Date: 20071214

Docket: T-127-07

Citation: 2007 FC 1317

Ottawa, Ontario, December 14, 2007

PRESENT: The Honourable Mr. Justice Shore

BETWEEN:

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

Applicants

and

LABORATOIRE RIVA INC. and THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

OVERVIEW

[1] After all cross-examinations had taken place in this application under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (Regulations) and approximately one week before the applicants' Application Record was due, the respondent generic company, Laboratoire Riva Inc. (Riva), brought a motion to seek leave to file further evidence, namely an affidavit of Mr. Jean-Paul Lefebvre (Lefebvre Affidavit). The motion was heard on December 3, 2007.

[2] Leave was granted, allowing Riva to file the further evidence by Order, dated December 5, 2007.

[3] In so doing, an error occurred in fact, law and/or principle.

FACTS

The Application

[4] Riva sent a letter, dated December 5, 2006 (NOA) asserting non-infringement of Canadian Patents 2,382,549 and 2,382,387 (collectively the "HOPE Patents"). While the Riva NOA also alleges patent invalidity on several bases, Riva has abandoned all of its invalidity attacks, and the sole live allegation is non-infringement of the HOPE Patents which claim the HOPE Indication, the main use for ramipril in Canada today. (Affidavit of Guy Pridham (Pridham Affidavit), Exh. C; Sanofi-Aventis' Motion Record (MR), Vol. 1, Tab 5, p. 202.)

[5] In the NOA, Riva refers (see page 2) to its pending product monograph provided to Sanofi-Aventis under a Protective Order in another proceeding and asserts (see page 4) that it will include a disclaimer in a revised product monograph as follows:

> … In its product monograph, Riva will include a statement that the Riva Product is approved for only the use and indication for which the NOC is issued, that it should be used for such uses and indication and that no statement or reference in the product monograph should be construed or interpreted to be an encouragement, suggestion or recommendation that the Riva Product is to be used for anything but the approved use and indication.

(Pridham Affidavit, Exh. C; MR, Vol. 1, Tab 5, p. 205.)

[6] In response to the NOA, Sanofi-Aventis commenced this application by Notice of Application, dated January 19, 2007, and subsequently filed its evidence on the merits.

[7] In September 2007, in response to Sanofi-Aventis' evidence on the merits, Riva filed its evidence consisting only of an affidavit of Dr. Guy Pridham (Pridham Affidavit), portions of which (paras. 7-9 and Exhibit A) are marked confidential subject to the Protective Order, dated August 10, 2007. The Pridham Affidavit gives evidence with respect to Riva's product monograph and Health Canada's requirements for regulatory submissions. (Pridham Affidavit; MR, Vol. 1, Tab 5, p. 128.)

[8] The Pridham Affidavit is silent with respect to the disclaimer referred to in Riva's NOA.

[9] Following the filing of all evidence on the merits, the respective sides proceeded to complete cross-examinations subject to outstanding questions.

[10] Dr. Pridham was cross-examined on November 2, 2007. Prior to his cross-examination, counsel for Sanofi-Aventis requested that Dr. Pridham bring "all versions of Riva's proposed product monograph (PM) for its ramipril capsules" to his cross-examination. The request was refused. (MR, Vol. 1, Tab 5, p. 250.)

[11] During his cross-examination, Dr. Pridham confirmed that the latest version of Riva's product monograph had not been produced. Sanofi-Aventis' request for the production of the latest product monograph was refused by Riva on the basis that it was not relevant to the merits.

(Transcript for the Cross-Examination of Guy Pridham, held November 2, 2007 (Pridham Transcript); MR, Vol. 2, Tab 5, pp. 343-344 (Qs. 367-373).)

[12] During his cross-examination, Dr. Pridham also gave answers, which Sanofi-Aventis submits, materially undermined his affidavit evidence and Riva's position in respect of its allegation of non-infringement. In particular, Dr. Pridham was candid in admitting that Riva will offer pharmacists financial inducements to add Riva's ramipril product to their inventories and to remove any other generic ramipril brand from their inventories. The admissions are relevant to whether Riva will be inducing or procuring pharmacists and patients to use Riva's ramipril for the patented HOPE Indication, not disputed to be the main use of ramipril. The admissions also appear to contradict Dr. Pridham's affidavit evidence to the effect that Riva will not be entering into exclusive sales agreements with pharmacists. (Pridham Transcript; MR, Vol. 2, Tab 5, pp. 321, 323, 352, 370 (Qs. 282-285, 292-293, 440-441, 475).)

