Date: 20071107

Docket: T-1351-07

Citation: 2007 FC 1156

Toronto, Ontario, November 7, 2007

PRESENT: Kevin R. Aalto, Esquire, Prothonotary

BETWEEN:

SANOFI-AVENTIS CANADA INC.

Applicant

and

THE MINISTER OF HEALTH,
THE ATTORNEY GENERAL OF CANADA and
LABORATOIRE RIVA INC.

Respondents

REASONS FOR ORDER AND ORDER

[1] This motion is brought on behalf of the Respondent, Laboratoire Riva Inc. ("Riva"), for, *inter alia*, an Order dismissing this Application for Judicial Review.

[2] The Application seeks to judicially review an alleged "decision" of Health Canada contained in a letter dated June 21, 2007 (the "Letter") sent by counsel for Health Canada addressed only to counsel for Riva. The relevant portion of the Letter for purposes of this motion states:

> ". . . Health Canada is no longer of the view that Riva cannot receive a notice of compliance until such time as the Pharmascience submission to which Riva's product is 'cross-referenced' is itself approved. As a result, should Riva be ultimately successful in the prohibition proceedings ongoing in T-127-07, and **otherwise meet all of its obligations** under the *Patented Medicines (Notice of Compliance) Regulations*, it will be eligible to receive a notice of compliance regardless of whether the Pharmascience submission has fully complied with the *NOC Regulations* and received a notice of compliance. I can also advise that Health Canada will soon be providing Riva with a letter confirming that this is so." [emphasis added]

[3] The Applicant seeks to quash this "decision" and require the Minister of Health to advise Riva that a Notice of Compliance ("NOC") will not issue until such time as the requirements of *Patented Medicines (Notice of Compliance) Regulations* (the "Regulations") are met and Pharmascience receives a NOC in respect of its abbreviated new drug submission ("ANDS") for rampiril 2.5, 5, and 10 mg. capsules.

[4] Riva brings this motion to dismiss the Application and is supported by the Minister of Health ("Minister") and the Attorney General of Canada. In essence, there are two grounds which are put forward in support of the motion. First, the Letter does not contain a decision of a federal board, commission or tribunal which gives rise to the remedy sought. Second, there is no duty owed by the Minister to the Applicant and the Applicant has no standing because it is not directly affected by the Minister's position.

[5] The Court may strike out a Notice of Application and dismiss the Application where it is "plain and obvious" that the application cannot succeed or the application is "so clearly improper as to be bereft of any possibility of success [see *Pharmacia Inc.* v. *Canada (Minister of National Health and Welfare)*, [1994] F.C.J. No. 1629 (F.C.A.)]. This is such a case.

The "Decision"

[6] In my view, the Letter does not contain a "decision" in the sense that is referred to in the jurisprudence. It is a Letter from counsel to the Minister addressed only to counsel for Riva in the context of other proceedings not involving this Applicant. The Letter simply advises Riva what the Minister may do if certain events transpire. It is speculative to the extent that the hurdles which Riva must overcome in order to obtain a NOC may not occur. Further, it is not a final decision of the Minister but merely an advance indication of a ministerial position. Such an indication has been held not to be subject to judicial review [see, *Rothmans, Benson & Hedges Inc.* v. *M.N.R.*, [1998] 148 F.T.R. 3 (T.D.)]. As noted in the Written Representations of the Minister:

> "Of course, what Sanofi [the Applicant] seeks to accomplish in this application is prevention of the issuance of a Notice of Compliance to Riva. Setting aside any issue of standing for the moment, Sanofi's opportunity to bring a challenge to such a decision would arise with the actual issuance of a Notice of Compliance by the Minister. By bringing the present application speculatively and prematurely, Sanofi seeks to prevent the Minister from exercising his lawful discretion to issue Notices of Compliance pursuant to the terms of the *Food and Drug Regulations*."

[7] If I am wrong in my determination that the Letter does not contain a judicially reviewable "decision" the other arguments of Riva and the Minister provide ample support for the proposition that this Application is bereft of any possibility of success.

Does the Applicant Have Standing?

[8] The answer to this question is - no. There is ample jurisprudence in this Court to the effect that judicial review is not available to a party that is not directly affected by the decision at issue. Section 18.1 of the *Federal Courts Act* provides as follows:

18.1 (1) An application for judicial review may be made by the Attorney General of Canada or by anyone directly affected by the matter in respect of which relief is sought.	18.1 (1) Une demande de contrôle judiciaire peut être présentée par le procureur général du Canada ou par quiconque est directement touché par l'objet de la demande.

[9] Here, the Applicant is not directly affected by the position of the Minister as set out in the Letter. To be directly affected, the matter involved must be one that affects the Applicant's legal rights or imposes legal obligations on it or prejudices it directly [see, *Apotex Inc.* v. *Canada (Governor in Council)*, [2007] F. C. J. No. 312 par. 20 and cases cited therein].

