Federal Court  Cour fédérale

Date: 20070221

Docket: T-1971-06

Citation: 2007 FC 196

Ottawa, Ontario, February 21, 2007

PRESENT: The Honourable Mr. Justice Simon Noël

BETWEEN:

SERVIER CANADA INC.
and ADIR

Applicants

and

MINISTER OF HEALTH
and APOTEX INC.

Respondents

REASONS FOR ORDER AND ORDER

[1] This is a motion brought by the Applicants (collectively "Servier") to amend their Notice of Application dated November 10, 2006 (Original Application) under Rule 75 of the *Federal Court Rules*, SOR/98-106, as amended. The amendments that the Applicants wish to make, relate to the fact that on February 1, 2007, Health Canada issued a Notice of Compliance (NOC) for perindopril erbumine to Apotex for their Apo-perindopril 8 mg tablets.

I. Facts

[2] ADIR is the patentee of Canadian Patent 1,341,196 (196 Patent). The 196 Patent contains claims for perindopril and its pharmaceutically acceptable salts, which include perindopril erbumine.

[3] Servier Canada obtained a NOC for perindopril erbumine in 2 and 4 mg tablets on September 21, 1994 and a NOC for perindopril erbumine in 8 mg tablets on October 16, 2002. The 2, 4 and 8 mg tablets of perindopril erbumine are distributed by Servier Canada under the trade-mark COVERSYL.

[4] On November 29, 2005, Apotex filed with Health Canada an Abbreviated New Drug Submission (ANDS) for the purpose of obtaining a NOC to market and sell generic perindopril erbumine in Canada under the name Apo-perindopril in 2, 4 and 8 mg tablets. COVERSYL served as the Canadian reference product.

[5] On December 12, 2005, Health Canada wrote to Apotex to inform them that Health Canada had taken the position that section 5 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 *(PMNOC Regulations)*, as amended, was only triggered in what concerns Apo-perindopril 2 and 4 mg tablets, and thus that Apotex was only required to address the 196 Patent in respect of COVERSYL 2 and 4 mg tablets. This decision was based on the fact that on March 15, 2001, Servier Canada had filed Form IV Patent Lists listing the 196 Patent in respect of COVERSYL 2 and 4 mg tablets, but did not file a Form IV Patent List in respect of COVERSYL 8 mg tablets.

[6] After recently learning of Health Canada's December 12, 2005 decision, the Applicant filed the present application for judicial review on November 10, 2006, requesting among others: (1) an Order confirming that Apotex must comply with subsection 5(1) of the *PMNOC Regulations*, as amended on October 5, 2006, in what concerns Apo-perindopril in 8 mg tablets and (2) an Order prohibiting the Minister of Health from issuing a NOC to Apotex in respect of Apo-perindopril in 8 mg tablets.

[7] On February 1, 2007, Health Canada issued a NOC to Apotex for Apo-perindopril 8 mg tablets, pursuant to paragraph C.08.004(1)(a) of the *Food and Drug Regulations*, notwithstanding the Original Application.

[8] Given this last event, the Applicants seek an order under Rule 75 of the *Federal Court Rules* to amend their Notice of Application as follows:

i) add the following prayer for relief after paragraph D:

E. An Order requiring the Minister of Health to revoke the Notice of Compliance issued to Apotex Inc. on or about February 1, 2007 for Apo-Perindopril 8 mg tablets.

ii) add the following after paragraph 11:

12. On or about February 1, 2007 the Minister of Health issued a Notice of Compliance to Apotex Inc. for Apo-Perindopril 8 mg tablets.

Moreover, the Applicants seek the following orders from the Court:

i) An order confirming that the affidavit of Denise Pope dated February 13, 2007 filed in support of the present motion is deemed to form part of the record before this Court for the purpose of hearing the application on the merits.

ii) An order setting this matter down for hearing on the merits for one half day on the earliest available date after March 20, 2007.

iii) An order setting the following schedule for pre-hearing steps:

a. Ms. Bowes' cross-examination to be completed by February 21, 2007.

b. Applicants' record to be served and filed by February 28, 2007.

c. Respondents' records to be served and filed within 20 days of the date that the Applicants' record is filed.

II. Issues

(1) Is the Minister of Health's issuance of a NOC to Apotex, for Apo-perindopril 8 mg tablets, a separate and distinct decision from the Minister's December 12, 2005 finding that the *PMNOC Regulations* do not apply to Apo-perindopril 8 mg tablets?

III. Analysis

(1) Is the Minister of Health's issuance of a NOC to Apotex, for Apo-perindopril 8 mg tablets, a separate and distinct decision from the Minister's December 12, 2005 finding that the *PMNOC Regulations* do not apply to Apo-perindopril 8 mg tablets?

