

Federal Court



Cour fédérale

Date: 20241120

Docket: T-1369-23

Citation: 2024 FC 1848

Ottawa, Ontario, November 20, 2024

PRESENT: Mr. Justice O'Reilly

BETWEEN:

**EMD SERONO, A DIVISION OF EMD INC., CANADA
and MERCK SERONO SA**

Applicants

and

THE MINISTER OF HEALTH and APOTEX INC.

Respondents

and

**CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION and
INNOVATIVE MEDICINES CANADA**

Interveners

JUDGMENT AND REASONS

I. Overview

[1] A company that holds a drug patent can protect the patent from infringement by other companies under rules set out in patented medicine regulations: *Patented Medicines (Notice of*

Compliance) Regulations, SOR/93-133 [Regulations] (provisions cited are set out in the Annex).

That protection begins when the Minister of Health lists the patent on the patent register. The listing date is critical.

[2] The applicants [collectively, Serono] are drug companies who argue that the Minister unreasonably delayed listing their patent on the register, resulting in a loss of their patent rights. The Minister's approach to listing patents, says Serono, fails to respect statutory, regulatory, and treaty obligations, as well as the Minister's own policies. Serono asks me to quash the Minister's decision and declare the patent listed as of the earlier date on which the Minister should have added it to the register. The intervener Innovative Medicines Canada [IMC] supports Serono's position.

[3] The respondents – the Minister of Health and Apotex, supported by the intervener the Canadian Generic Pharmaceutical Association [CGPA] – argue that the Minister's approach was reasonable and legally sound. The respondents ask me to dismiss Serono's application for judicial review of the Minister's decision.

[4] The sole issue is whether the Minister's decision was unreasonable.

[5] I find that the Minister's decision on the listing date for Serono's patent was not unreasonable in light of the governing Regulations and case law. The Minister adds patents to the register when they are eligible for listing – not sooner, not later. Accordingly, I must dismiss Serono's application for judicial review.

II. Background

A. *The Legal Framework*

[6] The Regulations refer to drug patent holders as “first persons” and generic drug companies as “second persons.”

[7] The Regulations impose on the Minister an obligation to maintain a register of patents for approved drugs. Before listing a patent, the Minister must decide whether the patent meets the requirements of the Regulations, namely, whether the patent relates to an approved medicine, contains a claim for an approved formulation of that medicine, identifies a claim for an approved dosage form, or specifies an approved use of the medicine (s 4(2)).

[8] Once the Minister has added a patent to the register, the Regulations prohibit second persons from entering the market for the same medicine, except in accordance with strict conditions (s 7(1)). In addition, a second person who seeks to market a generic version of the patented drug must first address any patents already listed on the register (ss 5(1) and 5(4)). This regulatory arrangement is often referred to as the “frozen register” because it freezes in time the patents that a second person must address. The second person can address the listed patents by accepting that it will not enter the market until the patents expire, by obtaining the first person’s consent, or by alleging that the patent is invalid or would not be infringed by the second person’s product (s 5(2.1)).

[9] Where the second person asserts that the listed patent is invalid or would not be infringed, it must serve a Notice of Allegation [NOA] on the first person (s 5(3)). The first person can then

bring an action for a declaration that the second person's product would infringe the patent (s 6(1)). The action bars the Minister from allowing the second person to enter the market for 24 months (s 7(1)(d)).

B. *Serono's Patent*

[10] Serono filed its application for Canadian Patent No 3,087,419 [the '419 patent] in December 2005. The patent is entitled "Cladribine Regimen for Treating Multiple Sclerosis." The Canadian Intellectual Property Office [CIPO] granted the '419 patent on March 7, 2023.

[11] On March 16, 2023, 9 days after the granting of the patent, Serono submitted patent lists for the '419 patent against a product called MAVENCLAD, a drug used in the treatment of adult patients with relapsing-remitting multiple sclerosis. Health Canada screened the patent lists the next day and then, on March 21, 2023, carried out a preliminary analysis of the patent's eligibility for listing. On March 23, 2023, the Office of Submissions and Intellectual Property [OSIP] informed Serono by letter that its patent lists had been added to the register as of that date – March 23, 2023, one week after Serono submitted its patent lists for the '419 patent.

[12] One day earlier, on March 22, 2023, Apotex filed its regulatory submission for a generic version of MAVENCLAD. Because Serono's patent lists had not yet been added to the register, it appeared that Apotex did not have to address the '419 patent.

[13] Nevertheless, on April 20, 2023, Serono asked OSIP to reconsider the listing date of March 23, 2023, arguing that the proper date should have been the date on which it had

submitted its patent lists – March 16, 2023. Based on that date, Apotex would have had to address the ‘419 patent on March 22, 2023.

C. *The Minister’s Decision*

[14] In response to Serono’s request, OSIP informed Serono that the Minister maintained the listing date of March 23, 2023, the date of the eligibility decision.