[13] Sanofi-Aventis brought a motion to compel production of the latest Riva product monograph and the Court disagreed with Riva's position. By Order, dated November 14, 2007, the Prothonotary ordered Riva's witness, Dr. Pridham, to "produce Riva's current product monograph for Riva-Ramipril". The Court Order states "[t]he NOA referred to a draft monograph which has evolved into another version of the product monograph. This document is relevant to the issue on this Application and should be produced". (Order of the Prothonotary, dated November 14, 2007; MR, Vol. 1, Tab 4, p.p. 110 and 113.)

[14] On November 20, 2007, Riva produced its current product monograph with comments from Dr. Pridham and counsel for Riva. Sanofi-Aventis objected to the comments and asked that they be deleted. Riva subsequently agreed that the comments should not properly be included but sought leave to file further evidence. (MR, Vol. 1, Tab 4, pp. 58, 96, 100, 101.)

[15] By Order, dated November 22, 2007, this Court ordered that the hearing of this application shall take place on January 15, 2008 and that Sanofi-Aventis' record shall be served and filed on or before December 7, 2007. (Order of the Prothonotary, dated November 22, 2007; MR, Vol. 1, Tab 4, p. 115.)

Riva's Motion under Appeal

[16] Riva subsequently moved to seek leave to file the proposed Lefebvre Affidavit, following the filing of all evidence on the merits and the cross-examination thereon.

[17] Mr. Lefebvre is not an employee of Riva, but is referred to as a Consultant, Regulatory Affairs for Riva. Mr. Lefebvre gave evidence on behalf of Riva. (Lefebvre Affidavit; MR, Vol. 1, Tab 4, p. 40, para. 1.)

[18] The Lefebvre Affidavit attaches Riva's most recent draft product monograph, which he confirms is on file with the Minister. (Lefebvre Affidavit; MR, Vol. 1, Tab 4, p. 40, para. 2, Exh. "A".)

[19] Paragraphs 2 to 6 of the Lefebvre Affidavit indicate that Riva updated reference 17 of its earlier draft product monograph to refer to Sanofi-Aventis' product monograph as of October 24, 2006. (Lefebvre Affidavit; MR, Vol. 1, Tab 4, p. 40-41, paras. 2-6.)

[20] The remainder of the Lefebvre Affidavit addresses Riva's intention to include the disclaimer set out in the NOA, dated December 5, 2006, into a further version of a product monograph, if the "Court deems it necessary". (Lefebvre Affidavit; MR, Vol. 1, Tab 4, p.41, paras. 7-8.)

[21] Consequently, the Lefebvre Affidavit (1) includes certain comments which Riva attempted to include in the Court ordered answers, but then agreed could not be properly included; (2) addresses the content of Riva's product monograph, including the disclaimer referred to in Riva's NOA; but it is not addressed in Riva's previous evidence on the merits; and (3) raises a matter not referred to in the NOA (namely, that the disclaimer will be offered only if required by the Court).

[22] The Lefebvre Affidavit is improper as Riva appears to be "splitting its case" at this late stage of the litigation after cross-examinations have been completed, and it raises a new matter not in the NOA. Moreover, it could have a prejudicial effect to Sanofi-Aventis' position on the merits because Riva could rely on it at the hearing on the merits on January 15, 2008. This could affect Sanofi-Aventis' evidence and argument in respect of inducing and procuring infringement of the HOPE Patents by others.

[23] By Order, dated December 5, 2007, Riva was granted leave to file the Lefebvre Affidavit and extended the due date for filing Sanofi-Aventis' application record by one week to December 14, 2007. (Order of the Prothonotary, dated December 5, 2007; MR, Vol. 1, Tab 2, p. 11.)