[9] Rule 75 of the *Federal Court Rules* provides that:

75. (1) Subject to subsection (2) and rule 76, the Court may, on motion, at any time, allow a party to amend a document, on such terms as will protect the rights of all parties.	**75.** (1) Sous réserve du paragraphe (2) et de la règle 76, la Cour peut à tout moment, sur requête, autoriser une partie à modifier un document, aux conditions qui permettent de protéger les droits de toutes les parties.
(2) No amendment shall be allowed under subsection (1) during or after a hearing unless	(2) L'autorisation visée au paragraphe (1) ne peut être accordée pendant ou après une audience que si, selon le cas :
(*a*) the purpose is to make the document accord with the issues at the hearing;	*a*) l'objet de la modification est de faire concorder le document avec les questions en litige à l'audience;
(*b*) a new hearing is ordered; or	*b*) une nouvelle audience est ordonnée;
(*c*) the other parties are given an opportunity for any preparation necessary to meet any new or amended allegations.	*c*) les autres parties se voient accorder l'occasion de prendre les mesures préparatoires nécessaires pour donner suite aux prétentions nouvelles ou révisées.

This rule applies to all proceedings, including applications.

[10] Although Rule 75 does not set out the criteria for amending a document, the Federal Court of Appeal determined in *Canderel Ltd v. Canada (Minister of National Revenue)*, [1994] 1 F.C. 3 (C.A.), that:

> […] while it is impossible to enumerate all the factors that a judge must take into consideration in determining whether it is just, in a given case, to authorize an amendment, the general rule is that an amendment should be allowed at any stage of an action for the purpose of determining the real questions in controversy between the parties, provided, notably, that the allowance would not result in an injustice to the other party not capable of being compensated by an award of costs and that it would serve the interests of justice.
>
> [Emphasis added.]

This test has become the norm for determining whether a motion for amending a document will succeed.

[11] This being said, Apotex opposes the Applicants' motion to amend their Original Application on the basis that the Applicants are not in compliance with Rule 302 of the *Federal Court Rules*. Rule 302 of the *Federal Court Rules states* that:

302. Unless the Court orders otherwise, an application for judicial review shall be limited to a single order in respect of which relief is sought.	**302.** Sauf ordonnance contraire de la Cour, la demande de contrôle judiciaire ne peut porter que sur une seule ordonnance pour laquelle une réparation est demandée.

[12] Rule 302 has been interpreted as establishing that an application for judicial review shall be limited to a single decision, unless the Court orders otherwise, and thus, where the review of multiple decisions is sought, an application for each decision must be filed (see *Jazz Air LP v. Toronto Port Authority*, 2006 FC 705 at para. 12, *Human Rights Institute of Canada v. Canada (Minister of Public Works & Government Services)*, [2000] 1 F.C. 475).

[13] In what concerns the case at hand, Apotex states that if the amendments sought by the Applicants were allowed, the Applicants' judicial review application would seek the review of two separate decisions made by the Minister of Health: the first being the Minister's decision that the *PMNOC Regulations* do not apply to Apo-perindopril 8 mg tablets; and the second being the Minister's decision under the *Food & Drug Regulations* to grant a NOC to Apotex in respect of Apo-perindopril 8 mg tablets.

[14] The Applicants, for their part, argue that there is only decision at issue, namely the December 12, 2005 decision of the Minister. According to the Applicants, the issuance of the NOC for Apo-perindopril 8 mg tablets was a consequence of the Minister's December 12, 2005 finding that the *PMNOC Regulations* were not engaged in what concerns Apo-perindopril 8 mg

tablets. Thus, the Applicants claim that the amendments they seek to make to their Original Application are justified, as a change of circumstance has taken place, and the amendments would allow the Court to deal with the issues at stake in the most efficient and economical manner.

[15] This being said, it is of essence that I point out that at the hearing, at the beginning of the Applicants' submissions, I asked whether the Applicants sought leave of this Court to challenge the Minister's December 12, 2005 finding that the *PMNOC Regulations* did not apply to Apo-perindopril 8 mg tablets and the Minister's issuance of a NOC to Apotex on February 1, 2007 for Apo-perindopril 8 mg tablets in one application. In response to this question, the Applicants' counsel clearly stated that leave was not sought as the Applicants believe that there is only one decision at issue and thus that Rule 302 of the *Federal Court Rules* does not apply to the situation at hand.

[16] Before I move on to analyzing the arguments of the parties, I must point out that I have limited myself to dealing with the arguments that the parties have presented in their written submissions and which they have backed up by their main oral arguments.

[17] This being said, the case law on the issue is clear, it is a contravention of Rule 302 for an applicant to challenge two decisions within one application, unless the Court orders otherwise or the applicant can show that the decisions at issue form part of a "continuous course of conduct" (*Khadr v. Canada (Minister of Foreign Affairs)*, 2004 FC 1145; *Truehope Nutritional Support Ltd. v. Canada (Attorney General)*, 2004 FC 658). In *Khadr*, above at paragraph 10, Justice von Finckenstein found that where "two sets of decisions were made at different times and involve a

different focus they cannot be said to form part of a 'continuing course of conduct.'" Moreover, in *Truehope Nutritional Support Ltd*, above at paragraph 6, Justice Campbell found that:

> Continuing acts or decisions may be reviewed under s.18.1 of the *Federal Court Act* without offending Rule 1602(4) [now Rule 302], however the acts in question must not involve two different factual situations, two different types of relief sought, and two different decision-making bodies […]