[15] The Minister observed that the Regulations distinguish between *submitting* a patent list and *adding* a patent to the register. The Minister must maintain a register of patents that have been *submitted* for listing by *adding* those patents that meet the applicable eligibility requirements, and by refusing to add patents that do not meet those requirements (s 3(2)). As mentioned, a patent is eligible to be added to the register if it claims an approved medicinal ingredient, formulation, dosage form, or use (s 4(2)).

[16] The Minister also cited the distinction between *submission* of a patent list and the *addition* of patents to the register in s 5(1) of the Regulations. That provision requires second persons to address patent lists that have been *submitted*. However, the statements and allegations in the second person’s NOA must be directed at patents that are *included* on the register (s 5(2.1)). The Minister found that, when read together, these provisions reinforce the distinction between the submission of patent lists and the addition of patents to the register.

[17] The Minister rejected Serono’s argument that eligible patent lists should be added to the register on the date they are submitted and that second persons should have to address those

patents as of the date of submission. The Minister pointed out that the Regulations provide that second persons do not have to address patents that were added to the register on or after the date the second person filed its submission for a notice of compliance (ss 5(1),(4)). Again, the regulatory provisions confirm the distinction between the *submission* of patent lists and the *addition* of patents to the register.

[18] In support of his analysis, the Minister cited the *2006 Regulatory Impact Assessment Statement*, SOR/2006-242, October 5, 2006, PC 2006-1077 [2006 RIAS] at 1510. In his view, the RIAS confirms that the Regulations require second persons to address patents that are eligible for addition to the register, and that have actually been added to the register. The Minister also cited Health Canada's Guidance Document for the Regulations, which reiterates that requirement, supporting the Minister's conclusion that the correct date for adding a patent to the register is the date on which it was found to be eligible, not the date on which it was submitted (Guidance Document – Patented Medicines (Notice of Compliance) Regulations (Revised date 2021/04/08)).

[19] The Minister also found that the purpose of the Regulations is to “balance effective patent enforcement over new and innovative drugs with the timely entry of their lower priced generic competitors.” In the Minister's view, that balance would be upset if second persons had to address patents added to the register after they had already filed their submissions.

[20] Finally, the Minister found that his position was supported by case law: *Eli Lilly Canada Inc v Canada (Attorney General)*, 2009 FC 474 [*Eli Lilly*]. There, Lilly had argued that the

Minister had a discretion to list a patent on the register on the date the patent list was filed.

Justice Robert Barnes rejected that argument and concluded that second persons must address patents that have been found to be eligible for listing and added to the register, not patents that have merely been filed.

III. Was the Minister's Decision on the Listing Date Unreasonable?

A. *The Submissions of Serono and IMC*

[21] Serono describes the provisions of the Regulations as setting up a race between first persons and second persons. First persons rush to get their patents added to the register; second persons hurry to file their generic drug submissions. Serono says it won the race against Apotex. Serono filed its patent lists on March 16, 2023; Apotex filed its drug submission on March 22, 2023. Serono attributes the one-week delay in the addition of its patent to the register (on March 23, 2023) to the Minister.

[22] Serono contends that the Minister's decision to add the patent to the register a week after it was submitted was unreasonable because the Regulations do not admit of any discretion to delay – the Minister must simply add eligible patents to the register (s 3(2)). Serono argues that any delay between submission of an eligible patent and its listing on the register risks depriving first persons of their patent rights, contrary to the intent of the Regulations. Serono maintains that the Minister failed to consider its argument that the Minister had arbitrarily delayed adding the '419 patent to the register, to Serono's prejudice, and that the Minister did not offer any explanation for the delay between March 16 and March 23.

[23] Serono offers an alternative to the Minister's interpretation of the Regulations, relying primarily on the wording of s 5(1). That subsection requires second persons to address patent lists that have been *submitted* by a first person. This language is consistent with the wording of s 3(2) of the Regulations, which requires the Minister to maintain a register of "patents that have been submitted for addition to the register." Serono contends that a second person must, therefore, address patents that were *submitted* by a first person before the second person filed its drug submission. The critical date, according to Serono, is the date on which the first person submits a patent for addition to the register, not the date on which it was actually added. Serono argues that any other interpretation of the Regulations would be unreasonable because it would fail to give meaning to the word "submitted."

[24] Serono submits that the *Eli Lilly* case on which the Minister relied is distinguishable. There, the Minister had found Lilly's patent ineligible for listing on the register. A year later, the patent was found to be eligible. Lilly asked the Minister to deem the patent to have been added to the register as of the date it was submitted, not the date on which it was found to be eligible. The Minister refused and Justice Barnes found that the Minister's decision was correct. Serono says that its argument differs from Lilly's: Serono does not contend that its patent should have been added to the register before it was found to be eligible – rather, it argues that the Minister had a duty to review and determine the patent's eligibility immediately, not a week after it was submitted.

