Date: 20070810

Docket: T-127-07

Citation: 2007 FC 832

Toronto, Ontario, August 10, 2007

PRESENT: Kevin R. Aalto, Esquire, Prothonotary

BETWEEN:

SANOFI-AVENTIS CANADA INC. and
SANOFI-AVENTIS DEUTSCHLAND GmbH

Applicants

and

LABORATOIRE RIVA INC. and
THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

[1] This is a motion by the Defendant (Riva) to strike out the Notice of Application of the Plaintiff (Sanofi-Aventis) or alternatively, to strike out portions of the Notice of Application. In the event the Notice of Application is not struck other ancillary relief is sought. The motion is brought pursuant to section 6(5)(b) of the *Patented Medicines (Notice of Compliance) Regulations* which reads as follows:

> 6(5) In a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application *in whole or in part*

> (b) on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents.
> (emphasis added)

Background

[2] On or about December 5, 2006, Riva served a Notice of Allegation (NOA) on Sanofi-Aventis regarding the drug product ramipril. Riva alleges that it intends to make and market ramipril only for the "old" use of essential hypertension. The patents in issue are Patent No. 2,382,549 and Patent No. 2,382,387 (collectively the HOPE Patents) both of which contain claims to new uses of the old compound ramipril.

[3] In response to the NOA, Sanofi-Aventis commenced this Notice of Application on January 19, 2007 seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance (NOC) to Riva. Sanofi-Aventis sought similar prohibition orders in T-1384-04 and T-1888-04 involving these same parties in respect to four other patents, three of which claimed new uses of ramipril. Those applications were dismissed by the Honourable Mr. Justice Harrington on May 17, 2007. This Notice of Application is the last hurdle to Riva from obtaining its NOC so it can enter the market with its drug ramipril.

[4] Riva's NOA alleges that it will not infringe any of the relevant use claims of the HOPE Patents nor will it induce or procure the infringement of the use claims. Riva's product monograph and other materials have been disclosed to Sanofi-Aventis in the prior proceedings. Riva states that it will include in its product monologue a statement that its ramipril product is approved only for the

use and indication for which the NOC is issued and the Riva product is not to be used for anything other than the approved use and indication.

[5] There are four issues raised in this Notice of Application by Sanofi-Aventis. They are:

1. Riva has no standing to deliver a NOA because it is a privy of Pharmascience Inc.;
2. Riva cannot get a NOC unless and until another generic, Pharmascience Inc., obtains a NOC from the Minister of Health (the Cross-Reference Issue);
3. the NOA is deficient; and,
4. the allegations of non-infringement are not justified.

Are Riva and Pharmascience Privies?

[6] Simply put, the answer is no. This issue was an issue which also arose in the prior proceedings involving these Parties. In *Sanofi-Aventis et al* v. *Laboratoire Riva et al*., [2007] FC 532. The Honourable Mr. Justice Harrington determined that Riva and Pharmascience were not privies. He noted at par. 27:

> However, I am not satisfied that the facts above and the fact that Riva's expert, Dr. Christensen, was first approached by Pharmascience establish that the two were privies. All that has been established is that they have a trade relationship, and that is not enough. (citations omitted).

[7] There is no evidence produced by Sanofi-Aventis in this proceeding which establishes in any way that Riva and Pharmascience are privies. This issue has no chance of success and need not be re-litigated. It is therefore struck out.

The Cross Reference Issue

[8] Sanofi-Aventis alleges in its Notice of Application that:

> 10. In a prior proceeding involving these parties (Court File T-1384-04) Riva's NOA referred to an "ANDS cross-referenced to pms-Ramipril". PMS is Pharmascience Inc. ("Pharmascience"). Pms-ramipril is a reference to a Pharmascience ramipril product.
>
> 11. Pursuant to the Order of Madam Justice Snider dated March 11, 2005, the Minister is prohibited from issuing a NOC to Pharmascience for ramipril until expiry of the patent at issue in the proceeding: 2005 FC 340; aff'd 2006 FCA 229.
>
> 12. No NOC can issue to Riva since any alleged Riva submission is cross-referenced to a submission for which the Minister cannot presently issue a NOC.

