Federal Court Cour fédérale

Date: 20240409

Docket: T-1369-23

Citation: 2024 FC 562

Toronto, Ontario, April 9, 2024

PRESENT: Mr. Associate Judge Michael D. Crinson

BETWEEN:

EMD SERONO, A DIVISION OF EMD INC., CANADA AND MERCK SERONO SA

Applicants

and

THE MINISTER OF HEALTH AND APOTEX INC.

Respondents

and

CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION AND INNOVATIVE MEDICINES CANADA

Interveners

ORDER AND REASONS

[1] The application for judicial review which provides the context for this motion brought by the Applicants, EMD Serono, a division of EMD Inc. and Canada Merck Serono SA (collectively "EMD Serono"), is in respect of a decision of the Minister, issued through the Office of Submissions and Intellectual Property (the "OSIP"), communicated to EMD Serono on June 15, 2023 (the "Final Decision") wherein the Minister of Health (the "Minister") determined: (1) that Canadian Patent No. 3,087,419 (the "419 Patent"), was found eligible for listing on the Patent Register for MAVENCLAD™ as of the date of the Minister's eligibility decision on March 23, 2023, and not March 16, 2023, the date that the patent lists for the '419 Patent were submitted to OSIP; 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 '419 Patent because that second person, the Respondent, Apotex Inc. ("Apotex") filed its drug submission comparing its drug to MAVENCLAD™ on March 22, 2023, before the Minister's eligibility decision on March 23, 2023.

[2] On this motion EMD Serono seeks four forms of relief in addition to costs:

A. leave to amend the Notice of Application in the form attached as Schedule "A" to the Notice of Motion;

B. an order compelling the Minister of Health (the "Minister") to serve and file an amended Certified Tribunal Record including the Standard Operating Procedure and "Patent List Screening and Eligibility" attached as Schedule "B" to the Notice of Motion (the "Additional Documents") and in the alternative, an Order allowing

the Applicants to depart from the Scheduling Order of this Court dated November 7, 2023 and serve and file the Additional Documents and any related correspondence in an affidavit; and

C. an order compelling the Minister to provide access to a knowledgeable witness for examination about the contents of Schedule B to the Notice of Motion.

[3] This motion was heard shortly before the very similar motion filed brought by Bayer Inc. in Court File No. T-2728-23, which is proceeding on a similar timetable and will be heard by the same judge.

[4] Section 4 of the *PM(NOC) Regulations*, permits an innovator, called a "first person" who has filed a new drug submission to submit to the Minister a patent list in relation to their submission for addition to the Patent register. Once a patent has been listed on the patent register, section 5 imposes obligations on the second person. A second person that submits a drug submission for the same drug must then elect either to await the expiry of listed patents or to challenge them. If the election is to challenge, section 5(3) requires the second person to serve a Notice of Allegation setting out the second person's non-infringement and invalidity allegations. Of significance in this application is that second persons are only required to address patents that are already listed on the patent register at the time they file their drug submissions.

I. LEAVE TO AMEND THE NOTICE OF APPLICATION

[5] The amendments to the original application proposed on this motion can be broadly described as changing the description of the communicated decision of June 15, 2023 to define it

as the “Final Decision”, and add in particulars of an alleged determination by the Minister on March 21, 2023 that the patent lists for the 419 Patent were eligible for listing such that a such that a second person who filed its drug submission after that date would be required to address the ‘419 Patent pursuant to the *PM(NOC) Regulations*.

[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.

[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, Apotex has not taken any steps in the litigation other than to serve and file a notice of appearance. On the evidence before the Court, 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 ‘419 Patent on the Patent Register for MAVENCLAD™. The Minister argues the issue is solely one of statutory interpretation. However, this overlooks the allegation in the notice of application that the Applicants are seeking an order to set aside the decision of the Minister of June 15, 2023 that the ‘419 Patent was found eligible for listing on the Patent Register for MAVENCLAD™ as of the date of March 23, 2023. While the Applicants had argued the appropriate date for listing is March 16, 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 Applicants seek to add on this motion.

[17] The real question in controversy here is what was the appropriate date for the Minister to list the ‘419 Patent on the Patent Register for MAVENCLAD™. 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 Applicants ask that the Minister serve an amended Certified Tribunal Record, which would include the Additional Documents.

[19] The Respondents appear 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 ‘419 Patent should have been added to the Patent Register. The Additional Documents are relevant to the process that was conducted leading to the decision regarding the 419 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.

[23] In light of this conclusion the Court need not address the alternative relief sought by the to serve and file the Additional Documents and any related correspondence in an affidavit.

III. Production of An Individual For Examination

[24] The Applicants rely upon Rule 4, the so called “gap rule”, as a basis for its request for an order requiring the Minister of Health to provide access to a knowledgeable witness for examination about the contents of Schedule B by the Applicants and leave to add any transcript of same to the Applicants’ application record. Rule 4 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.

[25] The Applicants provide no basis for concluding the lack of a right to compel a witness to attend for 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 Applicants are seeking a form of examination for discovery of an individual from the Minister.

[26] 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.

[27] 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*.

[28] 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.

[29] I am satisfied in light of the general scheme of the *Federal Court Rules* that there is no purported "gap" and what the Applicants are seeking by way of production of a witness from the

Minister is in effect an amendment to those Rules. The Applicants' motion for production of a witness, who has not sworn an affidavit in this proceeding is denied.

IV. Costs

[30] As success was divided on the motion and considering the complexity of the issues, costs of this motion shall be in the cause assessed at the high end of column IV.

ORDER

THIS COURT ORDERS that:

1. The Applicants 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 including the Standard Operating Procedure and "Patent List Screening and Eligibility" attached as Schedule "B" to the Notice of Motion.

3. The Applicants' motion for an order requiring the Minister of Health to provide access to a knowledgeable witness for examination about the contents of Schedule B to the Notice of Motion by the Applicants and leave to add any transcript of same to the Applicants' application record 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-1369-23
STYLE OF CAUSE:	EMD SERONO, A DIVISION OF EMD INC., CANADA AND MERCK SERONO SA v THE MINISTER OF HEALTH AND APOTEX INC. AND CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION AND INNOVATIVE MEDICINES CANADA
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	FEBRUARY 6, 2024
ORDER AND REASONS:	CRINSON A.J.
DATED:	APRIL 9, 2024

APPEARANCES:

Fiona Legere James Holtom Bohdana Tkachuk Veronica Van Dalen	FOR THE APPLICANTS
James Schneider Sahara Douglas	FOR THE RESPONDENT, MINISTER OF HEALTH
Harry Radomski Sandon Shogilev	FOR THE RESPONDENT, APOTEX

SOLICITORS OF RECORD:

McCarthy Tétrault LLP Toronto, Ontario	FOR THE APPLICANTS
Attorney General of Canada **Department of Justice** Toronto, Ontario	FOR THE RESPONDENT, MINISTER OF HEALTH
Goodmans LLP Toronto, Ontario	FOR THE RESPONDENT, APOTEX