[25] Serono compares itself to the applicant in *Abbott Laboratories Limited v Canada (Attorney General)*, 2007 FC 797 [*Abbott*]. There, the patent was added to the register 5 days

after issuance. After amendments to the Regulations, the Minister delisted the patent on the grounds that it was no longer eligible. On judicial review, the Court found that the patent should not have been delisted and ordered that it be relisted retroactively, to the date on which the Minister had delisted it. Serono argues that its patent should be added to the register as of the date on which it should have been added, namely, the date it was submitted. In the alternative, Serono proposes that its patent should have been added to the register on March 21, 2023, the date on which staff completed the screening and eligibility review form. There is no justification, says Serono, for the two-day delay between that review and the eligibility decision.

[26] In addition, says Serono, listing delays violate Canada's obligations under the *Canada-United States-Mexico Agreement*, 30 November 2018, Can TS 2020 No 5 (entered into force 1 July 2020) [CUSMA], which requires Canada to provide a fair system for balancing and litigating the interests of first and second persons. Similarly, the Minister's own *Standard Operating Procedure for Administration of the Patented Medicines (Notice of Compliance) Regulations* states that the Minister must examine patents "immediately," if possible.

[27] IMC concurs with Serono that the patent should have been added to the register on the date on which it was found by staff to be eligible – March 21, 2023. The Minister's two-day delay in communicating the eligibility decision, in effect, unreasonably penalized Serono.

[28] IMC also submits that a second person should be required to address any patent that was submitted for addition to the register before the second person filed its drug submission. This requirement, says IMC, better reflects the purpose of the Regulations, which is to ensure that

eligible patents are protected from infringement by second persons. The Regulations recognize the strong public interest in encouraging drug innovation and the high commercial value of patents by granting first persons a right of action to protect their patent rights against second persons and a 24-month stay against second persons entering the market. Accordingly, IMC maintains that the Minister must interpret the Regulations reasonably and with a view to respecting those significant interests.

[29] In addition, IMC argues that requiring a second person to address a patent submitted before, but added to the register after, the second person filed its drug submission would not cause any prejudice – second persons can always change or update their submissions to address those patents.

B. *The Minister's Decision was not Unreasonable*

[30] I do not agree with Serono's and IMC's characterization of the Minister's decision. The decision was not unreasonable in the context of the Regulations, the case law, and the facts.

[31] I agree with Serono's and IMC's description of the basic purposes of the Regulations and the balance they seek to achieve between first and second persons. However, I disagree that these factors point to an interpretation of the Regulations that would require the Minister to add patents to the register immediately upon submission, or after a preliminary review by staff, or that would require second persons to address patents that have not yet been added to the register. The Minister does not have a discretion to delay adding patents to the register, but the Minister does exercise discretion in determining whether patents are eligible for listing.

[32] To interpret the Regulations in the manner urged by Serono and IMC, one would have to read certain provisions in isolation; that is not a reasonable approach to interpreting the Regulations. For example, the opening words of subsection 3(2) say that the Minister must “maintain a register of patents that have been submitted for addition to the register...” On its own, this passage seems to require the Minister to maintain a register of *submitted* patents. If that were so, second persons would have to address patents *submitted* by first persons, not just those actually added to the register. Indeed, this interpretation is reinforced if one reads another provision in isolation, subsection 5(1). It states, in effect, that a second person must address patents that have been *submitted* by a first person. If the Regulations said no more, one might reasonably conclude that patents are added to the register when submitted, and that second persons must address those patents. But the Regulations do say more.

[33] According to the Regulations, read as a whole, the patent register contains those patents the Minister has determined to be eligible for addition. Patents are not added to the register immediately upon submission. In particular, reading the opening words of subsection 3(2) along with the ensuing paragraphs ((a) and (b)), the Regulations require the Minister to “maintain a register of patents that have been submitted for addition to the register” by adding them to the register if they meet the eligibility requirements, and by refusing to add them if they are ineligible.

[34] Similarly, reading subsection 5(1) along with the ensuing subsections, second persons must address patents that have been submitted by a first person by setting out statements and

allegations in its NOA with respect to each relevant patent *included* on the register (s 5(2.1)).

Second persons need not address patents that get added to the register later (s 5(4)(a)).

[35] To read the Regulations in the limited way Serono and IMC urge me to do would be unreasonable because it would overlook the language in these other provisions that provide additional information and context for the provisions on which they rely.

[36] The Minister reasonably relied on the 2006 RIAS in support of this interpretation of the Regulations. According to the RIAS, the intention of the Regulations is to require second persons to address patents that have been found to be eligible and added to the register, not those that have merely been submitted:

Only those patents which meet the current timing, subject matter and relevance requirements set out in section 4 of the regulations are entitled to be added to Health Canada's patent register and to the concurrent protection of the 24-month stay.

[...]

[A] generic manufacturer that files a submission . . . is only required to address the patents on the register in respect of the innovative drug as of that filing date. Patents added to the register thereafter will not give rise to any such requirement. The register will thus be "frozen" in respect of that generic manufacturer's regulatory submission.

(2006 RIAS at pp 1511, 1519).