[24] In brief reasons for the Order, it is noted that Sanofi-Aventis opposed Riva's motion to file further evidence on the merits "arguing that [Riva] is splitting its case, that the evidence was available earlier and that to permit filing at this time will cause prejudice". The Order states that "none of these arguments hold water". Furthermore, it is noted that "while the evidence was available earlier, Riva was not relying on it and had not produced it", "there is no prejudice to the Applicant" and the evidence "will assist the interests of justice and assist the Court". (Order of the Prothonotary, dated December 5, 2007; MR, Vol. 1, Tab 2, p. 12.)

ISSUE

[25] The sole issue on this motion is whether an error occurred in granting Riva leave to file the Lefebvre Affidavit.

ANALYSIS

Standard of Review

[26] On appeal, a judge may disturb a discretionary order of a Prothonotary, where:

a) the question raised in the motion is vital to the final issue of the case; or

b) the order is clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts.

(*Merck & Co., Inc. v. Apotex Inc.*, 2003 FCA 488, [2003] F.C.J. No. 1925 (QL), para. 19.)

Test for Filing Further Evidence in an Application under the Regulations

[27] Additional affidavits are not permitted in the ordinary course and constitutes extraordinary relief. In order to file such affidavits, the moving party must obtain leave of the Court. (Rule 312 of the *Federal Courts Rules*, SOR/98-106.)

[28] In an application under the Regulations, a supplemental affidavit should be allowed in only very limited circumstances. It cannot be used to introduce additional arguments. (*Solvay Pharma Inc. v. Apotex Inc.*, 2007 FC 857, [2007] F.C.J. No. 1129 (QL), para.18; *Abbott Laboratories Ltd. v. Nu-Pharm Inc.* (1998), 82 C.P.R. (3d) 216, at 219 (para. 11) (F.C.T.D.).)

[29] The Court has distilled the following test for filing further evidence in an application under the Regulations:

> … the Court may allow the filing of additional evidence if the following requirements are met:
>
> a) the evidence to be adduced will serve the interests of justice;
>
> b) the evidence will assist the Court;
>
> c) the evidence will not cause substantial or serious prejudice to the other side;
>
> d) the evidence was not available at an earlier date.

(*Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FC 984, [2006] F.C.J. No. 1243 (QL), para. 22; *Purdue Pharma v. Novopharm Ltd.*, 2006 FC 385, [2006] F.C.J. No. 497 (QL), para. 13.)

An error occurred in finding that Riva is not "splitting its case"

[30] Although it was correctly acknowledged that the evidence was available earlier, an error occurred in failing to appreciate that much of the evidence in the Lefebvre Affidavit was referred to in the NOA; therefore, Riva was previously relying on it and it was previously relevant to the merits of the application.

[31] As previously mentioned, in the NOA, Riva refers to its pending product monograph provided to Sanofi-Aventis under a Protective Order in another proceeding and asserts that it will include a disclaimer in a revised product monograph. Hence, the language of the NOA clearly contemplates that it will revise its product monograph to include the disclaimer. Riva had the intention in December 2006 to rely on a revised product monograph. The revised product monograph predates the Pridham Affidavit; therefore, any further evidence on Riva's revised product monograph should have been addressed in the Pridham Affidavit.

[32] As the Lefebvre Affidavit addresses the content of Riva's revised product monograph, including the disclaimer referred to in the NOA, the evidence was previously relied upon by Riva and was relevant to the merits of the application prior to the Court ordered production in November, 2007.

[33] In fact, the Order, dated November 14, 2007, recognizes that the revised product monograph was relevant to the issue on this application and should be produced. (Order of the Prothonotary, dated November 14, 2007; MR, Vol. 1, Tab 4, p.110.)

[34] A further error occurred in failing to appreciate that some of the evidence in the Lefebvre Affidavit went beyond the NOA which limited the legal and factual basis which could be relied on by Riva. In particular, the Lefebvre Affidavit led evidence that the disclaimer referred to in the NOA will be offered only if required by the Court. This evidence is clearly beyond the NOA and, thus, it is not open to Riva to file this evidence in an attempt to amend the NOA. (*AB Hassle v. Canada (Minister of National Health and Welfare)* (2000), 7 C.P.R. (4th) 272, paras. 21 and 27; *Hoffmann-La Roche Ltd. v. Apotex Inc.* (1997), 72 C.P.R. (3d) 480, at 485 (F.C.T.D.), aff'd (1998), 82 C.P.R. (3d) 384 (F.C.A.); *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1381, [2005] F.C.J. No. 1691 (QL), paras. 12-13.)

