

Federal Court



Cour fédérale

Date: 20240409

Docket: T-2728-23

Citation: 2024 FC 544

Toronto, Ontario, April 9, 2024

PRESENT: Mr. Associate Judge Michael D. Crinson

BETWEEN:

BAYER INC.

Applicant

and

AMGEN CANADA INC.

Respondent

ORDER AND REASONS

[1] The application for judicial review which provides the context for this motion brought by the Applicant, Bayer Inc., is in respect of a decision of the Minister, issued through the Office of Patented Medicines and Liaison (the “OPML”), dated December 20, 2023 (the “Final Decision”) wherein the Minister determined: (1) that Canadian Patent No. 2,970,315 (the “315 Patent”) was eligible for listing on the Patent Register for EYLEA® as of the Minister’s eligibility decision on August 30, 2023, and not the date of submission to the OPML of August 22, 2023; and (2) that a second person under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133

(“*PM(NOC) Regulations*”) was not required to address the ‘315 Patent because that second person, the Respondent, Amgen Canada Inc. (“Amgen”) filed its New Drug Submission (‘276955) on August 24, 2023, which submission was certified on August 31, 2023.

[2] On this motion Bayer seeks three forms of relief:

- A. leave pursuant to Rule 75(1) of the *Federal Courts Rules* for Bayer to serve and file the Amended Notice of Application attached as Schedule “A” to the Notice of Motion;
- B. an order compelling the Minister of Health (the “Minister”) to produce an amended Certified Tribunal Record in relation to the Amended Notice of Application; and
- C. an order compelling the Minister to produce for examination pursuant to Rule 39.03 of the *Ontario Rules of Civil Procedure* the individual with the initials AZ that conducted the eligibility assessment of the Form IVs in relation to Canadian Patent No. 2,970,315 (the “315 Patent”) and EYLEA®.

[3] Bayer also seeks its costs of this motion against Amgen. This motion was heard a mere week after the very similar motion filed by the applicants in Court File No. T-1369-23.

[4] Section 5 of the *PM(NOC) Regulations*, requires a “second person” who files a drug submission that directly or indirectly compares the drug with, or makes reference to, a first person’s drug that is marketed in Canada under an Notice of Compliance and which has patents listed on the Register, to “address” each listed patent. However, subsection 5(4) of the *PM(NOC) Regulations*, provides that a second person is not required to address a patent that is added to the

Register in respect of the first person's drug on or after the date of filing of the second person's drug submission. It is this regulation about the timing of the addition of the '315 Patent to the Register for EYLEA® that underlies this application.

I. LEAVE TO SERVE AND FILE THE AMENDED NOTICE OF APPLICATION

[5] The amendments to the original application proposed on this motion can be broadly described as changing the description of the August 30, 2023 event from the "Eligibility Decision" to "Communicated Eligibility Decision", and add in particulars of an alleged screening of the '315 Patent such that the Applicant in the proposed amended notice of application now alleges that "while the exact date of the eligibility of the '315 Patent was determined is unknown, the eligibility was sometime between August 22, 2023 and August 30, 2023".

[6] The Court may, on motion, at any time, allow a party to amend a pleading, on such terms as will protect the rights of all parties pursuant to Rule 75 of the *Federal Courts Rules* (the "Rules").

[7] The Court has previously held in *Farmobile, LLC v. Farmers Edge Inc.*, 2022 FC 22 at para 21:

An amendment must also yield a sustainable pleading. As a result, an amendment that does not disclose a reasonable cause of action or defence and is thus liable to be struck out under Rule 221, should not be permitted [*Mancuso v Canada (National Health and Welfare)*, 2015 FCA 227 at paras 16-20]. This includes amendments that are inadequately particularized to allow the opposing party to plead in response [citation omitted]. Similarly,

amendments that represent a radical departure from the party's prior position are abusive and should not be permitted. (*Farmobile, LLC v. Farmers Edge Inc.*, 2022 FC 22 at para 21).