[37] Similarly, the Minister reasonably relied on the Guidance Document for the Regulations in support of his conclusion. The Guidance Document, in the passages below, makes clear that patents are added to the register only after they have been reviewed and found to be eligible, and that second persons need only address patents that have actually been added:

- The requirements that must be met before a patent can be added to the Patent Register are provided by section 4 of the *PM(NOC) Regulations* (4.1, p 11).
- The RMOD [Resource Management and Operations Directorate] will not add any patent... until it has completed a final evaluation and is satisfied that the patent... meets the eligibility requirements set out in section 4 (4.8, p 18).
- The RMOD is required to add any patent on a patent list... that meets the requirements for addition to the Patent Register and to refuse to add any patent... that does not meet the requirements for addition to the Patent Register (7, p 28).

[38] The Minister's interpretation is also supported by the *Eli Lilly* case, which he cited. There, Lilly submitted its patent list in November 2006. Two months later, the Minister found Lilly's patent to be ineligible for listing. The parties communicated back and forth over the ensuing months until, in November 2007, the Minister agreed to list the patent. Lilly then asked the Minister to backdate the listing to November 2006, when the patent list had originally been submitted. Lilly argued that the date of submission was the proper date for the addition of a patent to the register because the submission itself provided sufficient notice to second persons who may be considering filing a drug submission for a generic version of the patented medicine. The Minister refused that request, finding that the proper date for listing was the date on which the patent was found to be eligible – in November 2007. Lilly asked the Minister to reconsider. The Minister refused, noting that the Regulations require that patents be added to the register after they have been found to be eligible, not when they are submitted for listing (para 5).

[39] On judicial review of the Minister's decision, Justice Barnes (there applying a standard of correctness, not unreasonableness) concluded that the Minister's decision was correct. He characterized Lilly's argument, essentially the same as Serono's and IMC's here, as "tenuous," "isolated," and "self-serving" (para 11). Justice Barnes reviewed the very provisions that I have considered above and arrived at the same interpretation of them (para 15):

The obvious intent of these provisions is that the listing of a patent on the register is to be done contemporaneously with the Minister's determination of the patent's eligibility for listing. The effect of this is that, under ss. 5(4), a second person need not address any patent added to the register after the date of the second person's submission for a NOC under ss. 5(1) or ss. 5(2).

[40] Justice Barnes observed that the burden of any passage of time between submission and listing falls on first persons. But that was a legislative choice. And the interpretation urged by Lilly would create its own problems by requiring second persons to address patents that are ineligible for listing.

[41] While Serono maintains that *Eli Lilly* can be distinguished from this case because it dealt with a situation where a patent was found first to be ineligible, and then eligible, I cannot see how that difference is relevant. Justice Barnes interpreted the same provisions of the Regulations that are in issue here and, subject to strong reasons to believe he erred, I am bound by his interpretation. I see no error in his judgment.

[42] I find that the cases on which Serono relies are distinguishable.

[43] In the *Abbott* case, the Minister had originally listed Abbott's patent in July 2006 but, after amendments to the Regulations in October 2006, the Minister found the patent no longer eligible for listing. He delisted it in February 2007. Justice Sandra Simpson found that the amendments specifically granted the Minister the power to delete from the register patents that were no longer eligible. However, she went on to find that the patent was not, in fact, ineligible for listing. She ordered that the patent be added to the register as of the date on which the Minister had delisted it. She did not, I note, order that the patent be added to the register as of the date it was originally submitted, or even as of the date it was originally listed. *Abbott* does not assist in interpreting the provisions of the Regulations in issue here; nor does it advance Serono's position.

[44] Serono also cites *Èquiterre v Canada (Health)*, 2016 FC 554 [*Èquiterre*]. There, the Minister had a statutory obligation to begin a special review of any pest control products that were banned by an OECD country (*Pest Control Products Act*, SC 2002, c 28, s 17(2)). The applicants asked the Minister to begin a number of special reviews of products prohibited in OECD countries; after several months, the Minister refused to initiate a review of some of them. Justice Michael Phelan held that the Minister's delay was unreasonable because the obligation to initiate a special review arose immediately upon becoming aware of an OECD ban (para 58).

[45] Serono maintains that the same obligation arises here – the Minister must immediately review patents submitted by first persons and must add them to the register immediately upon determining them to be eligible. I note, however, that while Justice Phelan stated that the Minister's obligation arose “immediately” upon becoming aware of an OECD ban, he went on to

say that this obligation required the Minister to commence special reviews within a “reasonable time,” and declined to define what a “reasonable time” was (para 59). Accordingly, *Équiterre* does not support Serono’s submission that the Minister must act “immediately.” Further, the evidence here shows that Health Canada screened Serono’s patent the day after it was submitted. Four days later, on March 21, 2023, staff completed the screening and eligibility review form. However, the day on which staff completed the screening and eligibility form is not the day of the Minister’s own determination of the patent’s eligibility to be listed. The Minister added the patent to the register on the same day that it was determined to be eligible, on March 23, 2023. There was no delay.

