Federal Court of Appeal | Cour d'appel fédérale

Date: 20250808

Docket: A-64-25

Citation: 2025 FCA 142

CORAM: **LOCKE J.A.**
LEBLANC J.A.
GOYETTE J.A.

BETWEEN:

BAYER INC.

Appellant

and

AMGEN CANADA INC. and THE MINISTER OF HEALTH

Respondents

Heard at Toronto, Ontario, on June 24, 2025.

Judgment delivered at Ottawa, Ontario, on August 8, 2025.

REASONS FOR JUDGMENT BY: LOCKE J.A.

CONCURRED IN BY: LEBLANC J.A.
GOYETTE J.A.

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REASONS FOR JUDGMENT

LOCKE J.A.

I. Overview

[1] This appeal concerns the interpretation and application of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (the Regulations), which link patent rights in medicines to market access for subsequent entry (generic or biosimilar) versions of those medicines. Specifically, this appeal concerns the timing of the addition of patents to the register

defined in the Regulations (the Patent Register) that a second person must address when seeking market access (a notice of compliance (NOC)) for a subsequent entry drug.

[2] This appeal arises from an unusual set of facts in which:

A. The appellant, Bayer Inc. (Bayer, a first person under the Regulations), submitted a patent list in relation to its Canadian Patent No. 2,970,315 (the 315 Patent) and drug submissions for its drug EYLEA (containing the medicinal ingredient aflibercept) on August 22, 2023;

B. The Office of Submissions and Intellectual Property (OSIP) of Health Canada, on behalf of the Minister of Health (the Minister), reviewed Bayer's submission and found the 315 Patent eligible for inclusion on the Patent Register on August 30, 2023;

C. In the interim, the respondent Amgen Canada Inc. (Amgen, a second person under the Regulations) filed a new drug submission (NDS) for its subsequent entry version of aflibercept on August 24, 2023;

D. Though the OSIP decided only on August 31, 2023 that Amgen's NDS was administratively complete, it treated the date of submission thereof (August 24, 2023) as its filing date.

[3] Because the 315 Patent had not yet been added to the Patent Register on August 24, 2023, the OSIP concluded that section 5 of the Regulations did not oblige Amgen to address the 315 Patent in its NDS. The OSIP relied on subsection 5(4) of the Regulations, which provides that a

second person need not address a patent that is added to the Patent Register on or after the date of filing of its NDS.

[4] Bayer sought judicial review of this decision by the OSIP (the OSIP Decision) before the Federal Court. However, the application for judicial review was dismissed by Justice James W. O'Reilly (2025 FC 107, the FC Decision).

[5] Bayer now appeals the FC Decision to this Court.

[6] An important hurdle for Bayer in this appeal concerns the standard of review. Since this is an appeal of a decision of the Federal Court on a judicial review, our task is to determine whether the Federal Court identified the appropriate standard of review to assess the OSIP Decision, and whether the Federal Court applied that standard of review correctly: *Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 S.C.R. 559 at para. 45 (*Agraira*). In other words, we must step into the shoes of the Federal Court: *Agraira* at para. 46. Where the Federal Court appears to have given a complete answer to all the arguments that the appellant advances, the appellant bears a strong tactical burden to show on appeal that the Federal Court's reasoning is flawed: *Bank of Montreal v. Canada (Attorney General)*, 2021 FCA 189, [2021] D.T.C. 5111 at para. 4.

[7] The Federal Court identified reasonableness as the appropriate standard of review and Bayer does not take issue with that aspect of the FC Decision. Instead, Bayer argues that the identification of the standard of review is unimportant since there is only one plausible

interpretation of the provisions in issue of the Regulations, and so correctness and reasonableness lead to the same result, as discussed in *Galderma Canada Inc. v. Canada (Attorney General)*, 2024 FCA 208, 210 C.P.R. (4th) 181 at para. 17.

[8] Despite this argument by Bayer, this Court's task remains to consider whether the OSIP Decision met the requirements of reasonableness as discussed in *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, [2019] 4 S.C.R. 653 (*Vavilov*). I have concluded that it did, and that this appeal should be dismissed.

II. Bayer's Arguments

[9] Bayer argues that the OSIP's interpretation of the Regulations is both unreasonable and incorrect in that the date of filing of Amgen's NDS was determined to be the date that it was submitted to OSIP (without regard to the date it was later found to be compliant), whereas the date the 315 Patent was determined to be included on the Patent Register was the date it was found to be eligible for inclusion (and not the earlier date when Bayer filed its submission). Bayer notes that the Regulations do not contemplate any passage of time between the filing of a submission for an addition to the Patent Register and the actual addition to the Patent Register, and therefore the addition should be considered to have occurred on the day of the submission, regardless of when eligibility was confirmed. Bayer argues that any other interpretation disturbs the balance between the interests of innovators and biosimilars that the Regulations strive to achieve.

