

CANADA / JUDGMENT

Bayer Inc. v. Amgen Canada Inc.

2024 FC 1849

COURT

Federal Court

DECIDED

4 December 2024

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Bayer Inc. v. Amgen Canada Inc.

Court (s) Database

Federal Court Decisions

Date

2024-12-04

Neutral citation

2024 FC 1849

File numbers

T-2137-23

Decision Content

Date: 20241204

Docket: T-2137-23

Citation: 2024 FC 1849

Toronto, Ontario, December 4, 2024

PRESENT: The Honourable Madam Justice Aylen

BETWEEN:

BAYER INC. and REGENERON PHARMCEUTICALS, INC.

Plaintiffs/ Defendants by Counterclaim

and

AMGEN CANADA INC.

Defendant/ Plaintiff by Counterclaim

PUBLIC ORDER AND REASONS

(Identical to the Confidential Order and Reasons issued on November 20, 2024)

- [1] The underlying proceeding is a patent infringement action brought under subsection 6(1) of the Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 [PMNOC Regulations] and a related counterclaim. The patents at issue are Canadian Patents No. 2,654,510 [510 Patent] and No. 3,007,276 [276 Patent]. The innovative drug relating to the action is EYLEA®, which is used to treat various eye-related disorders including neovascular (wet) age-related macular degeneration [AMD]. The active ingredient in EYLEA® is a biologic fusion protein called aflibercept.
- [2] Bayer Inc. [Bayer] is the “first person” in accordance with the PMNOC Regulations. Regeneron Pharmaceuticals, Inc. [Regeneron] is the registered owner of the 510 and 276 Patents and is a party to the action pursuant to subsection 6(2) of the PMNOC Regulations. The Plaintiffs claim that the making, constructing, using or selling by the Defendant, Amgen Canada Inc. [Amgen], of its biosimilar aflibercept product (known as ABP 938) in accordance with Amgen’s new drug submission will infringe various claims of the 510 and 276 Patents.
- [3] The commencement of the underlying action triggered an automatic 24-month stay preventing the regulatory approval of Amgen’s ABP 938, as the 510 and 276 Patents were listed on the Patent Register on the filing date of Amgen’s new drug submission.
- [4] Amgen denies infringement and asserts that both patents are invalid on a number of bases. In relation to the 276 Patent, Amgen asserts that the patent with respect to EYLEA® was and is not eligible for inclusion on the Patent Register pursuant to paragraph 4(3)(c) of the PMNOC Regulations, as the 276 Patent fails to meet the product specificity requirements for listing.
- [5] Now before the Court is a motion brought by Amgen, pursuant to subsection 6.07(1) of the PMNOC Regulations, for a declaration that the 276 Patent is ineligible for inclusion on the Patent Register and a declaration that the 24-month statutory stay be lifted in relation to the 276 Patent. Amgen asserts that the 276 Patent does not contain a claim for the very change of use approved through the issuance of a Notice of Compliance [NOC] with respect to the Plaintiffs’ Supplementary New Drug Submission [SNDS] 204121.
- [6] For the reasons that follow, I am satisfied that Amgen has demonstrated that the 276 Patent is ineligible for inclusion on the Patent Register. Accordingly, the motion shall be granted, with costs.

I. Background A. Wet AMD

- [7] Wet AMD is a medical condition affecting the macula (a tiny area of the retina at the back of the eye that is responsible for central vision) and can result in loss of central field vision. Wet AMD is characterized by the presence of abnormal blood vessels under the retina which leak blood or fluid in the area of the macula. As there is presently no cure for wet AMD, patients require ongoing treatment.
- [8] A protein called vascular endothelial growth factor [VEGF], which plays a critical role in the formation of new blood vessels, has been associated with the leaking of blood vessels in wet AMD. VEGF inhibitors, such as ranibizumab and aflibercept, have been developed to treat wet AMD by reducing VEGF-associated blood vessel leakage. Treatment with a VEGF inhibitor aims to “dry” the eye (remove intraretinal fluid buildup) and avoid the damage and vision loss caused by fluid.

B. EYLEA® and SNDS 204121

- [9] EYLEA® was approved by Health Canada in 2013, to treat wet AMD together with other ocular diseases.
- [10] In March 2017, Bayer filed SNDS 204121 for EYLEA®, which gave rise to the issuance of an NOC and accompanying changes to the Product Monograph approved on March 9, 2018 [2018 Product Monograph]. At that time, the Product Monograph had last been approved on December 10, 2015 [2015 Product Monograph].
- [11] In December 2019, Bayer submitted a request to Health Canada, by way of a Form IV, that the 276 Patent be added to the Patent Register in association with SNDS 204121. Bayer asserted that the 276 Patent claimed a “change in use” that was approved by SNDS 204121. Health Canada approved the request.
- [12] The approval resulted in changes to the Product Monograph. The key change at issue on this motion is related to the recommended dosing of EYLEA®. The chart below sets out side-by-side the “Recommended Dose and Dosage Adjustment – Treatment of Wet AMD” section of Product Monograph as it appeared in the 2015 Product Monograph and the 2018 Product Monograph:

2015 Product Monograph

2018 Product Monograph

Recommended Dose and Dosage Adjustment — Treatment of wet AMD

The recommended dose for EYLEA is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every month (4 weeks) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection every 2 months (8 weeks).

