The relevant paragraph of the Food and Drug Regulations, C.R.C. 1978, c. 870, is s. C.01.014.6(1)(a).

5 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 3(5).

6 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 3(7).

7 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 3(8).

8 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 3.1(1).

9 C.R.C. 1978, c. 870, s. C.01.014.6(1)(a).

10 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 3.1(2).

11 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(1).

12 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(1.1).

13 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(2).

14 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(2.1)(a).

15 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(2.1)(b).

16 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(2.1)(c).

17 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(3).

18 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(3.1).

19 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(5).

20 (CAN) Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, s. 4(6).