[10] Bayer notes that Amgen would not have been prejudiced by its proposed interpretation of the Regulations because it would have been able to amend its NDS to address any patent that was confirmed to have been added to the Patent Register after it filed its NDS.

[11] Bayer employs the metaphor of a race between the innovator (the first person) to add its patent to the Patent Register and the biosimilar (the second person) to file its NDS before the first person's patent is listed on the Patent Register. Bayer argues that, either the date of submission should apply to both, or the date of the OSIP's determination (of eligibility or compliance, as the case may be) should apply to both the first and second persons. In either case, Bayer argues, it won the race and should prevail in this case. It argues that it was unbalanced and unreasonable to apply the earlier date to Amgen's NDS but not to Bayer's patent list submission.

[12] Bayer also notes that a second person has access to public information about the impending issuance of a patent that might be added to the Patent Register, whereas a first person has no access to information concerning the filing of an NDS by a second person until after the NDS has been filed and found to be administratively complete. Bayer cites this as another example of imbalance in the Regulations resulting from the OSIP's interpretation.

[13] Finally, Bayer takes issue with the OSIP's and the Federal Court's reliance on *Eli Lilly Canada Inc. v. Canada (Attorney General)*, 2009 FC 474, [2009] F.C.J. No. 587 (*Eli Lilly*). In *Eli Lilly*, the Federal Court confirmed the Minister's conclusion that a patent was added to the Patent Register as of the date it was found to be eligible to be listed, and not the date of the submission of the patent list. The facts in *Eli Lilly* differed somewhat from the facts in the

present appeal in that the patent in *Eli Lilly* was initially found to be ineligible for listing. That conclusion by the Minister was later reversed after additional information was provided by Eli Lilly. Eli Lilly then asked that the patent in issue be considered to have been listed as of the date of the submission of the patent list. The refusal of that request by the Minister was later upheld by the Federal Court on the basis that there is a distinction between submitting a patent to be added to the Patent Register, and the actual addition of the patent to the Patent Register. The Federal Court recognized that its interpretation of the Regulations resulted in a risk of a time difference between the two events that could work to the innovator's (the first person's) disadvantage, but that this was a legislative choice that was inherent in the Regulations.

[14] Bayer argues that *Eli Lilly* is not binding on this Court, and that it is distinguishable and unpersuasive. Bayer notes that, contrary to the present case, no intervening NDS was filed by a second person during the pendency of the request to add the patent to the Patent Register in *Eli Lilly*. Bayer also notes that *Eli Lilly* includes no discussion of the reliability of a patent list submitted by a first person as a result of the requirement of paragraph 4(4)(f) of the Regulations for the first person to certify that the patent list is eligible for listing. Bayer further notes that subsection 3(2.3) of the Regulations, which empowers the Minister to review the listing of any patents in the Patent Register, was not yet in force when *Eli Lilly* was decided. Therefore, the Minister now has a tool that was not available when *Eli Lilly* was decided, which allows the Minister to remove a patent from the Patent Register that should not have been added.

III. Analysis

[15] The main problem with most of Bayer's arguments is that they effectively ask this Court to engage in its own interpretation of the Regulations instead of focusing on the OSIP's interpretation. This is contrary to the guidance of paragraphs 83 and 84 of *Vavilov*. I will focus on the reasoning in the OSIP Decision.

[16] I note first that the OSIP Decision comprises some 27 pages of tightly spaced text. It contains a detailed summary of the facts, as well as a description of the framework of the Regulations and an interpretive analysis of the provisions thereof that are relevant to this appeal. I note also that the OSIP reached its decision after considering submissions from the parties on a preliminary decision, which itself was prepared after considering submissions from the parties.

[17] Bayer's arguments do not assert that the OSIP Decision failed to consider its submissions. Rather, Bayer's arguments essentially express disagreement with OSIP's conclusions.

[18] From pages 9 to 16, the OSIP Decision presents a detailed analysis of the text, context and purpose of sections 3, 4 and 5 of the Regulations, and concludes that a patent list, if determined to be eligible, is added to the Patent Register as of the date of the eligibility decision, and not before. Having read this analysis, I find it eminently reasonable.

[19] The OSIP described the duty of the Minister pursuant to subsection 3(2) of the Regulations to ensure that only patents that are eligible for listing pursuant to section 4 are added to the Patent Register. The OSIP also described the detailed eligibility requirements of section 4.

[20] The OSIP concluded that the Regulations do not direct it to add a patent to the Patent Register on the date the patent list is submitted to the OSIP, or require it to assess eligibility immediately upon submission. The OSIP also noted that nothing in the Regulations directs retroactive effect of a patent eligibility decision. In my view, this discussion reasonably answered Bayer's argument that the Regulations do not contemplate any passage of time between filing a patent list and adding a patent to the Patent Register. Moreover, two other patent lists that Bayer submitted to the OSIP on August 22, 2023 in relation to EYLEA were found to be ineligible. This serves to emphasize the need for the OSIP to review eligibility prior to adding a patent to the Patent Register, which review cannot be instantaneous.