[9] Again, this issue has no chance of success. There are two compelling reasons why this is so. First, the undisputed evidence before the Court includes a letter dated June 21, 2007 from counsel for the Minister of Health to counsel for Riva in which it is stated:

> 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.

[10] Second, in the *Sanofi-Aventis* case, *supra*, Justice Harrington also dealt with this issue and for all intents and purposes the issue is now *res judicata*. Justice Harrington commented with respect to this issue as follows:

> Sanofi-Aventis also argues that these proceedings are abusive in that it is the Minister's policy not to issue an NOC where a submission cross-references an earlier submission, unless and until that earlier submission is successful. The application by Pharmascience was unsuccessful. However, I am not concerned with whatever policy the Minister may have. What are before me are allegations of invalidity and non-infringement, no more and no less. If the Minister decides not to issue an NOC on other grounds, then that decision might be the subject of a separate judicial review.

It is clear from both the letter and this passage that the Cross Reference Issue will not succeed. It is struck out.

Deficiency of NOA

[11] Sanofi-Aventis makes a number of allegations regarding the sufficiency of Riva's NOA. The primary allegation being that Riva has not produced the product monograph, labeling or marketing materials for its ramipril product. Those materials are specifically identified in the NOA as being the materials provided to Sanofi-Aventis and its counsel in proceedings T-1888-04 and T-1384-04, the cases decided by Justice Harrington. The NOA consents to Sanofi-Aventis and its counsel reviewing those materials "for the purpose of determining whether to proceed with litigation pursuant to the *Regulations*".

[12] In this proceeding, Sanofi-Aventis argues that because there were protective orders in those prior proceedings the review of the materials cannot be relied upon by Sanofi-Aventis. This argument is without merit. The materials are in the possession of Sanofi-Aventis by virtue of the prior proceedings, even though subject to a protective order, and Riva has unequivocally stated that Sanofi-Aventis may review them in this proceeding for the "purpose" of determining whether to

proceed with litigation. It can hardly be said that Sanofi-Aventis is in some way denied the opportunity to understand the product monograph, labeling or marketing materials or that it is somehow prejudiced by the protective order. The parties have litigated over Riva's ramipril product in prior proceedings.

[13] Further, the evidence filed by Sanofi-Aventis is to the effect that dispensing pharmacists usually do not have any reason "to consult the generic's product monograph" (Nenadovich Affidavit, par. 10). There is no evidence that Sanofi-Aventis will be influenced in any way by the contents of the product monograph. Thus, this allegation has no chance of success.

[14] Of the remaining allegations of insufficiency of the NOA, the only one worth mentioning is that Riva fails to specify what "reports of the HOPE Study" it is referring to in the NOA. The HOPE Study is specifically described in the NOA and it is readily available in the literature dealing with ramipril. Sanofi-Aventis knows the case it has to meet. The allegations of insufficiency of the NOA have no chance of success and are struck out.

Infringement

[15] Riva asserts in its NOA that it will not induce or procure infringement of the HOPE Patents. Sanofi-Aventis disputes this assertion and alleges that patients will infringe the HOPE Patents and that Riva will be connected to this infringement. Sanofi-Aventis has filed affidavits from ten individuals, seven of which did not file any evidence in the prior applications. The new affiants attest to the following facts:

- Contrary to Riva's allegations, the possibility that patients may be exposed to allegations and threats of infringement due to their use of a drug will not occur to physicians; their prescribing decisions are based on the demonstrated effectiveness of a drug; (Arnold Affidavit, paras. 24-25; Lin Affidavit, paras. 33-34)

- Most prescriptions for Sanofi-Aventis' ramipril products are given to patients for the HOPE indication; (Wilson Affidavit, para. 13; Gravel Affidavit, para. 25)

- Riva will likely promote its ramipril products based on price rather than for any specific indication; (Nenadovich Affidavit, para. 13)

- Riva will likely apply for full interchangeability listing at the provincial level and will proceed to negotiate exclusive supply contracts with independent pharmacy owners, retail chains and other buying groups, such that they will be *compelled* to dispense Riva's ramipril products for all uses, including the HOPE indication, which is the main use of ramipril in Canada today. (Gravel Affidavit, para. 25)

