Federal Court  Cour fédérale

Date: 20250120

Docket: T-2728-23

Citation: 2025 FC 107

Ottawa, Ontario, January 20, 2025

PRESENT: Mr. Justice O'Reilly

BETWEEN:

BAYER INC.

Applicant

and

AMGEN CANADA INC. and THE MINISTER OF HEALTH

Respondents

JUDGMENT AND REASONS

I. Overview

[1] This decision follows the release of my earlier judgment in *Serono v Canada (Health)*, 2024 FC 1848 [*Serono*], which raised substantially similar issues.

[2] As I pointed out in *Serono*, 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.

[3] The applicant, Bayer Inc., is a drug company who argues 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 Bayer, fails to respect statutory, regulatory, and treaty obligations, as well as the Minister's own policies. Bayer 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.

[4] The respondents, the Minister of Health and Amgen Canada Inc, argue that the Minister's approach was reasonable and legally sound. The respondents ask me to dismiss Bayer's application for judicial review of the Minister's decision.

[5] While Bayer argues that the proper standard of review of the Minister's interpretation of the Regulations is correctness, I find that the applicable standard is unreasonableness. Accordingly, the sole issue is whether the Minister's decision was unreasonable.

[6] I find that the Minister's decision on the listing date for Bayer'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 Bayer's application for judicial review.

II. Background

A. *The Legal Framework*

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

[8] 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)).

[9] 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)).

[10] 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. *Bayer's Patent*

[11] Bayer filed its application for Canadian Patent No 2,970,315 [the '315 patent] in December 2015. The patent is entitled "Use of Anti-VEGF Agents to Treat Lesions in Macular Degeneration Patients." The Canadian Intellectual Property Office [CIPO] granted the '315 patent on August 22, 2023.

[12] Also on August 22, 2023, Bayer submitted patent lists for the '315 patent against a product called EYLEA, a drug approved for treating, among other things, neovascular (wet) age-related macular degeneration. Health Canada screened the patent lists on the day they were submitted. Bayer points out that the Patent List Screening and Eligibility sheet in this case is missing the "Eligibility Analysis Date" field which was present on the same form in *Serono*. Bayer says it is unclear if this information was intentionally deleted or if the Minister refused to insert this date, and therefore that it is entirely possible the Minister completed the screening before August 24, 2023. In response, Amgen notes that there is Patent Annotation metadata showing timestamped comments by screening staff as late as August 28, 2023, suggesting that the review of the patent's eligibility for listing was ongoing on that date. On August 30, 2023, the Office of Submissions and Intellectual Property [OSIP] informed Bayer by letter that its patent lists had been added to the register as of that date – August 30, 2023, eight days after Bayer submitted its patent lists for the '315 patent.

[13] Six days earlier, on August 24, 2023, Amgen filed its regulatory submission for a generic version of EYLEA. Because Bayer's patent lists had not yet been added to the register, it appeared that Amgen did not have to address the '315 patent.

[14] Nevertheless, on September 7, 2023, Bayer asked OSIP to reconsider the listing date of August 30, 2023, arguing that the proper date should have been the date on which it had submitted its patent lists – August 22, 2023. Based on that date, Amgen would have had to address the '315 patent on August 24, 2023.

C. *The Minister's Decision*

[15] In response to Bayer's request, OSIP informed Bayer that the Minister maintained the listing date of August 30, 2023, the date of the eligibility decision.

[16] 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)).

[17] The Minister also noted that s 5(1) of the Regulations 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.

[18] The Minister rejected Bayer'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.

[19] 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]. 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)).

[20] 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.

[21] 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.

[22] Finally, the Minister found that his interpretation of the Regulations did not offend the *Canada-United States-Mexico Agreement*, 30 November 2018, Can TS 2020 No 5 (entered into force 1 July 2020) [CUSMA]. That agreement requires the parties to provide notice to patent holders when a company relies on information about the safety and efficacy of a previously approved product. The Regulations provide for that kind of notice and therefore meet the requirements of CUSMA.

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

A. *The Proper Standard of Review is Unreasonableness*

[23] Bayer argues that the appropriate standard of review of the Minister’s interpretation of the Regulations is correctness, not unreasonableness. Bayer suggests that the Minister and this Court have concurrent jurisdiction on the issue of listing dates, a circumstance, in Bayer’s view, that amounts to an exception to the usual presumption of a standard of review of

unreasonableness (*Society of Composers, Authors and Music Publishers of Canada v Entertainment Software Association*, 2022 SCC 30 at para 28).

[24] I disagree. This is not a situation of concurrent jurisdiction.