[18] In the case at hand, the two decisions which the Applicants seek to have reviewed cannot be considered part of a "continuing course of conduct" given the Court's case law relating to Rule 302. First, the two decisions in question were made at different times; the first was made on December 12, 2005, the second on February 1, 2007. The two decisions relate to different factual situations and were made under distinct statutory regimes each with their own decision making process: on December 12, 2005 Health Canada found that the *PMNOC Regulations* did not apply to Apo-perindopril 8 mg tablets; whereas on February 1, 2007, Health Canada issued a NOC for Apotex's Apo-perindopril 8 mg tablets under the *Food & Drug Regulations*. Furthermore, the Applicants seek two different types of relief: for the December 12, 2005 decision, the Applicants seek among their prayers for relief that are not academic given that an NOC was issued to Apotex for Apo-perindopril 8 mg tablets, a declaration that the *PMNOC Regulations* as amended on October 5, 2006 apply to the pending ANDS filed by Apotex in respect of Apo-perindopril 2, 4 and 8 mg tablets and an order that Apotex comply with subsection 5(1) of the *PMNOC Regulations*; whereas for the February 1, 2007, the Applicants seek an order requiring the Minister of Health to revoke the NOC issued. Therefore, I can but conclude that the amendments being sought by the Applicants to their Original Application relate to another decision, namely the February 1, 2007 decision by Health

Canada to issue a NOC to Apotex for Apo-perindopril 8 mg tablets. The issuance of an NOC to Apotex on February 1, 2007 is a distinct and separate decision from the December 12, 2005 decision of the Minister finding that the *PMNOC Regulations* do not apply to Apo-perindopril in 8 mg tablets, the decision which is the subject of the Original Application. So as to conform with Rule 302, the Applicants must seek leave of this Court to proceed with a review of two decisions in one application, in the case at hand, leave was not sought.

[19] Justice MacKay in *Merck Frost Canada Inc v. Canada (Minister of Health)*, [1997] F.C.J. no. 1273, dealt with a situation where an application was brought to challenge the Minister of Health's decision to issue a NOC to Apotex with regard to Apo-lovastatin but where the Applicant, Merck, sought to amend their allegations of fact so that they could challenge a number of decisions made by the Minister of Health, which lead to the issue of the NOC, in one application. At paragraph 25 of his decision, Justice MacKay wrote the following in what concerned the application of Rule 1602(4) of the *Federal Court Rules*, which has since been replaced by Rule 302:

> Adding a request for an order to revoke or suspend the decision of the Minister of July 11, 1997, in my opinion, would be inappropriate. An application for judicial review by the Court's Rule 1602(4) is to be with regard to a single decision, or failure to decide, and here the original and the amended notice of motion already seek review of the Minister's decision of March 26, 1997 to issue an NOC to Apotex with regard to its Apo-lovastatin product. At the hearing of this application counsel for Merck confirmed that the decision of March 26 is the key decision here sought to be set aside. While it was urged at the hearing that the amended detailed allegations of fact sought to be introduced make clear that Merck seeks to challenge in this proceeding the whole series of decisions made on behalf of the Minister leading to the issue of the NOC and its subsequent amendment, this would only be relevant to the extent the prior process is by law, or practice of the Minister, an integral aspect of the decision in question. Judicial review is not a proceeding to review an ongoing and continuous process; rather, its purpose, aside from declaratory relief, is to review a particular decision or action, or lack of decision or action if that is required by law.
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> [Emphasis added.]

[20] Given the Court's jurisprudence and the reasons above, I conclude that the Applicants have not complied with Rule 302 of the *Federal Court Rules* and as such their motion to amend their Original Application is denied.

IV. Costs

[21] I have heard the parties on costs. The Applicants ask for costs in the cause, whereas Apotex asks for a delay so that submissions on costs may be made. It is not necessary that a delay be accorded so that submissions on costs may be made. Given my findings above, I order costs of this motion in favour of Apotex.

ORDER

THIS COURT ORDERS THAT:

1. The Applicants motion to amend their Notice of Application is denied.

2. Costs of this motion in favour of Apotex.

"Simon Noël"

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Judge

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-1971-06
STYLE OF CAUSE:	SERVIER CANADA INC. and ADIR v. MINISTER OF HEALTH and APOTEX INC.
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	FEBRUARY 20th, 2007
REASONS FOR ORDER: AND ORDER	THE HONOURABLE JUSTICE SIMON NOËL
DATED:	February 21, 2007

APPEARANCES:

Mr. Brian Daley	FOR THE APPLICANTS
Mr. Daniel G. Cohen	FOR THE RESPONDENT Apotex Inc.
No appearance	FOR THE RESPONDENT Minister of Health

SOLICITORS OF RECORD:

Ogilvy Renault LLP Montréal, Québec	FOR THE APPLICANTS
Goodmans LLP Toronto, Ontario	FOR THE RESPONDENT Apotex Inc.
Mr. John H. Sims, Q.C. Deputy Attorney General of Canada Ottawa, Ontario	FOR THE RESPONDENT Minister of Health