The recommended dose for EYLEA is 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every month (4 weeks) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection every 2 months (8 weeks).

After the first 12 months of treatment with EYLEA, the treatment interval could be extended up to every 3 months (12 weeks) based on visual and/or anatomic outcomes. Patients should be evaluated regularly.

In AMD clinical trials, EYLEA dosed every 4 weeks or every 8 weeks was shown to be non-inferior to ranibizumab. However, no additional efficacy was demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks (see PART II: SCIENTIFIC INFORMATION – CLINICAL TRIALS – Treatment of Wet AMD: Study Results). At the discretion of the treating ophthalmologist and based on the monitoring of visual and anatomic outcomes, dosing every month (4 weeks) after the first 3 months (12 weeks) may be considered on the individual patient basis.

In AMD clinical trials, additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks (see PART II: SCIENTIFIC INFORMATION – CLINICAL TRIALS – Treatment of Wet AMD: Study Results).

After the first 12 months of treatment with EYLEA, the treatment interval could be extended up to every 3 months (12 weeks) based on visual and/or anatomic outcomes. Patients should be evaluated regularly.

[13] As the comparison demonstrates, the 2018 Product Monograph added a new recommended dose option in the first year of treatment as follows:

At the discretion of the treating ophthalmologist and based on the monitoring of visual and anatomic outcomes, dosing every month (4 weeks) after the first 3 months (12 weeks) may be considered on an individual patient basis.

[14] Additional changes were made to the clinical trial data to add efficacy outcomes for patients on a monthly dosing schedule throughout the first year, and to the “Proper Use of This Medication” section of the Patient Insert to add that patients could be “prescribed an EYLEA injection every month (4 weeks) after the first 3 months.”

C. The 276 Patent

[15] The 276 Patent, entitled “Use of VEGF Inhibitor to Treat Macular Degeneration in a Patient Population”, was filed by Regeneron on December 1, 2016, and issued by the Canadian Patent Office on December 28, 2021.

- [16] The 276 Patent contains 59 claims generally related to using a VEGF inhibitor to treat a patient with wet AMD, based on the patient being identified as having at least one single nucleotide polymorphism [SNP] selected from the group consisting of rs2056688, rs5962084, rs5962087, rs5915722, rs5962095 and/or rs1405303. An SNP is a substitution of a single nucleotide at a specific location on a patient's genome, which generally relates to a patient's genetic profile.
- [17] The 276 Patent describes a genome-wide association study [GWAS] conducted on 362 wet AMD patients enrolled in the VIEW 1 study, a multicentre Phase III clinical trial of wet AMD which evaluated the efficacy and safety of intravitreal aflibercept injections compared with ranibizumab and which was relied upon by Bayer for the initial approval of EYLEA® by Health Canada. The purpose of the GWAS was to identify genetic variants associated with anti-VEGF response as measured by visual acuity, anatomic outcomes and treatment frequency in the VIEW 1 study. The 276 Patent describes that the GWAS identified a suggestive association between a genetic variant (the claimed SNPs) and the presence of intraretinal fluid at 52 weeks as measured by time domain optical coherence tomography.
- [18] It is common ground between the parties that the eligibility for listing of the 276 Patent against EYLEA® must be established on the basis of Claim 58 of the 276 Patent, as it depends on Claim 49, as it depends on Claim 47, as it depends on Claim 46. The relevant claims read as follows:
46. A vascular endothelial growth factor (VEGF) inhibitor for treatment of macular degeneration in a subject, wherein the VEGF inhibitor is formulated for intravitreal administration to the subject in an amount of about 2 mg quarterly, and wherein the subject has at least one of the following single nucleotide polymorphisms: rs2056688, rs5962084, rs5962087, rs5915722, rs5962095, and rs1405303.
47. The VEGF inhibitor of claim 46, wherein the macular degeneration is wet macular degeneration.
- [...]
49. The VEGF inhibitor of claim 46 or 47, which is aflibercept.
- [...]
58. The VEGF inhibitor according to claim 49, where the subject was previously treated with a 2 mg dose of aflibercept every 4 weeks for about one year.

II. Legislative Framework and Applicable Legal Principles

- [19] A “first person” who files a new drug submission [NDS] or SNDS may, pursuant to subsection 4(1) of the PMNOC Regulations, submit to the Minister a patent for listing on the Patent Register with respect to the drug for which approval is sought. A patent will only be added to the Patent Register if the Minister is satisfied that the relevant regulatory criteria are met, both in terms of timing and product specificity. In this case, there is no issue regarding timing.
- [20] In the case of an SNDS related to a change in use of the medicinal ingredient, paragraph 4(3) (c) sets out the product specificity requirements that must be met for a patent to be listed on the Patent Register:
- (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
- (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 l’utilisation de l’ingrédient médicinal, s’il contient, selon le cas :
- [...]
- [...]
- (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.
- 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.
- [21] Subsection 6.07(1) of the PMNOC Regulations empowers a second person to bring a motion before this Court for a declaration that a patent is ineligible for inclusion on the Patent Register. While the Minister is given a right to intervene on any such motion pursuant to subsection 6.07(2), the Minister has chosen not to do so in this case.
- [22] Unlike a review of a Minister’s decision to delist or refuse to list a patent, a motion under subsection 6.07(1) is not analogous to a judicial review application. The fact that the Minister determined the 276 Patent as eligible for listing is not relevant. It is up to the Court to decide, based on the evidence before it, whether the 276 Patent is eligible for listing [see *Ratiopharm inc v Wyeth, Wyeth Canada*, 2007 FCA 264 at para 54 [Wyeth]].

