Date: 20080620

Docket: T-2300-06

Citation: 2008 FC 782

Ottawa, Ontario, June 20, 2008

PRESENT: The Honourable Madam Justice Mactavish

BETWEEN:

SANOFI-AVENTIS CANADA INC.

Applicant

and

PHARMASCIENCE INC. and THE MINISTER OF HEALTH

Respondent

and

SCHERING CORPORATION

Respondent / Patentee

REASONS FOR JUDGMENT AND JUDGMENT

[1] This proceeding under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("*PM(NOC) Regulations*") has proceeded in a somewhat unusual, two-stage fashion. Arguments relating to issue estoppel and abuse of process advanced by both sides were determined first. What remains in issue between the parties at this point are the form of the order that should go

disposing of Sanofi-Aventis' application for prohibition, as well as the determination of the issue of costs.

Background

[2] Canadian patent No. 1,341,206 (the "'206 patent") is owned by Schering Corporation. Under licences from Schering, Aventis Pharma Inc. and its successor, Sanofi-Aventis Canada Inc. manufacture a drug containing a medicine called ramipril, which is an ACE inhibitor. Ramipril is one of the compounds covered by the '206 patent.

[3] In a November 15, 2006 Notice of Allegation, Pharmascience Inc. asserted that the '206 patent was invalid on several different grounds, including lack of sound prediction, lack of utility, the claims being broader than the invention, and by operation of section 53(1) of the *Patent Act*, R.S., 1985, c. P-4.

[4] This was the second Notice of Allegation that had been served by Pharmascience alleging the invalidity of the '206 patent. An earlier NOA was found by Justice Snider not to have been justified: see *Aventis Pharma Inc. v. Pharmascience Inc.*, 2005 FC 340 ("*Aventis Pharma*"), aff'd (2006 FCA 229), leave to appeal to the Supreme Court of Canada denied ([2006] S.C.C.A. No. 362).

[5] In response to Pharmascience's November 15, 2006, Notice of Allegation, Sanofi-Aventis Canada Inc. commenced this application, seeking to prohibit the Minister of Health from issuing a Notice of Compliance to Pharmascience in relation to ramipril until after the expiry of the '206

patent. In its Notice of Application, Sanofi-Aventis also sought a declaration that Pharmascience's November 15, 2006 Notice of Allegation was "invalid".

[6] In its response to Sanofi-Aventis' Notice of Application, Pharmascience asserted that it was an abuse of process for Sanofi-Aventis to dispute Pharmascience's allegation that the '206 patent was invalid for lack of sound prediction, in light of my decision in *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283 ("*Apotex*").

[7] In *Apotex*, I found that Schering did not have a sound basis for predicting the utility of the invention claimed in the '206 patent at the time that it applied for the patent. My decision in *Apotex* was subsequently upheld by the Federal Court of Appeal: see *Aventis Pharma Inc. v. Apotex Inc.*, 2006 FCA 64. Leave to appeal was refused by the Supreme Court in April of 2006: [2006] S.C.C.A. 136.

[8] In an Order dated July 25, 2007, Prothonotary Tabib found that Pharmascience's and Sanofi-Aventis' arguments were interdependent, and that they had to be determined in advance of any determination as to whether the allegations in Pharmascience's NOA were justified. As a consequence, she ordered that Sanofi-Aventis' request for a declaration that Pharmascience's November 15, 2006 Notice of Allegation was not a valid NOA, and Pharmascience's argument that Sanofi-Aventis was estopped from arguing the validity of the '206 patent in this proceeding be determined first. These issues have been referred to collectively in this proceeding as "the First Issue".

[9] In *Sanofi-Aventis Canada Inc. v. Pharmascience Inc.*, 2007 FC 1057, I found that the reasoning of the Federal Court of Appeal in *Pharmascience Inc. v. Canada (Minister of Health) et al.*, 2007 FCA 140 ("*Abbott*") applied in this case. As a consequence, I held that as Pharmascience's allegations of invalidity asserted in its first NOA had been finally determined, issue estoppel should operate to preclude it from making further allegations of invalidity with respect to the '206 patent, on different grounds. I also declined to exercise my discretion to allow Pharmascience to proceed with its allegations of invalidity.

[10] My decision was recently upheld by the Federal Court of Appeal: see *Pharmascience Inc. v. Sanofi-Aventis Canada Inc.*, 2008 FCA 213.