[10] Potentially, the commercial interest of the Applicant may be affected. However, a commercial advantage conferred on a third party by the government does not give rise to standing to commence a judicial review application [see, *Rothmans of Pall Mall Canada Ltd.* V. *M.N.R.*, [1976] 2 F.C. 500 (C.A.); (1976), 67 D.L.R. (3d) 505]. In that case, Justice Le Dain noted:

> "The appellants do not contend, nor is there any evidence to suggest, that they themselves had any interest in marketing a cigarette with a tobacco portion of less than four inches but an overall length, including the filter tip, of more than four inches. They do not seek the interpretation which they contend to be the correct one in order to permit them to do anything in particular that they are not able to do

> now, but rather to prevent the respondent companies from doing something which is thought to give the latter a commercial advantage.
>
> I am in agreement with the learned trial Judge that such an interest is not sufficient to give the appellants the required status or *locus standi* to obtain any of the relief sought in their application. The appellants do not have a genuine grievance entitling them to challenge by legal proceedings the interpretation which the respondent officials have given to the definition of "cigarette" in s. 6 of the *Excise Act* for purposes of their administrative application of the Act. Such interpretation does not adversely affect the legal rights of the appellants nor impose any additional legal obligation upon them. Nor can it really be said to affect their interests prejudicially in any direct sense. . . .
>
> . . . **I know of no authority which supports a general duty, when considering a change of administrative policy to be applied in individual cases, to notify and offer anyone who may be interested an opportunity to make representations**." [emphasis added]

[11] As in the *Rothmans* case, the Applicant here may be affected in its commercial interests if, in fact, Riva successfully overcomes all of the hurdles necessary in order to be granted a NOC for its rampiril product. This commercial interest of the Applicant is insufficient to ground this application for judicial review.

[12] The Applicant argues that the position set out in the Letter is one of interpretation of the Regulations which impacts on potential liability of the Applicant under the Regulations and therefore it has standing. Alternatively, the Applicant argues it should be granted public interest standing. For the reasons outlined above, I am not persuaded by the arguments of the Applicant that it has standing as it is not directly affected by the position of the Minister as set out in the Letter.

[13] Counsel for the Applicant argued that the decision of the Federal Court of Appeal in *Ferring Inc.* v. *Apotex Inc.*, [2007] FCA 276, supported its position that it had standing. In that case, Chief Justice Richard observed at par. 5: [i]n our view, *Ferring Inc*. did have standing to challenge that decision because it was made by the Minister in the course of his administration of the NOC Regulations."

[14] However, the "decision" of the Minster in that case was very different than the position articulated by counsel for the Minister in the Letter. In the decision of Justice Hughes [*Ferring Inc.* v. *Canada (Minister of Health)*, [2007] F.C.J. No. 429] from which the appeal was taken, Ferring argued that it had standing to seek judicial review of a Minster's decision relating to the issuance of a NOC to a generic. The standing issue related to whether Ferring could seek judicial review of the Minister's decision that Novopharm was not a "second party" as defined in s. 5(1) of the Regulations, whereby Novopharm received the NOC it sought without engaging the provisions of the Regulations [par. 98]. Justice Hughes determined that this decision i.e. that Ferring had no right to be given notice or an opportunity to be heard before the Minister made a determination that the generic, in its particular circumstances, did not have to engage the Regulations, was insufficient to afford Ferring the right to judicially review the matter [par. 102].

[15] It can be seen that the issue raised by the Applicant in the *Ferring* case is very different than the position taken by the Minister in the Letter which is central to this case. Here, the Regulations are not engaged while the interpretation and application of the Regulations was put directly in issue

in the *Ferring* case. Here, the decision of whether and how the Minister's discretion is exercised in deciding whether an ANDS meets the requirements of the *Food and Drug Regulations* does not put the interpretation, application nor administration of the Regulations in issue and thus does not directly affect the interests of the Applicant.

[16] As for the alternative argument that the Applicant meets the criteria for public interest standing, again this also fails. A party seeking public interest standing must demonstrate, *inter alia*, that it has a direct or genuine interest in the matter [see, *Canadian Generic Pharmaceutical Association* v. *Canada (Governor in Council)*, [2007] F.C.J. No. 202]. For the reasons noted above, the Applicant does not meet this requirement nor the other criteria that there is a serious issue to be tried and that there is no other reasonable and effective manner in which the issue to court.

[17] The application will be dismissed with costs to the Respondents. If the parties are unable to agree on the disposition of costs they may make submissions as to costs, limited to three pages, within thirty days of the date of this decision.

ORDER

THIS COURT ORDERS that:

1. This application is dismissed.

2. The parties may submit written representations with respect to the disposition of costs, limited to three pages, within thirty days of the date of this Order.

"Kevin R. Aalto"
Prothonotary

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-1351-07
STYLE OF CAUSE:	SANOFI-AVENTIS CANADA INC. v. THE MINISTER OF HEALTH ET AL
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APPEARANCES:

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