

Date: 20090915

**Dockets: T-482-03
T-2300-06**

Citation: 2009 FC 915

Ottawa, Ontario, September 15, 2009

PRESENT: The Honourable Mr. Justice Zinn

Docket: T-482-03

BETWEEN:

**AVENTIS-PHARMA INC. and
AVENTIS PHARMA DEUTSCHLAND GmbH**

Applicants

and

**PHARMASCIENCE INC. and
THE MINISTER OF HEALTH**

Respondents

and

SCHERING CORPORTION

Respondent/Patentee

AND BETWEEN:

Docket: T-2300-06

SANOFI-AVENTIS CANADA INC.

Applicant

and

**PHARMASCIENCE INC. and
THE MINISTER OF HEALTH**

Respondents

and

SCHERING CORPORTION

Respondent/Patentee

REASONS FOR ORDER AND ORDER

[1] The Respondent Pharmascience Inc. (Pharmascience) brings a motion to set aside orders of prohibition and to dismiss applications previously granted by this Court under the *Patented Medicines (Notice of Compliance) Regulations* (the Regulations). It is seeking this remedy in light of a recent judicial determination relating to the patent at issue, Canadian Patent No. 1,341,206 (the '206 Patent).

[2] All parties are agreed that some direction or order of this Court is required; they differ on the terms such a direction or order ought to take. Although the motion was originally brought only with respect to File T-482-03, it was agreed by all parties at the hearing that these Reasons and Order would also apply to related File T-2300-06. Accordingly both actions are listed on the Style of Cause and these Reasons for Order and Order shall be placed on both Court Files T-482-03 and T-2300-06.

Background

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[3] On August 31, 2001, Pharmascience made a submission to the Minister of Health, pursuant to the Regulations, for the issuance of a Notice of Compliance (NOC) to market capsules of ramipril for the treatment of hypertension. Although originally two patents were put in issue, only the '206 Patent was germane to the Court's ultimate determination as the Court held that the allegation of non-infringement of the second patent was justified and accordingly the application was dismissed in respect of that second patent.

[4] Pharmascience alleged that the claims of the '206 Patent that covered ramipril were invalid only on the basis of double patenting. Justice Snider found that the claims of the '206 Patent were not invalid on the basis of double patenting: *Aventis Pharma Inc. v. Pharmascience Inc.*, 2005 FC 340, aff'd 2006 FCA 229, leave to appeal to the Supreme Court of Canada denied, [2006] S.C.C.A. No. 362.

[5] Justice Snider issued an Order on March 11, 2005, that, in relevant part, granted the application and prohibited The Minister of Health from issuing an NOC pursuant to the Regulations to Pharmascience in respect of ramipril until after the expiry of the '206 Patent.

Docket T-2300-06

[6] Following the decision in T-482-03, Pharmascience issued a new Notice of Allegation asserting that the '206 Patent was invalid on several additional grounds not argued in the previous application. Justice Mactavish held that Pharmascience's allegation of invalidity with respect to the '206 Patent had been finally determined by Justice Snider in T-482-03 and that issue estoppel operated to preclude Pharmascience from making further allegations of invalidity with respect to the '206 Patent, on different grounds: *Sanofi-Aventis Canada Inc. v. Pharmascience Inc.*, 2007 FC 1057. Accordingly, she issued a declaration to that effect by Order dated November 27, 2007. On June 20, 2008, she granted the application and issued an Order prohibiting the Minister of Health from issuing an NOC to Pharmascience in respect of its ramipril capsules until after the expiration of the '206 Patent.

The Invalidity of Some ‘206 Patent Claims

[7] In 2007 the Applicants and the Respondent/Patentee in T-482-03 and T-2300-06 commenced actions against Apotex Inc. (T-161-07) and Novopharm Limited (T-1161-07) for patent infringement arising from their sale of ramipril in Canada. After a trial of these actions, Justice Snider, by Judgment dated June 29, 2009, found that claims 1, 2, 3, 6, and 12 of the ‘206 Patent are invalid, void, unenforceable and of no force or effect: *Sanofi-Aventis Canada v. Apotex Inc.*, 2009 FC 676.

[8] It is common ground among all parties that the only claims of the ‘206 Patent that were relevant in Files T-482-03 and T-2300-06 are claims 1, 2, 3, 6, and 12 – the very claims that have now been found to be invalid.

[9] As a consequence of this Court’s recent findings of invalidity of these claims of the ‘206 Patent, Pharmascience, by message dated July 10, 2009, asked the Minister to issue the NOC for which it had previously applied for its ramipril capsules.

[10] Following a discussion, the Minister responded to Pharmascience’s request for an NOC as follows:

I am writing in reply to your correspondence of July 10, 2009 in which you requested that a Notice of Compliance (“NOC”) be issued to Pharmascience Inc. for the above-noted product as a result of the judgements rendered in Court File Nos. T-161-07 and T-1161-07.