[16] In summary, Sanofi-Aventis argues that Riva will use price and exclusive supply contracts to induce or procure infringement. Sanofi-Aventis alleges that this conduct by Riva will be the "more" (i.e. in addition to making and selling the drug) that establishes inducement or procurement. In *Pharmascience Inc* v. *Sanofi-Aventis et al*., [2006] FCA 299, Sharlow J.A. makes the point that mere marketing by a generic manufacturer "without more" does not amount to infringement by the generic manufacturer or infringement through inducement or procurement by others (see par. 35). On this issue, it is not "plain and obvious" that the allegation of inducement or procurement of

infringement has no possibility of success. In the prior proceedings heard by Justice Harrington, there was some discussion of inducing and procuring of infringement. In Sanofi-Aventis, *supra*, Justice Harrington noted:

> The NOAs were sufficiently detailed, and can hardly be Sanofi-Aventis to have taken Sanofi-Aventis by surprise. It may well be, as Sanofi-Aventis alleges, that provincial government, physicians, pharmacists and patients will infringe the patents. If so, the remedy is to give them notice, and to sue for patent infringement, notwithstanding that this might be a disastrous business plan. The remedy is not to prohibit the Minister from allowing the generic onto the marketplace. Furthermore, drawing on the Manitoba court of Appeal, and as discussed in the following paragraphs, a concession by a generic drug company does not constitute an admission binding on physicians and pharmacists (Astrazeneca Canada Inc. v. Apotex Inc., 2006 MBCA 21, [2006] M.J. 38 (QL) at paragraph 55).

[17] Sanofi-Aventis has now led specific evidence relating to the use of price and exclusive supply contracts by Riva to compel the use of Riva's rampiril product. This is a contentious issue and one that should not be struck at this point in the proceeding. It is not clear and obvious that Sanofi-Aventis has, without any doubt, no chance of success on this issue.

[18] During argument counsel for Sanofi-Aventis took issue with the jurisdiction of the Court to strike out or dismiss only parts of the Notice of Application. They argued that s. 6(5)(1) of the *Regulations* is an "all or nothing regime" and they do not permit the Court to dismiss or strike out portions of the Notice of Application. The phrase "in whole or in part" they argue does not mean that an issue or issues can be dismissed. They further argued that as this was a disputed interpretation of s. 6(5)(1)(b) that the correct interpretation could only be decided at a full hearing of the application. With respect, this argument makes no sense. The Notice of Application is akin to a

pleading and while it must be read as generously as possible the court has the jurisdiction under the *Regulations* to strike out the Notice of Application "in whole or in part". The plain meaning of the words "in whole or in part" in s. 6(5)(1)(b) when read in their entire context and in their grammatical and ordinary sense compels an interpretation that the Court has the authority to dismiss a part of the Notice of Application which can only rationally refer to specific grounds or issues raised.

[19] In their Notice of Motion, Riva seeks an order that this application proceed as a specially managed proceeding in the event the Court determines that all or part of it should continue. They also seek a confidentiality order in similar terms to the confidentiality order in the prior proceedings. During argument, counsel for Sanofi-Aventis did not take issue with designating this application as a specially managed proceeding nor did they make submissions on the form of the proposed draft confidentiality order. The proposed draft confidentiality order is limited only to the information contained in Riva's Abbreviated New Drug Submission. The proposed draft order shall issue in the form annexed as Schedule "A" to the Notice of Motion.

[20] As Riva has had substantial success on this motion they are entitled to their costs.

ORDER

THIS COURT ORDERS that

1. This proceeding shall continue as a specially managed proceeding.

2. The issues raised in paragraphs 10, 11, 12, 13, 14, 15 and 16 of the Notice of Application are struck out.

3. The confidentiality order attached as Schedule "A" to the Notice of Motion herein is approved and shall issue in that form.

4. The Applicant, on or before August 31, 2007, shall submit to the court a joint proposal for completing the remaining steps in this Application. In the event the parties are unable to agree on a joint timetable, each party shall submit its own timetable together with dates of availability for a case management teleconference.

5. The Respondent, Laboratoire Riva Inc., shall have costs of this motion in the cause.

"Kevin R. Aalto"
Prothonotary

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-127-07
STYLE OF CAUSE:	SANOFI-AVENTIS CANADA LTD. v. LABORATOIRE RIVA INC. ET AL
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DATE OF HEARING:	MONDAY, JULY 9, 2007
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DATED:	AUGUST 10, 2007

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