[46] In sum, the Minister’s interpretation of the Regulations was not unreasonable. The Regulations permit a first person to submit a patent for addition to the register. The Minister must add to the register those patents that meet the regulatory requirements, and must refuse to add patents that do not meet those requirements (ss 3(2)(a),(b)). Accordingly, once a patent has been submitted for addition to the register, the Minister must determine whether the regulatory requirements have been met (s 4(2)). The addition of a patent to the register is not automatic; it must await a determination of whether the patent is eligible. Determining eligibility requires a review of the patent to see whether it claims an approved medicinal ingredient, formulation, dosage form, or use.

[47] A second person must address those patents that have been submitted by a first person, reviewed by the Minister and added to the register (ss 5(1),(2.1)). A second person does not have to address a patent that was submitted by a first person for addition to the register but not yet

added to the register. Nor does a second person need to address a patent added to the register on or after the date of the second person's drug submission (s 5(4)(a)).

[48] Accordingly, the Minister's decision that Serono's patent was properly added to the register on the date it was found to be eligible – March 23, 2023 – was not unreasonable. When Apotex filed its drug submission on March 22, 2023, Serono's patent had not yet been added to the register; Apotex had no obligation to address it.

IV. Conclusion and Disposition

[49] The Minister's decision to list Serono's patent on the date on which the Minister determined it to be eligible for listing was not unreasonable given the facts and the regulatory context. Therefore, I must dismiss this application for judicial review.

[50] The parties agree that costs should be determined in accordance with the middle of Column III of Tariff B in the *Federal Courts Rules*, SOR/98-106, with no costs to be awarded in favour of or against the interveners. Should the parties wish to make submissions to the Court on costs, they may do so within 10 days of the issuance of this decision.

JUDGMENT IN T-1369-23

THIS COURT'S JUDGMENT is that:

1. The application for judicial review is dismissed.
2. Costs in favour of the respondents, shall be determined based on the middle of Column III of the Federal Court's Tariff B.
3. The parties may make submissions on costs within 10 days of the issuance of this judgment.

"James W. O'Reilly"

Judge

ANNEX

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133

Register and Patent List

3 (2) The Minister shall maintain a register of patents that have been submitted for addition to the register and certificates of supplementary protection in which any of those patents are set out

(a) by adding any patent on a patent list or certificate of supplementary protection that meets the requirements for addition to the register;

(b) by refusing to add any patent or certificate of supplementary protection that does not meet the requirements for addition to the register;

(c) by deleting any patent or certificate of supplementary protection

(i) that was added to the register due to an administrative error,

(ii) that has, under subsection 60(1) or 125(1) of the *Patent Act*, been declared to be invalid or void,

(iii) that has, under subsection 6.07(1), been declared to be ineligible for inclusion on the register, or

(iv) the deletion of which was requested by the first person in respect of the patent list that includes that patent;

(d) by deleting, in respect of a new drug submission or a supplement to a new drug submission, any patent that has expired, unless a certificate of supplementary protection in which the patent is set out is

Règlement sur les médicaments brevetés (avis de conformité), DORS/93-133

Registre et liste de brevets

3 (2) Le ministre tient un registre des brevets qui ont été présentés pour adjonction au registre et des certificats de protection supplémentaire qui mentionnent ces brevets. À cette fin, le ministre :

a) ajoute au registre tout brevet inscrit sur une liste de brevets et tout certificat de protection supplémentaire qui sont conformes aux exigences pour adjonction au registre;

b) refuse d'ajouter au registre tout brevet et tout certificat de protection supplémentaire qui ne sont pas conformes aux exigences pour adjonction au registre;

c) supprime du registre tout brevet ou tout certificat de protection supplémentaire :

(i) qui y a été ajouté à la suite d'une erreur administrative,

(ii) qui a été déclaré invalide ou nul aux termes des paragraphes 60(1) ou 125(1) de la Loi sur les brevets,

(iii) qui a été déclaré inadmissible à l'inscription au registre au titre du paragraphe 6.07(1),

(iv) qui fait l'objet d'une demande de suppression par la première personne à l'égard de la liste de brevets qui comprend ce brevet;

d) supprime, à l'égard d'une présentation de drogue nouvelle ou d'un supplément à une présentation de drogue nouvelle, tout brevet qui est expiré, sauf si un certificat de

included on the register in respect of that submission or supplement; and

(e) by deleting any certificate of supplementary protection that has expired.

[...]

4 (1) A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register.

[...]

(2) A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains

(a) a claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission;

(b) a claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of a notice of compliance in respect of the submission;

(c) a claim for the dosage form and the dosage form has been approved through the issuance of a notice of compliance in respect of the submission; or

(d) a claim for the use of the medicinal ingredient, and the use has been approved through the issuance of a notice of compliance in respect of the submission.

protection supplémentaire mentionnant ce brevet est inscrit au registre à l'égard de cette présentation ou de ce supplément;

e) supprime tout certificat de protection supplémentaire qui est expiré.

[...]

4 (1) La première personne qui dépose ou a déposé la présentation de drogue nouvelle ou le supplément à une présentation de drogue nouvelle peut présenter au ministre, pour adjonction au registre, une liste de brevets qui se rattache à la présentation ou au supplément.

[...]