Court File Nos. T-161-07 and T-1161-07 were patent infringement actions under the *Patent Act* filed by Sanofi-Aventis Canada Inc. against Apotex Inc. and Novopharm Limited respectively, with respect to Patent No. 1341206 (“the ‘206 patent”). The court

declared that claims 1,2,3,6 and 12 of the '206 patent are invalid, unenforceable and of no force or effect. However, no declaration was made regarding the remaining eight claims. Therefore, since there has not been a declaration by the court that the '206 patent is invalid, the '206 patent cannot be considered to be expired. This is in accordance with the principles established at, for example, paragraphs 56 and 58 of *Apotex Inc. v. Syntex Pharmaceuticals International Inc.*, 2009 FC 494.

In the application for prohibition, Court File No. T-2300-06, filed by Sanofi-Aventis Canada Inc. against Pharmascience Inc. with respect to the above-noted drug submission and the '206 patent, the court granted an order prohibiting the Minister of Health from issuing an NOC to Pharmascience for the 2.5, 5 and 10 mg capsules until the expiry of the '206 patent. As the '206 patent remains invalid, this order of prohibition remains in effect and the Minister remains bound by it.

Furthermore, as the '206 patent was added to the Patent Register on April 17, 2001, paragraph 3.1(1) of the *Patented Medicines (Notice of Compliance) Regulations (PM(NOC) Regulations)* is applicable.

Paragraph 3.1(1) of the *PM(NOC) Regulations* states:

- 3.1(1) The Minister shall not delete from the register a patent on a patent list that was submitted before June 17, 2006. unless
- (a) the patent has expired;
 - (b) a court has, under subsection 60(1) of the Patent Act, declared that the patent is invalid or void
 - ...
 - (d) the patent is found, under paragraph 6(5)(a), not to be eligible for inclusion on the register.

As none of the above exceptions apply, the '206 patent remains listed on the Patent Register. As such, pursuant to section 7 of the *PM(NOC) Regulations* [S.O.R./93-133 as amended], Pharmascience Inc. will not receive an NOC for the above-noted submission.

[11] As a consequence of this response, Pharmascience brought this motion seeking to set aside the two Orders of Prohibition previously granted by this Court and dismissing the applications in those two matters, notwithstanding that they had previously been granted.

[12] When the motion came on for hearing the Applicants informed the Court that an appeal of Justice Snider's Judgment of June 29, 2009 has been filed; however, they had no objection to Pharmascience being issued the NOC for ramipril. They took the position that it is unnecessary to set aside the Orders of Prohibition and that it would be unnecessary and inappropriate to dismiss the underlying applications. They speculate that Pharmascience is seeking to have the applications dismissed in order that it can take advantage of a claim for damages under section 8 of the Regulations.

[13] The Minister submitted a brief letter to the Court dated July 2, 2009, and attended at the hearing to make oral submissions. The Minister's position with respect to T-482-03 and T-2300-06, as set out in his letter, is as follows:

In light of Madam Justice Snider's Reasons dated June 29, 2009 in T-161-07 and T-1161-07 the Minister of Health requests directions to clarify the orders in T-482-03 and T-2300-06 under section 6 of the *Patented Medicines (Notice of Compliance) Regulations* which prohibited the Minister from issuing a notice of compliance to Pharmascience Inc. until expiry of the Canadian Patent No. 1,341,206 ("the '206 patent").

In particular, in T-161-07 and T-1161-07 the Court held that claims 1, 2, 3, 6 and 12 are invalid such that there are no longer claims to the compound ramipril in the '206 patent that was the basis for the prohibition orders in the above noted section 6 proceedings.

As there are no longer claims to ramipril in the '206 patent, the Minister requests clarification as to whether the prohibition orders remain in effect.

Pharmascience Inc. has taken the position that the effect of Madam Justice Snider's decision is that the '206 Patent is no longer a bar to issuing a notice of compliance to Pharmascience for ramipril.

[14] The Applicants submit that it is well established that pursuant to the Regulations, an Order of Prohibition ceases immediately to have effect upon expiry of the patent. They cite and rely upon the decisions in *Hoffman La Roche v. Canada (Minister of National Health and Welfare)*, (1999), 167 F.T.R. 111 (F.C.T.D.) at para 14, *Pharmascience Inc. v. Sanofi-Aventis Canada Inc.*, 2006 FCA 229 at paras. 11-12, *Zeneca Pharma Inc. v. Canada (Minister of National Health and Welfare)* (1996), 66 C.P.R. (3d) 169 at 174 (F.C.T.D.), *Aventis Pharma Inc. v. Apotex Inc.*, 2006 FCA 328 and *Apotex Inc. v. Syntex Pharmaceuticals International Ltd.*, 2009 FC 494 at para. 58 wherein Justice Hughes stated the law, as follows:

Thus the Minister need not delay in granting a Notice of Compliance to a generic if the relevant patent has expired by its term ending, or by lapse of that patent such as failure to pay maintenance fees, or if the Court in the *PMNOC* proceeding declares the patent invalid between the parties to that proceeding, or by any Court making, by operation of law such as under section 60 of the *Patent Act*, a declaration that the patent is invalid.

