Date: 20080131

Docket: T-1351-07

Citation: 2008 FC 129

Ottawa, Ontario, January 31, 2008

PRESENT: The Honourable Mr. Justice Hughes

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 is a motion which is brought within an application made by Sanofi-Aventis Canada Inc. to prohibit the Minister of Health from issuing a Notice of Compliance under the *Food and Drug Regulations*, C.R.C., c. 870 as amended, to the Respondent Laboratoire Riva Inc. The Respondents Riva and the Minister joined in a motion heard by Prothonotary Aalto to dismiss the application before it was heard on the merits. The Prothonotary did so, dismissing the application on two bases, first that the Applicant lacked standing and second that there was no matter or decision that could properly be the subject of review under section 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7.

[2] The Prothonotary's decision is one that is vital to the issues in the proceeding since it terminates the proceeding. All parties are in agreement, therefore, that I should consider the matter *de novo*. Thus, I will approach the matter afresh and not concern myself with whether the Prothonotary erred in respect of one point or another. Having so considered the matter, I find for the Reasons given herein that the decision of the Prothonotary should be set aside and the motion dismissed, with costs to be dealt with by the Judge hearing the application.

[3] A motion to strike an application is treated differently than a motion to strike an action. An application is dealt with more summarily than an action and, in many respects, a motion to strike an application can consume just as much of the Court's resources as would be consumed were the application to be heard on its merits. The savings to the parties and the Court in respect of an early determination by a motion to strike are usually far less in respect of an application than in respect of an action.

[4] In determining whether an application should be struck, the Court takes the kind of approach as considered by the Federal Court of Appeal in *Apotex Inc. v. Canada (Governor in Council),* 2007 FCA 374 at paragraph 14, which is, to examine the issue of standing first to see if there is a clear-cut issue in that regard. If the answer is yes, then the application is dismissed, there is no need to consider the merits. As the Court of Appeal said in *Laboratories Servier v. Apotex Inc.*, 2007 FCA 350 at paragraph 34, if the answer is no, the Court will thereafter examine the merits of the application but only to the extent of determining if there is some issue "worth considering". These two decisions had not been released before Prothonotary Aalto made his decision.

[5] These decisions can be illustrated by repeating what that Court said in *Apotex*, *supra* at paragraph 14:

> ***14*** *As a result, I conclude that the Motions Judge erred by commencing his analysis with a preliminary determination on the question of standing. The Motions Judge failed to explicitly exercise his discretion to make a preliminary determination of standing, as permitted in* Finlay v. Canada (Minister of Finance)*, [1986] 2 S.C.R. 607, 33 D.L.R. (4th) 321 at paragraph 16 and Sierra Club, supra, at paragraph 26. If a judge does not exercise her discretion to consider a preliminary question of law at the outset, then all legal issues considered in a motion to strike must be subsumed within the legal test for a motion to strike. Thus, absent a clear exercise of judicial discretion, it is not correct to make a final decision on standing and then decide on the motion. Rather, the legal standard to grant a motion to strike must inform all legal questions.*

and what that Court said in *Servier*, *supra* at paragraph 34:

> ***34*** *At paragraph 39 of its written submissions, Apotex submits, rightly in my view, that "if the responding party has put a conflicting interpretation 'worth considering', it is not plain and obvious that the claim will not succeed". Although it is clear the Motion Judge correctly understood the "plain and obvious" test enunciated in* Hunt, supra, *she did not answer the question of whether or not Apotex's proposed interpretation was "worth considering" or whether it had any chance of success. Rather, she reached her own conclusion on the disputed point of statutory interpretation. That, in my view, constitutes an error on her part. I therefore turn to the issue of whether or not Apotex's proposed interpretation has any chance of success.*

[6] An example of this approach is the case of *Rothmans of Pall Mall Canada Ltd. v. Canada (Minister of National Revenue)*, [1976] 2 F.C. 500 where the Court, on a motion to strike an application, determined that the applicant lacked standing to seek the relief requested thus the application was struck out. An example as to how the matter may turn out otherwise is exemplified

by the decision of Supreme Court of Canada in *Finlay v. Canada (Minister of Finance*), [1986] 2 S.C.R. 607. There, having determined that the applicant did have standing, the Court considered whether it was "plain and obvious" that the application would not succeed. They decided it was not "plain and obvious" thus, it would be up to the Judge hearing the application on its merits to make a determination.