[21] In addition, I find the OSIP's analysis of the text of subsections 5(1) and 5(2.1) of the Regulations particularly illuminating. Subsection 5(1) provides:

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 the submission the required statements or allegations set out in subsection (2.1).	**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 renvoi —, cette seconde personne inclut dans sa présentation les déclarations ou

	allégations visées au paragraphe (2.1).

[22] Though subsection 5(1) refers to a patent list that has been submitted, the requirements for the second person filing an NDS are stated to be those set out in subsection 5(2.1), and these are limited to patents that are "included on the register":

5(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…	**5(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 […]

[23] Moreover, subsection 5(4) explicitly excludes from the requirements for the second person any patents that are added to the Patent Register on or after the date of filing of its NDS. This is often referred to as the "frozen register".

[24] Though the OSIP's interpretation of the Regulations clearly disadvantages Bayer in this case because Amgen filed its NDS in the period during which Bayer's patent list was being considered, and hence Amgen was not required to address the 315 Patent, the OSIP was well aware of this issue and considered it as part of its analysis. Though Bayer is disappointed in the result, I see no flaw in the OSIP's analysis. I am not convinced by Bayer's argument that the only plausible interpretation of the provisions in issue of the Regulations is that a patent is added

to the Patent Register on the date of submission of the patent list. I do not accept that Bayer's metaphor of a race between the first person and the second person is apt.

[25] In discussing the context of the Regulations, the OSIP Decision cited the Regulatory Impact Analysis Statement (RIAS) that accompanied the 2006 amendments to the Regulations, *Regulatory Impact Analysis Statement*, Canada Gazette, Part II, Vol. 140, No. 21, S.O.R./2006-242, as well as Health Canada's Guidance Document for the Regulations. The OSIP quoted passages from both of these documents that lead to the conclusion that a patent is considered added to the Patent Register only once its eligibility has been confirmed, and that a second person's NDS need not address any patents that are added to the Patent Register after the NDS has been filed.

[26] In discussion of the purpose of the Regulations, at page 16 of its reasons, the OSIP stated as follows:

> …section 5 would not operate as intended and the balance underlying the [Regulations] would be skewed if a subsequent entry drug manufacturer would be required to address a patent on a patent list added to the Patent Register prior to determining patent eligibility or retroactively after determining patent eligibility, and as of the date the patent list is submitted by a first person in respect of a corresponding reference product.
>
> A subsequent entry drug manufacturer only knows that a patent on a patent list has been submitted by a first person for inclusion on the Patent Register once that patent is added to the Patent Register. The Patent Register does not include, in accordance with subsection 3(2) of the [Regulations], patent lists submitted by first persons, but not yet assessed for eligibility against the requirements in sections 3 and 4 of the [Regulations]. The Patent Register serves a notice function for a subsequent entry drug manufacturer at the time of filing of its drug submission and is required for the proper functioning of the scheme. A subsequent entry drug manufacturer cannot predict with certainty what steps the first person and the OSIP will take regarding a patent on a patent list, and therefore, the scheme necessarily contemplates the possibility of a subsequent entry drug submission being filed while the eligibility of a patent on a patent list

> in respect of the reference product is still under consideration. Furthermore, the scheme, specifically the "frozen" Patent Register, contemplates that there may be a patent on a patent list that is later added to the Patent Register and potentially infringed by a subsequent entry drug manufacturer who receives an NOC and markets its version of the reference product. However, the policy choice made by the Governor in Council was that such a patent on a patent list should not preclude the issuance of the NOC to the subsequent entry drug manufacturer for its version of the reference product as there is recourse for the first person under the *Patent Act*.

[27] In my view, this discussion is reasonable.

[28] The OSIP Decision also discussed *Eli Lilly*, quoting extensively from, and adopting, its analysis of the effective date of an addition to the Patent Register. The OSIP was aware of amendments to the Regulations after *Eli Lilly* but concluded that its teachings remained instructive. I see no error in this reasoning.

[29] On judicial review, the Federal Court rejected Bayer's arguments that the OSIP Decision was unreasonable. The Federal Court Decision also cited the OSIP's discussions of the RIAS accompanying the 2006 amendments to the Regulations, the Guidance Document and *Eli Lilly*, and found them to be reasonable. Again, I find no error in this conclusion.

IV. Conclusion

[30] For the foregoing reasons, I would dismiss the present appeal. Based on the agreement of the parties, I would award costs to the respondents in the all-inclusive amount of $4,500 each.

"George R. Locke"
J.A.

"I agree.
René LeBlanc J.A."

"I agree.
Nathalie Goyette J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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