[15] In all of these authorities, the patent as a whole was declared to be invalid. No case was cited by any party, nor is the Court aware of any, where consideration was given to the impact on a previous order under the Regulations where, subsequently, the relevant patent claims but not the entire patent had been found to be invalid. A declaration of partial invalidity only becomes relevant

to such a previous order when, as here, the very claims declared invalid are the only claims relevant to the application under the Regulations.

[16] The Court appreciates the concern of the Minister that the previous Orders of Prohibition made reference to the Minister being prohibited from issuing a notice of compliance until the expiry of the patent. In this case, the patent has not yet expired and only some of its claims have been held to be invalid. Thus, unlike the cases where the patent as a whole has been found to be invalid or has expired, it is not plain and obvious that the Orders of Prohibition no longer prevent the Minister from issuing an NOC to Pharmascience. In order to come to the conclusion that the Minister ought no longer to be prevented from issuing the NOC, one must look behind the orders to the real issues that were determined and that were in dispute.

[17] The wording of the Orders of Prohibition that issue from this Court in NOC matters is a direct reflection of the wording of section 6 of the Regulations which limits the Court to issuing a prohibition order “until after the expiration of a patent that is the subject of allegation.” On a strict interpretation of the provision this Court has no jurisdiction to issue an Order of Prohibition until after the expiration or invalidity of the relevant claims of a patent that are the subject of allegation.

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.

[18] In spite of the able submissions of the Applicants, I am not persuaded that an order setting aside the prohibition orders is not necessary in order that the Minister may issue the notice of compliance. The Applicants submit that if such an order issues, it should take effect only as of the issue date of the order. Rule 392(2) of the *Federal Courts Rules* provides that “unless it otherwise provides, an order is effective from the date that it is endorsed in writing and signed by the presiding judge or prothonotary.” I see no reason why an order setting aside these prohibition orders should be effective from any earlier date than the date hereof.

[19] Pharmascience is also seeking an order dismissing the applications which had previously been granted by Justices Snider and Mactavish. The Applicants oppose such an order and advance the following arguments.

1. If granted, Pharmascience may be permitted to take advantage of section 8 of the Regulations and claim damages from the Applicants. It would be improper to permit that to occur given that the original applications were properly decided and, in one case, affirmed by the Court of Appeal. They submit that they “should not be penalized for bringing an application which has been judicially decided to be meritorious.”

2. The jurisprudence indicates that it is unnecessary to issue an order dismissing an original application that was granted. In *Hoffman La Roche*, Justice Reed granted the order being sought but did so only to provide greater certainty as she was of the view that it was unnecessary to do so. Justice Hughes in *Syntex* shared that view.

[20] The application in T-482-03 was granted because Pharmascience had argued that the '206 Patent was invalid only on the grounds of double patenting. That decision found that the patent was not invalid on that basis. That finding has not been upset by Justice Snider's recent finding in her decision in 2009 FC 676 that Claims 1, 2, 3, 6 and 12 are invalid on the basis of lack of utility. Further, she expressly states in paragraph 8 of that decision that having found invalidity on the grounds of utility it was unnecessary to consider the other grounds advanced, however, she goes on to state that had it been necessary she would not have found that it was invalid for double patenting, thus affirming her earlier decision.

[21] The application in T-2300-06 was granted by Justice Mactavish on the basis that issue estoppel applied to prevent Pharmascience from attacking the '206 Patent on other grounds, having been unsuccessful in its attack in T-482-03 on the one limited ground it advanced. That finding has not been upset by Justice Snider's recent decision in 2009 FC 676.

[22] Accordingly, it is my view that it would be improper for the Court now to set aside the findings of the Court in those cases by issuing orders that would dismiss those two previous applications. However, an order setting aside the Orders of Prohibition is warranted in order that

the Minister may issue the notice of compliance to Pharmascience without being in breach of the previous prohibition orders issued by this Court.

[23] The issues raised in this motion are unique and of sufficient significance that it is appropriate in my judgment that no costs be awarded.

ORDER

THIS COURT ORDERS AND ADJUDGES that:

1. The Order of this Court issued in T-482-03 dated March 11, 2005, which states that “The Minister of Health is prohibited from issuing a Notice of Compliance pursuant to the Patented Medicines (Notice of Compliance) Regulations to the Respondent, Pharmascience Inc. to market the capsules of ramipril” is hereby set aside; and
2. The Order of this Court issued in T-2300-06 dated June 20, 2008, which states that “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 is hereby set aside; and
3. No costs are ordered.

“Russel W. Zinn”

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET: T-482-03

STYLE OF CAUSE: AVENTIS PHARMA INC. ET AL. v.
PHARMASCIENCE INC. ET AL. and
SCHERING CORPORATION

DOCKET: T-2300-06

STYLE OF CAUSE: SANOFI-AVENTIS CANADA INC. v.
PHARMASCIENCE INC. ET AL. and
SCHERING CORPORATION

PLACE OF HEARING: Toronto, Ontario

DATE OF HEARING: August 24, 2009

**REASONS FOR ORDER
AND ORDER:** Zinn J.

DATED: September 15, 2009

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