- [23] On this motion, the burden of proof lies with Amgen and the factual elements must be decided on the basis of the normal standard of proof in civil matters, the balance of probabilities [see Wyeth, supra at para 56].
- [24] In considering whether a patent listed in relation to a particular SNDS meets the product specificity requirement of paragraph 4(3)(c) of the PMNOC Regulations, the Court must apply what is known as the Abbott test, as originally set out by Justice Hughes in Abbott Laboratories Limited v Canada (Attorney General), 2008 FC 700 and later affirmed in Abbott Laboratories Limited v Canada (Attorney General), 2008 FCA 354 and applied by the Federal Court of Appeal in a number of other cases, such as GD Searle & Co v Canada (Health), 2009 FCA 35 [Searle], Purdue Pharma v Canada (Attorney General), 2011 FCA 132 [Purdue], Gilead Sciences Canada Inc v Canada (Health), 2012 FCA 254 [Gilead] and Eli Lilly Canada Inc v Canada (Attorney General), 2015 FCA 166.
- [25] Pursuant to the Abbott test, the Court must consider the following three issues: (i) what use is claimed in the patent; (ii) what is the change in use approved by the NOC issued in response to the SNDS; and (iii) does the patent claim the very change in use approved by the NOC issued in response to the SNDS [see Abbott, supra at para 57].

III. Evidence [26] In support of its motion, Amgen relies on an expert report from Dr. Derek Godinho, a retinal specialist and ophthalmologist, and the affidavit of Giovanna Araus, a law clerk employed by counsel for Amgen.

- [27] In response to the motion, the Plaintiffs rely on an expert report from Dr. David Wong, a vitreoretinal surgeon and ophthalmologist, an expert report from Dr. Diether Lambrechts, a genetic researcher, and an affidavit from Nan Lin, a senior manager in pharmacogenomics at Regeneron.
- [28] All of the experts were cross-examined and the Court was provided with transcripts of their cross-examinations.
- [29] In their submissions, the Plaintiffs levelled a number of criticisms at Dr. Godinho, including that: (a) aspects of the 276 Patent were beyond his expertise given their pertinence to genetics; (b) he expressed irrelevant opinions and concerns about the validity of the 276 Patent despite not being asked to consider or instructed on how to address issues related to validity; and (c) he performed an undisclosed prior art search and construed the 276 Patent in light of a published abstract that he found and failed to disclose. However, as will be detailed more fully below, there was no meaningful disagreement between the experts as to the construction of the 276 Patent or the change in use approved by the NOC issued in response to SNDS 204121. Moreover, my determination in relation to the third step of the Abbott test did not turn on Dr. Godinho's evidence. As such, I need not address the validity of these criticisms.

IV. Issues for Determination

[30] The issues for determination on this motion are:

What use is claimed by Claim 58 (as it depends on earlier claims) of the 276 Patent?

What change in use was approved by the NOC issued in response to SNDS 204121?

Does Claim 58 of the 276 Patent claim the very change in use approved by the NOC in response to SNDS 204121?

A. What use is claimed by Claim 58 (as it depends on earlier claims) of the 276 Patent?

[31] This question is concerned solely with the construction of the 276 Patent and its relevant claims, which requires that the patent be construed in accordance with the principles set out in *Whirlpool Corp v Camco Inc*, 2000 SCC 67 [see *Purdue*, supra at para 17].

[32] The first step involves defining the Skilled Person to whom the patent is said to be addressed. The parties agree that the 276 Patent is directed to a skilled team comprising of: (a) a skilled geneticist; and (b) a skilled physician (ophthalmologist and/or retina specialist) specifically trained and experienced in treating wet AMD patients with VEGF inhibitors like EYLEA®.

[33] The second step is defining the Common General Knowledge [CGK] of the Skilled Person, which is the knowledge generally known by the Skilled Person at the relevant time in the field of art or science to which the patent relates [see *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at para 37]. It includes what the Skilled Person may reasonably be expected to know and to be able to find out [see *Novopharm Limited v Janssen-Ortho Inc*, 2007 FCA 217 at para 25(3)].