(2) Est admissible à l'adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache à la présentation de drogue nouvelle, s'il contient, selon le cas :

a) une revendication de l'ingrédient médicinal, l'ingrédient médicinal ayant été approuvé par la délivrance d'un avis de conformité à l'égard de la présentation;

b) une revendication de la formulation contenant l'ingrédient médicinal, la formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;

c) une revendication de la forme posologique, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation;

d) une revendication de l'utilisation de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard de la présentation.

(2.1) The following rules apply when determining the eligibility of a patent to be added to the register under subsection (2):

(a) for the purposes of paragraph (2)(a), 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;

(b) for the purposes of paragraph (2)(b), 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; and

(c) for the purposes of paragraph (2)(d), 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

(i) the submission includes additional medicinal ingredients,

(ii) the submission includes other additional uses of the medicinal ingredient, or

(iii) the use that is included in the submission requires the use of the medicinal ingredient in combination with another drug.

[...]

5 (1) If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person

(2.1) Les règles ci-après s'appliquent au moment de la détermination de l'admissibilité des brevets pour leur adjonction au registre aux termes du paragraphe (2) :

a) pour l'application de l'alinéa (2)a), un brevet qui contient la revendication de l'ingrédient médicinal est admissible même si la présentation comprend, en plus de l'ingrédient médicinal revendiqué dans le brevet, d'autres ingrédients médicinaux;

b) pour l'application de l'alinéa (2)b), un brevet qui contient la revendication de la formulation est admissible si la présentation comprend les ingrédients non médicinaux précisés dans la revendication — si des ingrédients non médicinaux y sont précisés — , même si la présentation contient des ingrédients non médicinaux additionnels;

c) pour l'application de l'alinéa (2)d), un brevet qui contient la revendication de l'utilisation de l'ingrédient médicinal est admissible si la présentation comprend l'utilisation revendiquée dans le brevet, même si :

(i) la présentation comprend l'utilisation d'ingrédients médicinaux additionnels,

(ii) la présentation comprend d'autres utilisations,

(iii) l'utilisation comprise dans la présentation requiert l'utilisation de l'ingrédient médicinal en conjonction avec une autre drogue.

[...]

5 (1) Dans le cas où la seconde personne dépose une présentation pour un avis de conformité à l'égard d'une drogue, laquelle présentation, directement ou indirectement, compare celle-ci à une autre drogue commercialisée sur le marché canadien aux

and in respect of which a patent list has been submitted, the second person shall include in the submission the required statements or allegations set out in subsection (2.1).

(2) If a second person files a supplement to a submission referred to in subsection (1) seeking a notice of compliance for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient and the supplement directly or indirectly compares the drug for which the supplement is filed with, or makes reference to, another drug that has been marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall include in the supplement the required statements or allegations set out in subsection (2.1).

(2.1) The statements or allegations required for the submission or the supplement, as the case may be, are — with respect to each patent included on the register in respect of the other drug and with respect to each certificate of supplementary protection in which the patent is set out and that is included on the register in respect of the other drug — the following:

(a) a statement that the owner of that patent has consented to the making, constructing, using or selling in Canada of the drug for which the submission or supplement is filed by the second person;

(b) a statement that the second person accepts that the notice of compliance will not issue until that patent or certificate of supplementary protection, as the case may be, expires; or

(c) an allegation that

termes d'un avis de conformité délivré à la première personne et à l'égard de laquelle une liste de brevets a été présentée — ou y fait renvoi —, cette seconde personne inclut dans sa présentation les déclarations ou allégations visées au paragraphe (2.1).

(2) Dans le cas où la seconde personne dépose un supplément à la présentation visée au paragraphe (1), en vue d'obtenir un avis de conformité à l'égard d'une modification de la formulation, d'une modification de la forme posologique ou d'une modification de l'utilisation de l'ingrédient médicinal, lequel supplément, directement ou indirectement, compare la drogue pour laquelle le supplément est déposé à une autre drogue commercialisée sur le marché canadien aux termes de l'avis de conformité délivré à la première personne et à l'égard duquel une liste de brevets a été présentée — ou y fait renvoi —, cette seconde personne inclut dans son supplément les déclarations ou allégations visées au paragraphe (2.1).

(2.1) Les déclarations ou allégations exigées pour la présentation ou le supplément, selon le cas, à l'égard de chaque brevet inscrit au registre pour l'autre drogue — et à l'égard de chaque certificat de protection supplémentaire qui mentionne le brevet et qui est inscrit au registre pour cette autre drogue — sont les suivantes :

a) soit une déclaration portant que le propriétaire du brevet a consenti à la fabrication, à la construction, à l'exploitation ou à la vente au Canada de la drogue à l'égard de laquelle la présentation ou le supplément a été déposé par la seconde personne;

b) soit une déclaration portant que la seconde personne accepte que l'avis de conformité ne soit pas délivré avant l'expiration du brevet

(i) the statement made by the first person under paragraph 4(4)(d) is false,

(ii) that patent or certificate of supplementary protection is invalid or void,

(iii) that patent or certificate of supplementary protection is ineligible for inclusion on the register,

(iv) that patent or certificate of supplementary protection would not be infringed by the second person making, constructing, using or selling the drug for which the submission or the supplement is filed,

(v) that patent or certificate of supplementary protection has expired, or

(vi) in the case of a certificate of supplementary protection, that certificate of supplementary protection cannot take effect.