[35] The facts were misapprehended in concluding that Riva is not "splitting its case" at this late stage of the litigation or an error in law occurred by incorrectly applying the applicable jurisprudential test for the filing of further evidence in a case under the Regulations.

An error occurred in the finding that, by permitting Riva to file the further evidence at this late stage of the litigation, it would not cause prejudice to Sanofi-Aventis

[36] It was not recognized that Riva is "splitting its case" at this late stage of the litigation which, by its very nature, results in prejudice to Sanofi-Aventis and that the brief extension granted to Sanofi-Aventis is not sufficient to alleviate the resulting prejudice to Sanofi-Aventis.

[37] In a similar situation, this Court has disallowed the filing of further evidence recognizing that the opposing party could suffer a prejudice given the time constraint in a case under the Regulations. (*Solvay*, above, paras. 26 and 27.)

[38] This Court has also disallowed the filing of further evidence as the further late filing would cause prejudice to the opposing party even though the moving party suggested the Court extend the opposing party the courtesy of a further reply. (*Abbott*, above, para. 11.)

[39] In this case, Riva attempted to file the Lefebvre Affidavit which could alter the context with respect to Dr. Pridham's cross-examination answers; thus, the Lefebvre Affidavit is clearly improper, as Riva, for all intents and purposes, appears to be "splitting its case" at this late stage of the litigation and raises a new matter not raised in the NOA. Allowing Riva to split its case, at this stage, appears prejudicial to Sanofi-Aventis's position on the merits.

An error occurred in finding that the further evidence will assist the interests of justice and the Court

[40] While the interests of justice are better served if the Court has all relevant information before it, filing further evidence must be done pursuant to the rules and there are limits, also, for the very purpose of ensuring the interests of justice are understood and met. (*Solvay*, above, para. 23.)

[41] It is not in the interests of justice to allow a party to proceed far into an application and then to change its litigation approach, as is the case here, because applications under the Regulations are meant to be dealt with in an expeditious manner. It is not in the overall interests of justice that leave

be granted to file the further evidence in circumstances where, after the completion of cross-examinations and just before the hearing date, Riva appears to have changed its litigation strategy to lead evidence with respect to the proposed revised product monograph referred to in the NOA. (*AstraZeneca AB v. Apotex Inc.*, 2004 FC 71, [2004] F.C.J. No. 54 (QL), paras. 41 and 42.)

[42] Moreover, with respect to the proposed evidence on the disclaimer, an error occurred in finding that the evidence will assist the interests of justice and the Court despite that Riva did not explain, in its motion materials, how this proposed evidence will serve the interests of justice and will assist the Court in its determination of the merits. Quite simply, it clearly does not appear in the interests of justice to permit a party to split its case.

Brief Extension of Time without delaying the date of the hearing for January 15, 2008

[43] Riva has agreed to make Mr. Lefebvre available for cross-examination on his affidavit on December 17, 2007.

[44] Riva agreed to the Applicants' request for an extension of the deadline for filing its Record on December 21, 2007.

[45] The Court, pursuant to Rule 53, extends Riva's deadline for filing its Application Record, to January 7, 2008.

[46] Thus, the hearing fixed for January 15, 2008 will not be delayed and will proceed as scheduled.

CONCLUSION

[47] In view of the foregoing, paragraphs 1 and 2 of the Prothonotary's Order, dated December 5, 2007, is set aside, with costs.

ORDER

THIS COURT ORDERS that paragraphs 1 and 2 of the Prothonotary's Order, dated December 5, 2007, be set aside, with costs.

"Michel M.J. Shore"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-127-07
STYLE OF CAUSE:	SANOFI-AVENTIS CANADA INC. and SANOFI-AVENTIS DEUTSCHLAND GmbH and LABORATOIRE RIVA INC. and THE MINISTER OF HEALTH
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	December 13, 2007
REASONS FOR ORDER AND ORDER:	SHORE J.
DATED:	December 14, 2007

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