[25] Bayer points to the Minister's obligation to maintain a register of patents that have been submitted for addition to the register (s 3(2)). At the same time, the Court can receive motions to declare patents ineligible for inclusion on the register (s 6.07(1)). Accordingly, says Bayer, both the Minister and the Court have responsibility for the register.

[26] The Minister does have a duty to maintain the register and the Court can rule on the ineligibility of patents for inclusion on the register. But these are not equivalent functions; the Regulations separate the roles of the Minister and the Court. Therefore, their responsibilities cannot be described as concurrent.

[27] Accordingly, the proper standard of review to be applied to the Minister's decision is unreasonableness.

B. *The Submissions of Bayer on the Listing Date*

[28] Bayer contends that the Minister's decision to add the patent to the register eight days 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)). Bayer 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.

[29] Bayer 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." Bayer 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 Bayer, 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.

[30] Bayer maintains that the 1993 and 1999 RIAS support its position that ss 3 and 5 of the Regulations create a duty to maintain a register of submitted patent lists. Bayer says these versions of the RIAS do not differentiate between "submitted" and "added." It also says that the Minister erred in relying on the 2006 RIAS, which provides no guidance on when submitted patents are deemed to be added to the register, given that the 2006 amendments were not aimed at this question, but at the issue of "ever-greening" by submitting supplemental new drug submissions.

[31] Bayer notes that the purpose of the Regulations is to counterbalance the "early working exception" with an effective means of patent enforcement. It says this balance is upset if it only allows patents to be added to the register after an arbitrary review period by the Minister.

[32] Further, Bayer alleges that the Minister failed to account for the certification required to be made by first persons under s 4(4)(f), confirming that the information submitted is accurate and that the list meets the eligibility requirements in ss 4(2)-(3).

[33] Bayer argues that, if a second person has to address a submitted patent that is later found ineligible, the person can rely on s 7(3), which provides that deleted patents no longer block a second person's notice of compliance. By contrast, the Minister's interpretation creates a situation where a first person has no recourse against a second person who files a drug submission while the Minister is assessing the eligibility of a submitted patent, except to bring an infringement action. Bayer says the harm to first persons in this scenario is catastrophic, far exceeding the potential harm for second persons who might have to address patents later found to be ineligible.

[34] Bayer 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. Bayer says that its argument differs from Lilly's: Bayer 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 eight days after it was submitted.

[35] Bayer says that in *Abbott Laboratories Limited v Canada (Attorney General)*, 2007 FC 797 [*Abbott*] this Court put second persons in the position of retroactively addressing a re-listed patent. There, the patent was added to the register five 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. As a result, according to Bayer, second persons would have had to address the re-listed patent if they filed their notice of compliance during the interim period. This is an example, says Bayer, of a situation where, hypothetically, the Court accepted that second persons might have had to address a patent re-listed after they submitted their notices of compliance, if they did so during the time Abbott's patent was temporarily removed from the register.

[36] In addition, says Bayer, listing delays violate Canada's obligations under the 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.

[37] Finally, Bayer raises an issue with the Minister's having selected Amgen's submission date of August 24, 2023 as a "retroactive" filing date for Amgen's new drug submission, which was deemed eligible on August 31, 2023, while listing Bayer's patent on the day it was determined to be eligible, August 30, 2023. Bayer's alternative argument is that, in fairness both

to first persons and second persons, adding a patent to the register must also be retroactive to the filing date.

C. *The Minister's Decision Was Not Unreasonable*

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

[39] I agree with Bayer'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 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.

[40] To interpret the Regulations in the manner urged by Bayer, 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 s 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, s 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.

[41] 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 s 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.

[42] Similarly, reading s 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)).

[43] To read the Regulations in the limited way Bayer urges 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.

[44] 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).

[45] 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).

[46] 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).

[47] 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 Bayer'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).

[48] 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.

[49] 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.

[50] In the *Abbott* case Bayer relies on, 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 Bayer's position.

[51] The evidence here shows that Health Canada screened Bayer's patent lists the day they were submitted. While the date the eligibility analysis was completed by staff is missing from the standard form, this is of no consequence to the date of the Minister's eligibility decision, because the day on which staff complete their screening and eligibility analysis 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 August 30, 2023. There was no delay.

[52] 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.

[53] 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)).

[54] Accordingly, the Minister's decision that Bayer's patent was properly added to the register on the date it was found to be eligible – August 30, 2023 – was not unreasonable. When Amgen filed its drug submission on August 24, 2023, Bayer's patent had not yet been added to the register; Amgen had no obligation to address it.

IV. Conclusion and Disposition

[55] The Minister's decision to list Bayer'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.