(3) A second person who makes an allegation referred to in paragraph (2.1)(c) shall

(a) serve on the first person a notice of allegation relating to the submission or supplement filed under subsection (1) or (2) on or after its date of filing;

(b) include in the notice of allegation

(i) a description of the medicinal ingredient, dosage form, strength, route of administration and use of the drug in respect of which the submission or supplement has been filed, and

(ii) a statement of the legal and factual basis for the allegation, which statement must be detailed in the case of an allegation that the patent or certificate of supplementary protection is invalid or void;

ou du certificat de protection supplémentaire, selon le cas;

c) soit toute allégation portant que :

(i) la déclaration faite par la première personne en application de l'alinéa 4(4)d) est fausse,

(ii) le brevet ou le certificat de protection supplémentaire est invalide ou nul,

(iii) le brevet ou le certificat de protection supplémentaire est inadmissible à l'inscription au registre,

(iv) en fabriquant, construisant, exploitant ou vendant la drogue pour laquelle la présentation ou le supplément est déposé, la seconde personne ne contrefera pas le brevet ou le certificat de protection supplémentaire,

(v) le brevet ou le certificat de protection supplémentaire est expiré,

(vi) dans le cas d'un certificat de protection supplémentaire, celui-ci ne peut pas prendre effet.

(3) La seconde personne qui inclut une allégation visée à l'alinéa (2.1)c) est tenue de prendre les mesures suivantes :

a) signifier à la première personne un avis de l'allégation à l'égard de la présentation ou du supplément déposé en vertu des paragraphes (1) ou (2), à la date de son dépôt ou à toute date postérieure;

b) insérer dans l'avis de l'allégation :

(i) une description de l'ingrédient médicinal, de la forme posologique, de la concentration, de la voie d'administration et de l'utilisation

(c) serve the following documents with the notice:

(i) a certification by the Minister of the date of filing of the submission or supplement,

(ii) a document setting out the second person's address for service for the purpose of any action that may be brought against them under subsection 6(1), along with the names of and contact information for their anticipated solicitors of record if that action is brought,

(iii) a searchable electronic copy of the portions of the submission or supplement that are under the control of the second person and relevant to determine if any patent or certificate of supplementary protection referred to in the allegation would be infringed, and

(iv) if the second person is alleging that the patent or certificate of supplementary protection is invalid or void, an electronic copy of any document — along with an electronic copy of it in English or French if available — on which the person is relying in support of the allegation;

(d) provide, without delay, to the first person any portion of a submission or supplement referred to in subparagraph (c)(iii) that is changed on or before the later of the 45th day after the day on which the notice of allegation is served and the day of the disposition of any action that has been brought under subsection 6(1); and

(e) provide to the Minister proof of service of the documents referred to in paragraphs (a) and (b), along with a copy of the notice of allegation.

[...]

de la drogue visée par la présentation ou le supplément,

(ii) un énoncé du fondement juridique et factuel de l'allégation, lequel énoncé est détaillé dans le cas d'une allégation portant que le brevet ou le certificat de protection supplémentaire est invalide ou nul.

c) signifier, avec l'avis, les documents suivants :

(i) une attestation par le ministre de la date du dépôt de la présentation ou du supplément,

(ii) un document indiquant l'adresse de la seconde personne aux fins de signification dans le cas où une action serait intentée contre elle en vertu du paragraphe 6(1), ainsi que les noms et les coordonnées des avocats qui seraient inscrits au dossier dans un tel cas,

(iii) une copie électronique — pouvant faire l'objet de recherches — de toute partie de la présentation ou du supplément qui est sous le contrôle de la seconde personne et qui est pertinente pour établir si un brevet ou un certificat de protection supplémentaire visé par l'allégation serait contrefait,

(iv) si la seconde personne allègue que le brevet ou le certificat de protection supplémentaire est invalide ou nul, une copie électronique — ainsi qu'une copie électronique en français ou en anglais si une telle copie est disponible — de tout document à l'appui de son allégation;

d) transmettre à la première personne, dans les plus brefs délais, toute partie de la présentation ou du supplément visée au sous-alinéa c)(iii) qui est modifiée au plus tard le quarante-cinquième jour suivant la date de signification de l'avis d'allégation ou, si elle est postérieure à ce jour, à la date à laquelle

(4) A second person is not required to comply with

(a) subsection (1) in respect of a patent, or a certificate of supplementary protection that sets out the patent, that is added to the register in respect of the other drug on or after the date of filing of the submission referred to in that subsection, including one added under subsection 3(2.2) or (5); and

(b) subsection (2) in respect of a patent, or a certificate of supplementary protection that sets out the patent, that is added to the register in respect of the other drug on or after the date of filing of the supplement referred to in that subsection, including one added under subsection 3(2.2) or (5).