[34] There was no material dispute between the parties as to the CGK of the Skilled Person which was expressed by Dr. Wong and Dr. Godinho in their respective reports and on cross-examination. Of note, the experts agree that a patient's visual and anatomic conditions are assessed using various tests and/or methods before starting treatment with a VEGF inhibitor, and then on a continuing basis as the treatment progresses. A treating physician assesses a patient's response to treatment by considering visual outcomes (improvement in vision, i.e., a gain in letters) and anatomic outcomes (decrease in fluid in the retina and decrease in abnormal blood vessels leaking fluid). The experts further agree that a patient's genetics are not visual or anatomic outcomes and treating physicians do not base their treatment decisions based on a patient's genetics.

[35] I now turn to the construction of Claim 58, as it depends on earlier claims. The applicable principles of claim construction were summarized by the Federal Court of Appeal in *Tearlab Corporation v I-MED Pharma Inc.*, 2019 FCA 179 at paras 30–34.

- [36] The experts agree that the 276 Patent teaches that the six SNP variations were found to be negatively associated with the presence of intravitreal fluid at week 52 after treatment with a VEGF inhibitor, where they had been treated on a monthly or bi-monthly dosing schedule, and that patients with any of the claimed SNPs are more amenable to longer dosing intervals. The experts further agree that patient treatment can be maintained on a quarterly dosing schedule after about a year of previous, more aggressive treatments.
- [37] As stated by Dr. Wong, “the 276 Patent provides skilled physicians with a reasonable, science-based rationale for modifying the dosing interval based on a wet AMD patient’s genetics including at least one of the claimed SNPs.”
- [38] Turning to the construction of Claim 58 (as it depends on earlier claims), Amgen confirmed at the hearing of the motion that it agrees with the Plaintiffs’ construction, namely that Claim 58 is:
- ...specific to the use of 2 mg aflibercept injections in wet AMD patients who have any of the claimed SNPs on a less frequent quarterly dosing schedule after having been dosed on a more frequently monthly dosing schedule throughout their first year of treatment.
- [39] Despite some initial controversy, the parties also agree (as do the experts) that the use claimed by Claim 58 requires knowledge of the patient’s SNP status. As noted by the Plaintiffs, with this knowledge, “a physician can take advantage of the teachings of the 276 Patent and make use of the claimed invention.”
- [40] Dr. Wong and Dr. Godinho were also generally in agreement that the extension to quarterly dosing after the first year of monthly dosing cannot be based on the assessment of visual and/or anatomic outcomes independent of patient genetics. Put differently, the experts agreed that Claim 58 requires that the patient’s SNP status factor into the physician’s assessment of the visual and/or anatomic outcomes.
- [41] I see no basis to interfere with the agreement of the parties and their experts regarding the use claimed by Claim 58. Accordingly, I find that the use claimed by Claim 58 is the use of 2 mg aflibercept injections in wet AMD patients who have any of the claimed SNPs (their SNP status being known by the patient’s treating physician and factored into the physician’s assessment of the patient’s visual and/or anatomical outcomes) on a less frequent quarterly dosing schedule after having been dosed on a more frequent monthly dosing schedule throughout their first year of treatment.

B. What change in use was approved by the NOC issued in response to SNDS 204121?

- [42] There is no dispute between the parties and their experts that there was a change in use approved by the NOC issued in response to SNDS 204121. The change in use is that which is set out in the 2018 Product Monograph issued at the same time as the new NOC and, in particular, the new language added to the “Recommended Dose and Dosage Adjustment – Treatment of Wet AMD” section of the Updated Product Monograph. Specifically:

At the discretion of the treating ophthalmologist and based on the monitoring of visual and anatomic outcomes, dosing every month (4 weeks) after the first 3 months (12 weeks) may be considered on an individual patient basis.

[43] Prior to March 2018, the only approved use of EYLEA® for the treatment of wet AMD during the first year was 2 mg (0.05 mL or 50 microliters) administered by intravitreal injection every month (4 weeks) for the first three months, followed by 2 mg (0.05 mL) via intravitreal injection every two months (8 weeks). With the 2018 Product Monograph, treating physicians were given a second option during the first year, to be used at their discretion and based on the monitoring of visual and anatomic outcomes, to dose EYLEA® every month (4 weeks) after the first three months (12 weeks). As such, during the first year of treatment, treating physicians had two treatment options after the delivery of the loading doses during the first three months: (i) injections every four weeks for the balance of the year; and (ii) injections every eight weeks for the balance of the year.

[44] With respect to treatment after the first year, the language in the Product Monograph did not change following the issuance of the NOC in response to SNDS 204121. It continued to read:

After the first 12 months of treatment with EYLEA, the treatment interval could be extended up to every 3 months (12 weeks) based on visual and/or anatomic outcomes. Patients should be evaluated regularly.

[45] At the hearing of the motion, the Plaintiffs asserted that a proper characterization of the change in use is not limited to the dosing options available in the first year of treatment. Rather, that the change in use was a new long-term treatment option, as treatment in year one is linked to treatment in year two and beyond. Under the Plaintiffs' assertion, for example, a physician could now treat a patient with monthly injections for all of year one and continue with monthly injections thereafter. As this was not something that could be done before, a treating physician now has more options with how to treat a patient in year two and beyond.