[11] In the order issued on November 27, 2007 with respect to the First Issue, I observed that other issues relating to this application remained to be determined, stating that:

> These issues may include - but are limited to - whether a prohibition order should issue, whether the application should be deemed to have been discontinued, the implications of my decision in relation to section 8 of the *PM(NOC) Regulations*, and who should bear the costs relating to the application (apart from those associated with the resolution of the First Issue).

[12] Based upon the parties' submissions, it appears that what actually remains in issue at this point are the form that the order disposing of Sanofi-Aventis' application for prohibition should take, and the determination of issues of costs.

What Form Should the Order Disposing of Sanofi-Aventis' Application Take?

[13] As I understand Pharmascience's argument, it says that as a result of the decision of the Federal Court of Appeal in *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 163 ("*Novopharm*"), "the validity of the '206 patent is not a fact that can be put into play by Sanofi-Aventis". As a result, Pharmascience says, Sanofi-Aventis cannot seek an order of prohibition, given that such relief is only available in relation to a valid patent.

[14] In *Novopharm*, the Federal Court of Appeal held that it was an abuse of process for an innovator company to assert the validity of a patent in a Notice of Application under the *PM(NOC) Regulations* involving one generic, if the same allegation of invalidity had already been found to be justified in an earlier *PM(NOC)* proceeding involving a different generic.

[15] Given that I found in *Apotex* that the generic's allegations of invalidity with respect to the '206 patent were justified, Pharmascience says that there is no basis on which prohibition can issue in favour of Sanofi-Aventis in this case.

[16] This was essentially the argument that was advanced by Pharmascience in relation to the First Issue. In this regard, I found that Sanofi-Aventis' allegation that Pharmascience is precluded from making further allegations of invalidity in relation to the '206 patent by the doctrines of abuse of process, *res judicata* and/or issue estoppel had to be determined before addressing Pharmascience's contention that it was an abuse of process for Sanofi-Aventis and Schering to argue the validity of the '206 patent.

[17] Having then found that Pharmascience was estopped from relying on allegations of invalidity in relation to the ’206 patent in its second Notice of Allegation, I concluded that the question of the scope of Sanofi-Aventis’ ability to assert the validity of the patent in its Notice of Application did not arise in this case.

[18] In determining whether prohibition should issue here, it is helpful to have regard to the wording of section 6 of the *PM(NOC) Regulations*, which provides that:

6. (1) A first person may, within 45 days after being served with a notice of allegation under paragraph 5(3)(*a*), apply to a court for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of a patent that is the subject of the notice of allegation.	**6.** (1) La première personne peut, au plus tard quarante-cinq jours après avoir reçu signification d’un avis d’allégation aux termes de l’alinéa 5(3)*a*), demander au tribunal de rendre une ordonnance interdisant au ministre de délivrer l’avis de conformité avant l’expiration du brevet en cause.
(2) The court shall make an order pursuant to subsection (1) in respect of a patent that is the subject of one or more allegations if it finds that none of those allegations is justified.	(2) Le tribunal rend une ordonnance en vertu du paragraphe (1) à l’égard du brevet visé par une ou plusieurs allégations si elle conclut qu’aucune des allégations n’est fondée.

[19] Pharmascience acknowledges that the sole substantive allegation raised by its November 15, 2006, Notice of Allegation is its allegation that the ’206 patent is invalid. Given my earlier ruling that Pharmascience is estopped from asserting the invalidity of the ’206 patent, it follows that there is no allegation contained in the November 15, 2006, Notice of Allegation that is justified.

[20] As a consequence, based upon subsection 6(2) of the Regulations, I am satisfied that an order should issue prohibiting the Minister from issuing a notice of compliance to Pharmascience until after the expiration of the ’206 patent.

Costs

[21] In my order relating to the First Issue, I awarded Sanofi-Aventis its costs associated with the determination of the First Issue, including the cost of second counsel, to be assessed at the upper end of Column 5 of Tariff B, as well as its reasonable disbursements. In light of the limited role that Schering played in the proceeding, I awarded it its costs at the upper of Column 3 of Tariff B.

[22] What remains to be determined are the costs to be awarded in relation to the balance of this application, including those relating to the motion for summary dismissal brought by Pharmascience. In dismissing that motion, Prothonotary Tabib ruled that the costs of that motion should be in the cause.