[8] The requirement that the amendment have a reasonable prospect of success has become a threshold issue: (*Remo Imports Ltd. v. Jaguar Cars Ltd.*, 2005 FC 870 at para. 49). In determining whether a proposed amendment has a reasonable prospect of success, its chance of success must be examined in the context of the law and the litigation process and a realistic view must be taken (*Teva Canada Limited v Gilead Sciences Inc*, 2016 FCA 176 at para. 30). The absence of a reasonable prospect of success is a well-established reason for a Court to dismiss a motion for leave to amend: (*Bauer Hockey Corp. v. Sport Maska Inc.*, 2014 FCA 158 (F.C.A.) at para. 16). The burden is on the amending party to demonstrate such a reasonable prospect of success (*Merck & Co Inc v Apotex*, 2003 FCA 488 at para 46).

[9] The Court is satisfied, taking a realistic view based on the records before it, that the proposed amended notice of application when examined in the context of the law and the litigation process meets the threshold of having a reasonable prospect of success. The Minister has not argued to the contrary.

[10] When faced with a motion to amend the overarching consideration is whether it is more consonant with the interests of justice that the amendment be permitted or that it be denied (*Janssen Inc. v. Abbvie Corporation*, 2014 FCA 242 (CanLII), at para. 3). In other words, a pleadings amendment should be allowed at any stage of an action for the purpose of determining the real questions in controversy, provided that allowing the amendment would not result in an injustice to the other party that is not capable of being compensated by an award of costs and the

amendment would serve the interests of justice, see (*Apotex Inc. v Bristol-Myers Squibb Company*, 2011 FCA 34, at para. 4).

[11] In determining whether it is more consonant with the interests of justice that the amendment be permitted or that it be denied, the factors the Court should consider include:

- A. the timeliness of the motion to amend;
- B. the extent to which the proposed amendments would delay the expeditious hearing of the matter;
- C. the extent to which a position taken originally by one party has led another party to follow a course of action in the litigation which it would be difficult or impossible to alter, and;
- D. whether the amendments sought will facilitate the Court's consideration of the true substance of the dispute on its merits to guide the exercise of its discretion.

[12] These factors are non-exhaustive and not limiting. No single factor predominates nor is its presence or absence necessarily determinative, and all must be assigned their proper weight in the context of the particular case (*Janssen Inc. supra*, at para. 3).

[13] The motion to amend has been brought in a timely manner by the Applicant. The evidence shows the Applicant became aware of the Additional Documents to which the amendments relate and provided a proposed Amended Notice of Application within two business days.

[14] The amendments will cause some delay in getting to the application hearing. However, to the extent there is delay caused by the amendment it is not of such a nature or magnitude that it cannot be addressed through case management.

[15] The Respondent, Amgen, has not taken any steps in the litigation other than to serve and file a notice of appearance. As a result, the proposed amendment cannot be said to have led another party to follow a course of action in the litigation which it would be difficult or impossible to alter.

[16] The heart of this application is a dispute about the date that the Minister listed the '315 Patent on the Patent Register. The Minister argues the issue is solely one of statutory interpretation. However, this overlooks the allegation in the notice of application that the applicant is seeking an order to set aside the decision of the Minister that the '315 Patent was only eligible for listing on the Patent Register for EYLEA® as of August 30, 2023. While the Applicant has argued the appropriate date for listing is August 22, 2023, it is open to the Court to conclude it is either or neither of these dates. This may be a mixed question of fact and law informed by the particulars the applicant seeks to add on this motion.

[17] The real question in controversy here is what was the appropriate date for the Minister to list the '315 Patent on the Patent Register for EYLEA®. In light of this it is more consonant with the interests of justice in this case that the proposed amendments be permitted.

II. Production of an amended Certified Tribunal Record

[18] The Applicant asks that four additional documents (the “Additional Documents”) be added and produced in an amended Certified Tribunal Record. Those Additional Documents, as referred to in exhibit B of the affidavit of Chirani Mudunkotuwa sworn January 30, 2024 are:

- A. Standard Operating Procedure for Administration of the *Patented Medicines (Notice of Compliance) Regulations*;
- B. Processing of Drug Submissions Standard Operating Procedure;
- C. Annotated version of Claims of Canadian Patent No. 2,970,315 with notes added by Patent Officer - Science during patent audit;
- D. Patent List Screening and Eligibility Sheet completed by Program Officer and Patent Officer – Science.

[19] The Respondent appears to concede that if the proposed amendments to the application are permitted the Additional Documents should be included in an amended Certified Tribunal Record. This Court agrees but would have ordered the inclusion of the Additional Documents even if the application for judicial review were not amended.