[56] 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. 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-2728-23

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	*Règlement sur les médicaments brevetés (avis de conformité)*, DORS/93-133
Register and Patent List	**Registre et liste de brevets**
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	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) by adding any patent on a patent list or certificate of supplementary protection that meets the requirements for addition to the register;	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) by refusing to add any patent or certificate of supplementary protection that does not meet the requirements for addition to the register;	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) by deleting any patent or certificate of supplementary protection	c) supprime du registre tout brevet ou tout certificat de protection supplémentaire :
(i) that was added to the register due to an administrative error,	(i) qui y a été ajouté à la suite d'une erreur administrative,
(ii) that has, under subsection 60(1) or 125(1) of the *Patent Act*, been declared to be invalid or void,	(ii) qui a été déclaré invalide ou nul aux termes des paragraphes 60(1) ou 125(1) de la Loi sur les brevets,
(iii) that has, under subsection 6.07(1), been declared to be ineligible for inclusion on the register, or	(iii) qui a été déclaré inadmissible à l'inscription au registre au titre du paragraphe 6.07(1),
(iv) the deletion of which was requested by the first person in respect of the patent list that includes that patent;	(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) 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	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.

[…]

(3) A patent on a patent list in relation to a supplement to a new drug submission is eligible to be added to the register if the supplement is for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, and

(a) in the case of a change in formulation, the patent contains a claim for the changed

(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.

[…]

(3) Est admissible à l’adjonction au registre tout brevet, inscrit sur une liste de brevets, qui se rattache au supplément à une présentation de drogue nouvelle visant une modification de la formulation, une modification de la forme posologique ou une modification de

formulation that has been approved through the issuance of a notice of compliance in respect of the supplement;

(b) in the case of a change in dosage form, the patent contains a claim for the changed dosage form that has been approved through the issuance of a notice of compliance in respect of the supplement; or

(c) in the case of a change in use of the medicinal ingredient, the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of a notice of compliance in respect of the supplement.

[…]

(4) A patent list shall contain the following:

[…]

(f) a certification by the first person that the information submitted under this subsection is accurate and that each patent on the list meets the eligibility requirements of subsection (2) or (3).

[…]

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 and in respect of which a patent list has been submitted, the second person shall include in

l'utilisation de l'ingrédient médicinal, s'il contient, selon le cas :

a) dans le cas d'une modification de formulation, une revendication de la formulation modifiée, la formulation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément;

b) dans le cas d'une modification de la forme posologique, une revendication de la forme posologique modifiée, la forme posologique ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément;

c) dans le cas d'une modification d'utilisation de l'ingrédient médicinal, une revendication de l'utilisation modifiée de l'ingrédient médicinal, l'utilisation ayant été approuvée par la délivrance d'un avis de conformité à l'égard du supplément.

[…]

(4) La liste de brevets comprend :

[…]

f) une attestation de la première personne portant que les renseignements fournis aux termes du présent paragraphe sont exacts et que chaque brevet qui y est inscrit est conforme aux conditions d'admissibilité prévues aux paragraphes (2) ou (3).

[…]

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 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

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

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

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 ou du certificat de protection supplémentaire, selon le cas;

c) soit toute allégation portant que :

(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;

(c) serve the following documents with the notice:

(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 contreferait 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 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

(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.

[…]

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

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 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) 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).

[…]

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).

[…]

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

[…]

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 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.

6.07 (1) In an action brought under subsection 6(1), the Federal Court may, on the motion of the second person, declare that a patent or certificate of supplementary protection is ineligible for inclusion on the register.

[…]

[…]

6.07 (1) Lors de l'action intentée en vertu du paragraphe 6(1), la Cour fédérale peut, sur requête de la seconde personne, déclarer qu'un brevet ou un certificat de protection supplémentaire est inadmissible à l'inscription au registre.

[…]

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

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

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

(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.

[…]

(3) Paragraphs (1)(a) to (d) do not apply in respect of a patent or certificate of supplementary protection if it is deleted from the register under any of paragraphs 3(2)(c) to (e) or subsection 3(2.3) or (3).

(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.

supplémentaire — autres que ceux qui ont été tenus non contrefaits dans une action visée à l'alinéa e) — qui, à la fois :

(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.

[…]

(3) Les alinéas (1)a) à d) ne s'appliquent pas à l'égard d'un brevet ou d'un certificat de protection supplémentaire s'il est supprimé du registre en application de l'un ou l'autre des alinéas 3(2)c) à e) ou des paragraphes 3(2.3) ou (3).

(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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APPEARANCES:

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