[23] Pharmascience says that it is content to have Sanofi-Aventis and Schering receive their costs on the same scales as were awarded in relation to the First Issue, subject to two caveats.

[24] Firstly, Pharmascience says that Sanofi-Aventis should not be entitled to reimbursement for the costs of its expert witnesses, whose evidence was directed to the validity of the ’206 patent, given that Sanofi-Aventis was not in a position to assert the validity of the patent.

[25] Secondly Pharmascience says that the motion for summary dismissal brought before Prothonotary Tabib was not frivolous, and that this should affect the costs awarded in this regard.

[26] Pharmascience also objects to certain portions of the affidavit of Gunars Gaikis, filed in relation to the issue of costs. Mr. Gaikis was lead counsel to Sanofi-Aventis throughout much of this proceeding. According to Pharmascience, portions of Mr. Gaikis' affidavit contain contentious statements relating to matters which are for the Court to decide, which statements should be given little or no weight by the Court.

[27] Dealing first with Mr. Gaikis' affidavit, I note that the affidavit does not deal with substantive matters relating to this application, but is confined to the issue of costs. That said, I am prepared to give little weight to those portions of Mr. Gaikis' affidavit identified at paragraph 99 of Pharmascience's memorandum of fact and law.

[28] Insofar as the costs of Sanofi-Aventis' four expert witnesses are concerned, I note that the affidavits of these witnesses were sworn between April 5 and April 13, 2007. The Federal Court of Appeal's decision in *Novopharm* was not released until April 23, 2007.

[29] As a result, at the time that the affidavits were prepared, it was not yet clear whether it was an abuse of process for an innovator company to assert the validity of a patent in a Notice of Application under the *PM(NOC) Regulations* involving one generic, if the same allegation of

invalidity had already been found to be justified in an earlier *PM(NOC)* proceeding involving a different generic.

[30] As the jurisprudence notes, in awarding costs, the need for adducing the evidence of expert witnesses should not be determined with the benefit of hindsight. Rather, the task for the Court is to ascertain whether the party's conduct in adducing the evidence in question was reasonable at the time that the evidence was led: see, for example, *Rothmans, Benson & Hedges et al. v. Imperial Tobacco Ltd.* (1993), 50 C.P.R. (3d) 59 at 65.

[31] In these circumstances, I am satisfied that it was reasonable for Sanofi-Aventis to have filed expert evidence relating to the issue of validity, when faced with an NOA from Pharmascience alleging that the '206 patent was invalid. As a consequence, Sanofi-Aventis is entitled to the costs of its expert witnesses, namely Professor Wuest and Drs. Nelson, Timmermans and Chong.

[32] I am also satisfied that Sanofi-Aventis and Schering should have their costs associated with Pharmascience's motion for summary dismissal, at the upper end of Column 5 of Tariff B, in Sanofi-Aventis' case, and the upper end of Column 3 of Tariff B in the case of Schering, together with their reasonable disbursements. None of these costs would have been incurred had Pharmascience not endeavoured to re-litigate a battle that it had already fought and lost.

[33] Finally, I do not understand Pharmascience to take issue with Sanofi-Aventis' entitlement to the costs of second counsel. In any event, this was a matter of some complexity, and both sides

were represented by two counsel. In the circumstances, Sanofi-Aventis should be entitled to the costs of second counsel.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES that:

1. The application is granted;

2. The Minister of Health is prohibited from issuing a Notice of Compliance to Pharmascience in respect of its ramipril capsules 1.25 mg, 2.5 mg, 5 mg and 10 mg, until after the expiration of Canadian patent No. 1,341,206;

3. Sanofi-Aventis shall have its costs of this application, as agreed by the parties or as assessed, at the upper end of Column 5 of Tariff B, including the costs of second counsel, the costs of the summary dismissal motion, the costs of the expert witnesses and any other reasonable disbursements, but not including the costs already awarded to Sanofi-Aventis in relation to the determination of the First Issue; and

4. Schering shall have its costs of this application, as agreed by the parties or as assessed at the upper of Column 3 of Tariff B, together with its reasonable disbursements, but not including the costs already awarded to Schering in relation to the determination of the First Issue.

"Anne Mactavish"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

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