[20] In determining the evidence to be produced pursuant to Rule 317 this Court should be cautious not to exclude arguable evidence and thereby usurp the role of the judge hearing the merits of the application. The Court should not exclude documents for which there is an arguable case that the documents will be relevant to the grounds or relief in the application. Inclusion of such evidence does not prevent the opposing parties from arguing at the hearing on the merits the

documents are not relevant. In the words of the Federal Court of Appeal in *Canadian National Railway Company v Canadian Transportation Agency*, 2023 FCA 245 at paragraph 17:

In assessing relevance, the Court must also remember that Rule 317 is not a summary judgment provision. It is not meant to be a tactical opportunity for a respondent to nip in the bud a judicial review or statutory appeal before complete disclosure is made and analyzed. If there is an arguable case that the documents sought might well be relevant to the grounds or relief set out in the pleading, they should be disclosed. Fine, precise and final determinations of relevance are for the judge or panel hearing the merits of the application or appeal. By then, the judge or panel will have the benefit of the parties' submissions on the complete evidentiary and legal picture and, thus, will be empowered to make the best possible decision on relevance.

[21] The Court should also take a broad approach to assessing the relevance of documents based on a realistic view of the essential character of the issues raised in the notice of application and the nature of the decision being challenged:

What is “relevant to an application [or appeal]” under Rule 317? The answer is found in the pleading: in the case of judicial reviews, the notice of application or in the case of statutory appeals, the notice of appeal.

The Court must read the pleading “with a view to understanding the real essence of the application [or appeal]” and gaining “a realistic appreciation’ of the [proceeding’s] ‘essential character’”. The Court must not fall for skilful pleaders who are “[a]rmed with sophisticated wordsmithing tools and cunning minds”. Instead, it must read the pleading “holistically and practically without fastening onto matters of form”.

In assessing what material is responsive to a Rule 317 request, the Court must pay close attention to context. For example, take a decision concerning a one-off, isolated matter. All of the documents and information leading to the decision will be found in the one specific file for the case. But take a decision that is just the latest chapter in an ongoing regulatory project consisting of multiple decisions. The documents and information will rest in the specific file for the case but also in related files. (*Canadian*

National Railway Company v Canadian Transportation Agency,
2023 FCA 245 at paragraphs 14-16, citations omitted)

[22] The issue in this application is on what date a patent eligible for listing should be added to the Patent Register, and more specifically, on what date the ‘315 Patent should have been added to the Patent Register. The Additional Documents are relevant to the screening process that was conducted leading to the decision regarding the ‘315 Patent which is the subject matter of the application for judicial review. Thus, there is an arguable case that the documents are relevant to the grounds and relief sought in this application for judicial review and they should be included in an amended certified tribunal record.

III. Production of An Individual For Examination

[23] The Applicant relies upon Rule 4, the so called “gap rule”, as a basis for its request for an Order for production of an individual from the Minister to attend for cross-examination. That Rule provides:

4. On motion, the Court may provide for any procedural matter not provided for in these Rules or in an Act of Parliament by analogy to these Rules or by reference to the practice of the superior court of the province to which the subject-matter of the proceeding most closely relates.

[24] The Applicant provided no basis for concluding the lack of a right to compel a witness to attend for cross-examination where the witness has not sworn an affidavit in an application is a “gap” rather than an intentional choice in the context of an application. In effect, the Applicant is seeking a form of examination for discovery of an individual from the Minister.

[25] An application for judicial review is intended to be a summary and expeditious proceeding. As the Federal Court of Appeal held in *Canadian National Railway Company v Canadian Transportation Agency*, 2023 FCA 245 at paragraph 15 "...attempts to conduct discovery of material to see whether a ground of judicial review might exist-the proverbial fishing expedition-also cannot be permitted." This Court in *Sierra Club of Canada v. Canada (Minister of Finance)*, 1999 CanLII 7756 (FC) at paragraph 14 recognised the expeditious nature of applications for judicial review and the absence of examinations for discovery:

[14] To begin this analysis, and this is perhaps trite, a proceeding by way of an application, such as the present, is very different from a proceeding by way of an action. The former is to be "...without delay and in a summary manner" (section 18.4(2) of the *Federal Court Act*) with the proceeding to be moved along to a conclusion as quickly as possible, without pleadings and with a minimum of distraction including without unnecessary procedural delays. The latter, in contrast, involves an exchange of pleadings, discovery of documents and examinations for discovery, which are usually much more protracted than mere cross-examination on an affidavit in support of a judicial review application.