[...]

Right of Action

6 (1) The first person or an owner of a patent who receives a notice of allegation referred to in paragraph 5(3)(a) may, within 45 days after the day on which the first person is served with the notice, bring an action against the second person in the Federal Court for a declaration that the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) would infringe any patent or certificate of supplementary

toute action intentée en vertu du paragraphe 6(1) est réglée;

e) transmettre au ministre la preuve de la signification des documents visés aux alinéas a) et b), ainsi qu'une copie de l'avis d'allégation.

[...]

(4) La seconde personne n'est pas tenue de se conformer :

a) au paragraphe (1) en ce qui concerne tout brevet, ou tout certificat de protection supplémentaire qui mentionne le brevet, ajouté au registre à l'égard de l'autre drogue — y compris celui ajouté en application des paragraphes 3(2.2) ou (5) — à compter de la date de dépôt de la présentation visée au paragraphe (1);

b) au paragraphe (2) en ce qui concerne tout brevet, ou tout certificat de protection supplémentaire qui mentionne le brevet, ajouté au registre à l'égard de l'autre drogue — y compris celui ajouté en application des paragraphes 3(2.2) ou (5) — à compter de la date de dépôt du supplément visé au paragraphe (2).

[...]

Droits d'action

6 (1) La première personne ou le propriétaire d'un brevet qui reçoit un avis d'allégation en application de l'alinéa 5(3)a) peut, au plus tard quarante-cinq jours après la date à laquelle la première personne a reçu signification de l'avis, intenter une action contre la seconde personne devant la Cour fédérale afin d'obtenir une déclaration portant que la fabrication, la construction, l'exploitation ou la vente d'une drogue, conformément à la présentation ou au

protection that is the subject of an allegation set out in that notice.

[...]

Notice of Compliance

7 (1) The Minister shall not issue a notice of compliance to a second person before the latest of

(a) the day after the expiry of all of the patents and certificates of supplementary protection in respect of which the second person is required to make a statement or allegation under subsection 5(1) or (2) and that are not the subject of an allegation;

(b) the day on which the second person complies with paragraph 5(3)(e);

(c) the 46th day after the day on which a notice of allegation under paragraph 5(3)(a) is served;

(d) the day after the expiry of the 24-month period that begins on the day on which an action is brought under subsection 6(1);

(e) the day after the expiry of all of the patents and certificates of supplementary protection in respect of which a declaration of infringement has been made in an action brought under subsection 6(1); and

(f) the day after the expiry of all of the certificates of supplementary protection, other than any that were held not to be infringed in an action referred to in paragraph (e), that

(i) set out a patent referred to in paragraph (a) or (e),

supplément visé aux paragraphes 5(1) ou (2), contreferait tout brevet ou tout certificat de protection supplémentaire visé par une allégation faite dans cet avis.

[...]

Avis de conformité

7 (1) Le ministre ne peut délivrer d'avis de conformité à la seconde personne avant le dernier en date des jours suivants :

a) le lendemain du premier jour où sont expirés tous les brevets et certificats de protection supplémentaire à l'égard desquels la seconde personne est tenue de faire une déclaration ou une allégation en application des paragraphes 5(1) ou (2) et qui ne font pas l'objet d'une allégation;

b) le jour où la seconde personne se conforme à l'alinéa 5(3)e);

c) le quarante-sixième jour après la date de signification de l'avis d'allégation visé à l'alinéa 5(3)a);

d) le lendemain du dernier jour de la période de vingt-quatre mois qui commence à la date à laquelle une action a été intentée en vertu du paragraphe 6(1);

e) le lendemain du premier jour où sont expirés tous les brevets et les certificats de protection supplémentaire faisant l'objet d'une déclaration de contrefaçon faite dans une action intentée en vertu du paragraphe 6(1);

f) le lendemain du premier jour où sont expirés tous les certificats de protection supplémentaire — autres que ceux qui ont été tenus non contrefaits dans une action visée à l'alinéa e) — qui, à la fois :

(ii) are not the subject of a statement or allegation made under subsection 5(1) or (2), and

(iii) are included on the register in respect of the same submission or supplement as the patent.

[...]

(4) Paragraph (1)(d) does not apply in respect of a patent or a certificate of supplementary protection that has been declared in the action referred to in that paragraph by the Federal Court to be ineligible for inclusion on the register.

(i) mentionnent un brevet visé aux alinéas a) ou e),

(ii) ne font pas l'objet d'une déclaration ou d'une allégation faite en application des paragraphes 5(1) ou (2),

(iii) sont inscrits au registre à l'égard de la même présentation ou du même supplément que le brevet.

[...]

(4) L'alinéa (1)d) ne s'applique pas à l'égard d'un brevet ou d'un certificat de protection supplémentaire qui a été déclaré par la Cour fédérale inadmissible à l'inscription au registre dans l'action visée à cet alinéa.

FEDERAL COURT

SOLICITORS OF RECORD

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