[46] I agree with the Plaintiffs that treatment options for year two and beyond changed as a result of the new language in the 2018 Product Monograph. Under the 2015 Product Monograph, a treating physician had the following options for year two onwards: (i) injections every two months (the original year one option); or (ii) extending the injection interval from two months up to three months. Under the 2018 Product Monograph, a treating physician now has the following options for year two onwards: (i) injections every month for those patients who received monthly injections for all of year one; (ii) extending the injection interval for those patients who received monthly injections for all of year one from one month up to three months; and (iii) extending the injection interval from two months up to three months for those patients who received injections in year one every two months after their loading dose (as was the case under the 2015 Product Monograph).

[47] While Amgen also acknowledged at the hearing that the aforementioned treatment options for year two and beyond became approved as a result of the new language in the 2018 Product Monograph, Amgen asserts that this does not constitute “the” change in use for the purpose of this motion. Rather, the change in use is the ability to treat patients with monthly injections in year one, following the loading doses, based on a patient’s visual and anatomic outcomes. This change in use, according to Amgen, is specific to the first year of treatment only.

[48] In considering the Plaintiffs’ submission, I note that a multi-year treatment strategy with more options for year two and beyond was not the change in use articulated by Dr. Wong in his expert report. For example, at paragraph 18 of his report where he summarizes his opinions, he stated:

18. Change in use: The EYLEA® product monograph approved in March 2018 included a change to the use of the drug. Specifically, permitting it to be dosed on a monthly (q4) basis throughout the first year of treatment. Previously, using the drug on a q4 basis was limited to the first three loading doses. After that, the labelling required the drug to be used with bi-monthly (q8) dosing for the remainder of the first year of treatment. After the first year of treatment, both before and after the March 2018 change to the monograph, quarterly (q12) dosing is permitted. The EYLEA® product monograph approved in March 2018 embraces the use of EYLEA® to treat all wet AMD patients, including patients having any of the six SNPs claimed in the 276 Patent, on various dosing schedules, including continued monthly dosing in the first year of treatment followed by quarterly dosing.

[Emphasis in original.]

[49] In paragraph 18 of his report (as well as paragraphs 70-79 thereof which provide his detailed analysis of this issue), Dr. Wong makes no reference to the change in use being a long-term treatment option that links year one with the years thereafter. Rather, he describes the change in use as being specific to the first year of treatment.

[50] I also note that a multi-year treatment strategy, with more options for year two and beyond, was also not the change in use as summarized by the Plaintiffs in their written representations, where they stated:

40. Accordingly, the March 2018 monograph first approved monthly dosing for the first year of treatment followed by extension to quarterly dosing thereafter where the physician’s assessment of the visual and/or anatomic outcomes of the first year’s treatment accounted for whether the patient had one or more of the claimed SNPs.

- [51] For the purpose of this motion, I accept that the relevant change in use is that as articulated by Dr. Wong above and as submitted by the Plaintiffs in their written materials. I recognize that the change to the 2018 Product Monograph leaves open the possibility of new treatment options for year two onward that were not available under the 2015 Product Monograph, but, for the reasons set out below, such additional changes in use are, in any event, not material to my determination of this motion.
- [52] The parties agree that the change in use reflected in the 2018 Product Monograph applies to all wet AMD patients and is not limited to those with the claimed SNPs. Just as with the 2015 Product Monograph, the 2018 Product Monograph provides no guidance to treating physicians as to how monitor or assess visual and/or anatomic outcomes. The experts agreed that they would not expect the Product Monograph to provide direction on how to assess visual and/or anatomic outcomes as these assessments are part of a treating physician's clinical expertise. Neither the 2015 Product Monograph nor the 2018 Product Monograph make any reference to a consideration of a patient's genetics; and both experts agree that there is nothing in either Product Monograph that would preclude a treating physician from considering a patient's genetics (including if the patient had any of the claimed SNPs).
- [53] Accordingly, I find that the change in use approved by the NOC issued in response to SNDS 204121 was to provide treating physicians with a second treatment option during year one — namely, the use of EYLEA® for any patient (with or without the claimed SNPs) every month (4 weeks) after the first three months (12 weeks) during the first year of treatment, at the treating physician's discretion and based on the monitoring of visual and anatomic outcomes.

C. Does Claim 58 of the 276 Patent claim the very change in use approved by the NOC in response to SNDS 204121?

- [54] It is at this stage of the Abbott test that the parties' positions greatly diverge. Generally speaking, the divergence between the parties relates to the degree of "matching" that is required. The Plaintiffs assert that it is sufficient if the changes in use as reflected in the 2018 Product Monograph are broad (multiple treatment regimens for the entire patient population, one of which is monthly injections in the first year followed by an extension to quarterly injections in year two and beyond), and the use claimed in Claim 58 (albeit for only a patient subpopulation) falls within those changes in use. Specifically, the Plaintiffs assert that as long as the use claimed by Claim 58 is specific to one of the uses approved in the 2018 Product Monograph, the fact that the NOC in response to SNDS 204121 approved other uses that are not specifically claimed by Claim 58 does not make the 276 Patent ineligible for listing.
- [55] Amgen disagrees and states that paragraph 4(3)(c) of the PMNOC Regulations requires a more exacting level of "matching" between the claimed use in Claim 58 and the change in use reflected in the 2018 Product Monograph. Amgen asserts that there is a fatal mismatch