[26] The Federal Court of Appeal in *David Bull Laboratories v. Pharmacia Inc.*, [1995] 1 F.C. 588 at 595 (FCA), stated that the absence of a provision in the *Federal Courts Rules* does not mean there is a gap if it can be explained by the general scheme of those Rules:

For Rule 5 [now Rule 4] to apply there must be a "gap" in the *Federal Court Rules*. Simply because those Rules do not contain every provision found in provincial court rules does not necessarily mean that there is a gap. If the absence of such a provision can be readily explained by the general scheme of the *Federal Court Rules* then that absence must be considered intentional and any application by analogy of provincial court rules or other provisions of the *Federal Court Rules* which are on their face inapplicable would amount to an amendment of the *Federal Court Rules*.

[27] Applications, including applications for judicial review, are summary procedures and accordingly, applicants are not entitled to conduct discovery of materials. In *iFIT Inc v Safe Sweat Fitness Ltd.*, 2023 FC 1747, Associate Judge Cotter recently reiterated the distinction between an application and an action in respect of disclosure of evidence in order to achieve an expeditious proceeding by way of an application:

The Applicant filed a notice of application rather than a statement of claim, which provides the benefit of a more expeditious proceeding, but it also means more limited opportunities to compel the opposing party to disclose evidence (see *Sierra Club of Canada v Canada (Minister of Finance)*, 1999 CanLII 7756 (FC), [1999] FCJ No 306 at para 14, 163 FTR 109 [*Sierra Club*]). Thus, the Applicant “cannot expect to be able to make his case out of the mouth of the respondent”: *Merck & Frost Canada Inc. v Canada (Minister of National Health and Welfare)*, [1994] FCJ No 662 at para 26, 169 NR 342 [*Merck (1994)*]; *Eli Lilly Canada Inc v Apotex Inc*, 2007 FC 455.

[28] I am satisfied in light of the general scheme of the *Federal Court Rules* that there is no purported “gap” and what the Applicant is seeking by way of production of a witness from the Minister is in effect an amendment to those Rules. The Applicant’s motion for production of a witness, who has not sworn an affidavit in this proceeding is denied.

IV. Costs

[29] The parties to the motion agree that costs on this motion should be assessed at the high end of column IV but disagree as to who should be awarded those costs. As success was divided on the motion costs of this motion shall be in the cause assessed at the high end of column IV.

ORDER

THIS COURT ORDERS that:

1. The Applicant shall serve and file an Amended Notice of Application in the form attached as Schedule A to the Notice of Motion within 5 days of the date of this Order.
2. The Minister shall, within 5 days of the date of this Order, transmit to the parties an amended certified tribunal record incorporating the Additional Documents comprising the (i) Standard Operating Procedure for Administration of the *Patented Medicines (Notice of Compliance) Regulations*; (ii) Processing of Drug Submissions Standard Operating Procedure; (iii) Annotated version of Claims of Canadian Patent No. 2,970,315 with notes added by Patent Officer - Science during patent audit; (iv) Patent List Screening and Eligibility Sheet completed by Program Officer and Patent Officer – Science.
3. The applicant’s motion for an order compelling the Minister to produce for examination pursuant to Rule 39.03 of the *Ontario Rules of Civil Procedure* the individual with the initials AZ that conducted the eligibility assessment of the Form IVs in relation to Canadian Patent No. 2,970,315 (the “315 Patent”) and EYLEA® is dismissed.
4. Costs of this motion shall be in the cause assessed at the high end of column IV.

"Michael D. Crinson"

Associate Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-2728-23

STYLE OF CAUSE: BAYER INC. v AMGEN CANADA INC.

THE MATTER WAS HELD BY WAY OF VIDEOCONFERENCE

DATE OF HEARING: FEBRUARY 13, 2024

ORDER AND REASONS: CRINSON A.J.

DATED: APRIL 8, 2024

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