[7] A review of the factual background is necessary in the present case. Much of that can be found in a recent decision of Justice Mactavish of this Court in *Sanofi-Aventis Canada Inc. v. Pharmascience Inc.*, 2007 FC 1057 which I am informed is currently under appeal but to which I refer for its thorough factual analysis. Briefly, Sanofi-Aventis markets a drug containing the medicine ramipril as an active ingredient. It has authority in respect of patents allegedly directed to that drug and has, as an innovator or "first party" as it is called under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended (NOC Regulations) obtained a Notice of Compliance (NOC) and Supplementary Notices of Compliance (SNOC) in respect of that drug.

[8] Various generic drug companies, often referred to as "second parties" under the NOC Regulations have sought to market their generic versions of Sanofi-Aventis's ramipril drug in Canada. As a result these generics have engaged the NOC Regulations by serving Notices of Allegation on Sanofi-Aventis and, in turn, Sanofi-Aventis has commenced proceedings under those Regulations in this Court. Among such generics are Pharmascience and Apotex. Pharmascience

under the NOC Regulations sent a Notice of Allegation challenging the validity of certain Sanofi-Aventis patent rights. Sanofi-Aventis commenced proceedings and ultimately prevailed including on appeal. Apotex also asserted invalidity of those patent rights and in its NOC proceeding it won on grounds not alleged by Pharmascience. Pharmascience then sent another Notice of Allegation to Sanofi-Aventis raising the new grounds of invalidity that Apotex had risen. Justice Mactavish in the decision previously referred to determined that Pharmascience could not rely on the new grounds since it previously had an opportunity to contest validity and had lost. It should have put its best foot forward at the beginning.

[9] In the meantime, Pharmascience and Riva had entered into an arrangement known as cross-referencing or X-REF. Under such an arrangement, one drug company for the purpose of securing a Notice of Compliance for its drug product will simply cross-reference the application of another drug company and assert that its drug product (including such things as labels, packaging and monograph as well as the composition and ingredients of the drug itself) is identical to that which it has cross-referenced except for things such as trade-name. It is a form of "piggy-backing" done with the assent of the referenced drug company so that, in the case of a generic, if the referenced drug is demonstrated to the satisfaction of the Minister to be bioequivalent to an innovator's drug that already has an NOC, then both generics will get their own NOC for their version of the drug. All of this presupposes however that there is no intervening situation raised by the NOC Regulations.

[10] Justice Lemieux of this Court discussed this situation in *GlaxoSmithKline Inc. v. Canada (Attorney General)*, 2004 FC 1302 in referring to the affidavit of Ms. Bowes, an official from the branch of the Minister (TPD) dealing with these matters at paragraphs 24 and 25:

> ***24*** *Anne Elizabeth Bowes deposes when a manufacturer of a currently marketed drug licences another manufacturer to sell the identical drug in Canada under a different name, the licencee is required to file an administrative new drug submission and such submission must be "cross-referenced" i.e. that it be a certification that all aspects of the drug product to be approved are identical to that of the previously approved product (the cross-referenced product) except for the manufacturer's name and/or product name.*
>
> ***25*** *She adds a cross-referenced submission includes an explicit authorization from the manufacturer of the previously approved product in which its consent to the cross-reference is provided. She also confirms the only other essential element to a cross-referenced submission is the filing of a copy of the proposed product monograph ("PM") for the product to be approved.*

[11] In the present case, Riva has cross-referenced Pharmascience's application. Sanofi-Aventis does not assert that these parties are "privies". If fact, Justice Harrington of this Court found that they were not privies on the evidence before him in another case, *Sanofi-Aventis Inc. v. Laboratoire Riva Inc.* (2007), 2007 FC 532 at paragraphs 21 to 30.

[12] In the present case, Riva appears to have been in discussions, through counsel, with the Minister who appears originally to have taken the position that the Minister would not issue an NOC to Riva since Pharmascience, whose application Riva had cross-referenced, was prohibited by Court Order from proceeding with its application until the relevant Sanofi-Aventis patent rights had expired. This caused Riva to commence judicial review proceedings Court File No. T-896-07.

Evidently discussions between counsel continued. On June 21, 2007 counsel for the Minister wrote a letter to counsel for Riva reversing the Minister's position. The relevant text that letter says:

> *I write in response to your letter of June 14, 2007 in which you asked that the Minister of Health reconsider the decision which is the subject of the above-noted application for judicial review.*
>
> *As discussed, I can advise you that Health Canada did revisit the matter and has, in fact, revised its position with respect of the eligibility of Laboratoire Riva Inc. to receive a notice of compliance for its 'cross-referenced' new drug submission.*
>
> *In particular, 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 ultimately be 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.*
>
> *In light of the above, I look forward to receiving confirmation that Riva has discontinued the above-noted application on a without costs basis.*

[13] Following the date of that letter, Riva discontinued proceedings T-896-07. Other proceedings referred to in that letter, T-127-07, are NOC proceedings brought by Sanofi-Aventis against Riva respecting other alleged patent rights in the drug ramipril. A hearing has taken place in this Court in mid-January 2008 before Justice Martineau and his decision is, at this time, under reserve. There is reference in the letter of June 21, 2007 to a letter which the Minister "will soon be providing to Riva" but that letter is not in the record before me.