between Claim 58 and the 2018 Product Monograph. Specifically, Amgen asserts that Claim 58 is focussed on how to treat a patient in year two, whereas the change in use in the 2018 Product Monograph relates to a new way to dose patients in year one. Further, Amgen asserts that Claim 58 identifies the conditions of a patient that is to be treated by less frequent quarterly dosing in year two (such conditions being having one of the claimed SNPs and having previously been treated every four weeks for year one) whereas the change in use in the 2018 Product Monograph has nothing to do with: (a) less frequent dosing; (b) less frequent dosing based on genetic traits; and (c) the claimed SNPs or any reference to a patient's genetics.

[56] I will begin by considering the question of the degree of “matching” required under paragraph 4(3)(c) of the PMNOC Regulations. There have been few cases that have addressed this third step of the Abbott test in the context of paragraph 4(3)(c) or otherwise.

[57] In *Canada (Attorney General) v Abbott Laboratories Ltd*, 2008 FCA 244 [Abbott 244], Justice Pelletier commented on the level of specificity required under paragraph 4(3)(c). The debate in that case concerned the eligibility for listing of a patent in relation to an NOC issued pursuant to an SNDS approving a new use. The Federal Court had concluded that the patent was eligible for listing because it could be construed as including the new approved use notwithstanding that it was not explicitly claimed in the patent. The Federal Court of Appeal disagreed, stating:

[47] It stands to reason that if a patent must contain a claim for the changed use identified in Abbott's SNDS, that patent cannot simply claim the use which formed the basis of the original submission. Such a patent does not specifically claim the changed use, even though the changed use may come within the claims of the patent. In other words, the Regulations envisage as a condition of listing a patent in respect of a change in the use of a medicinal ingredient that the patent specifically claims the changed use as opposed to non-specific claims which are wide enough to include the changed use.

[...]

[49] [...] I conclude that paragraph 4(3)(c) of the Regulations requires, as a condition of listing a patent on the Patent Register, that the patent must specifically claim the very change in use which was approved by the issuance of a Notice of Compliance with respect to an SNDS.

[Emphasis added. Italics in original.]

[58] In a way, the factual circumstances in Abbott 244 were the opposite of those before the Court. In Abbott 244, the use claimed by the patent was broad (so broad that it included the original approved use) and the change in use as set out in the related Product Monograph was narrow. Here, the use claimed by Claim 58 is narrow (and no one is asserting that it is covered by the original approved use for EYLEA®) and the change in use set out in the 2018 Product Monograph is broad.

- [59] In *Searle*, *supra*, the Minister of Health removed a patent from the Patent Register on the basis that it was ineligible for listing. This Court found no error on the part of the Minister in delisting the patent and the Federal Court of Appeal was seized with an appeal of that decision. In that case, the relevant claim of the patent was for the use of Celebrex for treating pain if the nature of the pain is such that the use of a cox-2 inhibitor is indicated for its treatment. The new approved use of Celebrex was the short term (≤ 7 days) management of moderate to severe acute pain in adults, in conditions such as: musculoskeletal and/or soft-tissue trauma including sprains, post-operative orthopedic, and pain following dental extraction. On the third step of the Abbott test, the Federal Court of Appeal found that the relevant claim of the patent did not claim the very use approved by the issuance of the NOC in response to the SNDS because the use claimed in the claim (“for pain”) was “simply too general” and so broad as to cover most of the known uses of Celebrex, including those that had been approved by the initial NOC [see *Searle*, *supra* at para 45].
- [60] In *Purdue*, *supra*, the Federal Court of Appeal considered, for the first time, the application of paragraph 4(2)(c) and specifically whether a patent whose relevant claim for a dosage form contained only one medicinal ingredient was eligible for listing on the Patent Register when the approved dosage form consisted of two medicinal ingredients. In doing so, the Federal Court of Appeal held that guidance can be gleaned from cases considering paragraph 4(3)(c), and considered *Abbott 244*. The Federal Court of Appeal ultimately held that “[a]bsent precise and specific matching, the patent is not eligible for listing on the patent register” [see *Purdue*, *supra* at para 43].
- [61] In *Gilead*, *supra*, the Federal Court of Appeal considered whether, pursuant to paragraph 4(2)(b) of the PMNOC Regulations, a patent was eligible for listing with respect to an NDS where the medicinal ingredients claimed in the patent did not match up with those in the NDS. The Federal Court of Appeal held that:
- [40] The wording of the PM (NOC) Regulations, as well as their object and purpose, suggest that the product specificity requirement sets a high threshold of consistency. Thus, in the case at bar, “the” medicinal ingredients, i.e., tenofovir, emtricitabine, and rilpivirine, must be set out in the patent claims and the NOC for the patent to be eligible on the register.
- [Emphasis added.]
- [62] The Federal Court of Appeal went on to state that the “high threshold of consistency” was not limited to paragraph 4(2)(b), finding that “the wording of section 4 is consistent across the four subsections and requires a high degree of specificity between the wording of the claim and the NOC” [see *Gilead*, *supra* at para 45].
- [63] In referring to the *Purdue* and *Gilead* decisions, I am mindful that the PMNOC Regulations were amended in 2015 to specifically address, among other decisions, the Federal Court of Appeal’s decision in *Gilead* and “clarify ambiguities regarding the listing requirements, as they relate to patents containing a claim for the medicinal ingredient and combination drugs” [see the Regulatory Impact Analysis Statement [RIAS] as related to the Regulations