SANOFI-AVENTIS' POSITION

[14] Sanofi-Aventis' position is that it seeks to challenge the position taken by the Minister, reversing the earlier position, not to preclude Riva from obtaining an NOC until Pharmascience had achieved its own NOC in respect of the cross-referenced product. Sanofi-Aventis argues that just as an assignee or licensee of Pharmascience should not be allowed to continue with an application for an NOC that had been prohibited as a result of proceedings taken in this Court, so equally should a cross-referenced generic be prohibited even if it were not found to be a privy of the prohibited party. It points to a number of recent decisions in the Federal Court of Appeal criticizing multiple NOC proceedings once findings as to infringement and validity had been made even if the parties are different (e.g. *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 163).

[15] Sanofi-Aventis relies on the decision of the Federal Court of Appeal in *Ferring Inc. v. Canada (Minister of Health)*, 2007 FCA 276 paragraph 5 where that Court reversed a finding that I had made in the Trial Division reported at 2007 FC 300 at paragraphs 98 to 103, affirming that an innovator drug company or "first person", Ferring, had status to challenge a determination of the Minister that certain generics were not "second parties" under the NOC Regulations. The Federal Court of Appeal at paragraph 5 said:

> *"… 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."*

[16] Sanofi-Aventis says that the position taken by the Minister to allow Riva's cross-referenced application to proceed is a decision which directly affects Sanofi-Aventis since it has patents listed in respect of that drug under the NOC Regulations which it has already successfully defended

against a challenge raised by Pharmascience. It argues that the cross-referencing party Riva should not have an opportunity to do so again.

RIVA'S / MINISTER'S POSITION

[17] Riva and the Minister argue that no "decision" was made by the Minister, rather the Minister simply advised Riva that Riva's application for an NOC would continue unimpeded by the negative finding against the cross-referenced drug of Pharmascience. They say that, unlike *Ferring*, *supra*, the NOC Regulations have not been engaged, only the *Food and Drug Regulations*.

[18] They say that Sanofi-Aventis can assert its rights, if any, under the NOC Regulations once Riva's application proceeds and Riva is required to serve a Notice of Allegation. Only then, do they say, that the NOC Regulations would be engaged. Until then, they say, the matter is simply one between the Minister and Riva involving only the *Food and Drug Regulations* and, Sanofi-Aventis has at best, only a commercial interest in the matter. Such interest is, they argue, insufficient to give standing to Sanofi-Aventis citing *Aventis Pharma Inc. v. Canada (Minister of Health)* 2005 FC 1396.

DISPOSITION

[19] At this time, I do not have to make a final determination on the issue of standing unless it is clear and beyond any reasonable doubt that Sanofi-Aventis has no standing to bring this application. I cannot make such a finding. There is some argument to be made that the NOC Regulations have

been engaged and that Sanofi-Aventis' first party rights may be affected. I do not say that Sanofi-Aventis will succeed on that issue and expressly decline to make any determination in that regard. At this time, all that needs to be said is that, given that this is an application, not an action, the Court's resources should not be further expended on the matter by way of a motion to strike. Let the matter be resolved at a hearing of the application itself.

[20] The same disposition applies to the issue as to whether there exists a "decision" or "matter" as would come under the scope of section 18.1 of the *Federal Courts Act*. A reversal of an earlier "decision" may arguably be said to be a "decision". Again, I decline to make any finding and leave the matter to be argued at the hearing of the application

[21] I repeat, except in the clearest of cases, motions of this kind respecting an application should be avoided.

[22] I will leave the disposition of costs to the Judge hearing the application.

ORDER

For the Reasons given:

1. The decision of Prothonotary Aalto dated November 7, 2007 is set aside;

2. The motion to strike is dismissed;

3. Costs are reserved to be dealt with by the Judge hearing the application.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1351-07
STYLE OF CAUSE:	Sanofi-Aventis Canada Inc. v. The Minister of Health et al
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	January 24, 2008
REASONS FOR ORDER AND ORDER:	HUGHES, J.
DATED:	January 31, 2008

APPEARANCES:

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