Amending the Patented Medicines (Notice of Compliance) Regulations, SOR/2015-169 at page 7]. The amendments clarified the eligibility rules for adding to the Patent Register a patent containing a claim for the medicinal ingredient, a claim for the formulation and a claim for the use of the medicinal ingredient in relation to an NDS, all by way of amendments that impacted subsection 4(2) of the PMNOC Regulations.

[64] However, I find that none of the 2015 amendments nor the commentary in the 2015 RIAS detract from the Federal Court of Appeal's finding that the PMNOC Regulations' product specificity requirement sets a high threshold of consistency. I find that these comments continue to reflect the manner in which this Court is to approach the application of paragraph 4(3)(c).

[65] That said, I agree with the Plaintiffs that the 2015 RIAS provides commentary that guides the Court's application of paragraph 4(3)(c). The 2015 amendments added subsection 4(2.1) to the PMNOC Regulations to provide clarity as to when a patent is eligible for listing on the Patent Register in relation to an NDS and, in particular, where the patent contains a claim for the use of the medicinal ingredient (paragraph 4(2)(d)). The relevant portion of subsection 4(2.1) provides:

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

(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) :

[...]

[...]

(c) 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) 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 :

[...]

[...]

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

(ii) la p présentation comprend d'autres utilisations,

[66] The 2015 RIAS provides the following commentary on these provisions, stating at page 9:

Amendments are also made with respect to patents containing a claim for the use of the medicinal ingredient, aligning the policy intent behind the listing eligibility rule for patents claiming a use of the medicinal ingredient with the rule that applies to patents containing a claim for the medicinal ingredient. Accordingly, a patent that contains a claim for the use of the medicinal ingredient is eligible to be added to the register if the submission includes the use claimed in the patent. The submission in respect of which the patent is sought to be listed may include additional medicinal ingredients, or additional uses of the medicinal ingredient.

[67] Importantly, the 2015 RIAS went on to state at page 14:

With respect to supplemental new drug submissions made under subsection 4(3) of the Regulations, a court may interpret the particular eligibility criteria under subsection 4(3) in a manner consistent with the rules in subsection 4(2.1). However, in keeping with well settled jurisprudence in respect of this subsection, the amendments are not intended to modify the existing requirement that an eligible claim must include the very change approved in the supplemental new drug submission.

[Emphasis added.]

[68] Therefore, I accept that the policy intent of the PMNOC Regulations, as expressed in the 2015 RIAS, supports the Plaintiffs' general proposition that it is sufficient, for the purpose of paragraph 4(3)(c), if the changes in use as reflected in the amended product monograph are broad and the use claimed in the patent falls within those changes in use. For example, one could imagine a situation where an NOC issued in response to an SNDS approves the change in use of a medicinal ingredient to treat four new medical conditions and the patent at issue claims the use of the medicinal ingredient to treat only one of those medical conditions.

[69] However, accepting the Plaintiffs' general proposition does not lead to the automatic conclusion that the 276 Patent must therefore be listable. The Court must still be satisfied that the use claimed in Claim 58 is one of the very changes in use approved by the NOC in response to SNDS 204121.

[70] Turning now to that question, it must be recalled that:

The use claimed by Claim 58 is the use of 2 mg aflibercept injections in wet AMD patients who have any of the claimed SNPs (their SNP status being known by the patient's physician and factored into the physician's assessment of the patient's visual and/or anatomical outcomes) on a less frequent quarterly dosing schedule after having been dosed on a more frequent monthly dosing schedule throughout their first year of treatment.

The change in use approved by the NOC in response to SNDS 204121 is the use of EYLEA® for any patient (with or without the claimed SNPs) every month (4 weeks) after the first three months (12 weeks) during the first year of treatment at the treating physician's discretion and based on the monitoring of visual and anatomic outcomes.

- [71] As noted above, Amgen has advanced a number of arguments as to why there is a fatal mismatch between the use claimed in Claim 58 and the very change in use approved by the NOC with respect to SNDS 204121. However, only one of Amgen's arguments has merit and is thus determinative of this motion — namely, that there is a fatal mismatch as the use claimed in Claim 58 requires knowledge and consideration of the patient's SNP status in making treatment decisions, whereas the change in use approved by the NOC in response to SNDS 204121 is divorced from any consideration of the patient's genetics.
- [72] I accept that Claim 58 claims the use of aflibercept on a monthly dosing schedule during the first year of treatment followed by a less frequent quarterly dosing schedule in subsequent years. Only to that extent does Claim 58 claim the very change in use as approved by the NOC in response to SNDS 204121. However, the use claimed in Claim 58 is not just a new dosing regime for all wet AMD patients. Rather, the focus of the 276 Patent is the use of a new dosing regime specific to patients with one of the claimed SNPs and, importantly, it is the patient's known genetics that inform the dosing regime chosen by their treating physician. In that regard, Dr. Wong stated at paragraph 56 of his report that, "...the 276 Patent provides skilled physicians with a reasonable, science-based rationale for modifying the dosing interval based on a wet AMD patient's genetics including at least one of the claims SNPs." [Emphasis added.]
- [73] However, the change in use in the 2018 Product Monograph permits the additional dosing regime for all patients, regardless of whether they have any of the claimed SNPs, and provides that the treating physician's treatment decision is guided by the patient's visual and/or anatomic outcomes, with no reference to a patient's genetics. This is not surprising, given that both Dr. Wong and Dr. Godinho agreed that treating physicians do not run genetic testing on patients. As such, they would not generally know if a patient has one of the claimed SNPs. While Dr. Lambrechts' evidence was that approximately 26–37% of the male wet AMD patient population and 46–61% of the female wet AMD patient population have one of the claimed SNPs, it would be pure happenstance that a treating physician would treat a patient using the new dosing regime who, unbeknownst to the treating physician, has one of the claimed SNPs. In that regard, Dr. Wong admitted on cross-examination that, when treating patients, he does not take into consideration whether a patient has any of the claimed SNPs.
- [74] It is this divorcing of the genetic component of the 276 Patent from the change in use approved by the NOC in response to SNDS 204121 that leads me to conclude that the use claimed in Claim 58 is not the "very change in use" at issue.
- [75] The Plaintiffs attempt to "weave" a consideration of the patient's genetics into the change in use approved by the NOC in response to SNDS 204121 by asserting that the 276 Patent teaches that SNP status is relevant to the absence of fluid in the eye (an anatomic outcome) after a year of more aggressive treatment and is also relevant to visual outcomes (as no fluid is relevant to vision loss) such that when a treating physician assesses a patient's visual and anatomic outcomes under the 2018 Product Monograph, they do so "in light of the patient's

SNP status.” This is a strained argument that I simply cannot accept and is, in any event, completely undermined by the fact that a treating physician would have no knowledge of a patient’s SNP status and thus can make no decisions “in light of” an unknown SNP status.

[76] Having found that the use claimed in Claim 58 of the 276 Patent is not the very change in use approved by the NOC in response to SNDS 204121, I find that the 276 Patent is ineligible for listing on the Patent Register. Accordingly, Amgen’s motion shall be granted.

V. Costs [77] In advance of the hearing of the motion, the parties reached an agreement on the issue of costs — namely, that the successful party/parties would be awarded their costs assessed at the mid-point of Column IV of Tariff B and payable in the cause. As Amgen was successful on the motion, it shall be awarded its costs in accordance with the parties’ agreement.

ORDER in T-2137-23

THIS COURT ORDERS AND DECLARES that:

The Defendant’s motion is granted.

Canadian Patent No. 3,007,276 [276 Patent] is ineligible for inclusion on the register of patents maintained by the Minister in accordance with subsection 3(2) and section 4 of the PMNOC Regulations with respect to EYLEA® 2 mg/0.05 mL solution, Drug Identification Numbers 02415992 (single vial) and 02505355 (pre-filled syringe).

Paragraph 7(1)(d) of the PMNOC Regulations does not apply to the Defendant’s New Drug Submission 276955 with respect to the 276 Patent.

The Plaintiffs shall pay to the Defendant its costs of this motion assessed at the mid-point of Column IV of Tariff B, payable in the cause.

“Mandy Aylen”

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:

T-2137-23

STYLE OF CAUSE:

BAYER INC. AND REGENERON PHARMACEUTICALS, INC. v AMGEN CANADA INC.

PLACE OF HEARING:

held by way of videoconference

DATE OF HEARING:

NOVEMBER 1, 2024

ORDER AND REASONS

aylen j.

CONFIDENTIAL ORDER and reasons issued:

nOVEMBER 20, 2024

PUBLIC ORDER AND REASONS ISSUED:

dECEMBER 4, 2024

APPEARANCES:

William Boyer David Tait James Holtom Kendra Levasseur

For The PLAINTIFFS/ DEFENDANTS BY COUNTERCLAIM

Dominique Hussey Melissa Dimilta William Bortolin

For The DEFENDAnt/ PLAINTIFF BY COUNTERCLAIM

SOLICITORS OF RECORD:

McCarthy Tétrault LLP Barristers and Solicitors Toronto, Ontario

For The PLAINTIFFS/ DEFENDANTS BY COUNTERCLAIM

Gowling WLG LLP Barristers and Solicitors Ottawa, Ontario

For The PLAINTIFFS/ DEFENDANTS BY COUNTERCLAIM

Bennett Jones LLP Barristers and Solicitors Toronto, Ontario

For The DEFENDAnt/ PLAINTIFF BY COUNTERCLAIM

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Prepared on 28 October 2026 · Esheria