Date: 20071017

Docket: T-2300-06

Citation: 2007 FC 1057

BETWEEN:

SANOFI-AVENTIS CANADA INC.

Applicant

and

PHARMASCIENCE INC. and
THE MINISTER OF HEALTH

Respondents

and

SCHERING CORPORATION

Respondent / Patentee

REASONS FOR JUDGMENT

MACTAVISH J.:

[1] In a pair of recent decisions, the Federal Court of Appeal has clearly attempted to limit the proliferation of pharmaceutical litigation under the *Patented Medicines (Notice of Compliance) Regulations ("PM(NOC) Regulations")*, and to encourage the efficient use of scarce judicial resources.

[2] In *Pharmascience Inc. v. Canada (Minister of Health) et al.*, 2007 FCA 140 ("*Abbott*"), the Federal Court of Appeal determined that a generic drug manufacturer who wishes to challenge the validity of a patent owned by an innovator company by means of the *PM(NOC) Regulations* must do so by "putting its best foot forward". If the generic's allegations of invalidity are found not to be justified, issue estoppel will operate to preclude the same generic from raising allegations of invalidity, based on different grounds, in a second Notice of Allegation.

[3] In *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 163 ("*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.

[4] Both factual situations arise in this case.

[5] Relying on *Abbott*, Sanofi-Aventis Canada Inc. and Schering Corporation say that Pharmascience Inc. should be estopped from alleging the invalidity of patent in dispute in a second Notice of Allegation, as this Court has found previous allegations of invalidity made by Pharmascience in relation to the same patent not to be justified.

[6] In contrast, Pharmascience says that the combined effect of a decision of this Court involving a different generic, which found that allegations of invalidity with respect to the patent in

issue were justified, and the Federal Court of Appeal's decision in *Novopharm*, is that Sanofi-Aventis and Schering are estopped from asserting the validity of the patent.

[7] For the reasons that follow, I am of the view that the reasoning of the Federal Court of Appeal in *Abbott* applies here. Pharmascience's initial allegation of invalidity has been finally determined, and issue estoppel should operate to preclude it from making further allegations of invalidity, albeit on different grounds. I further decline to exercise my discretion to allow Pharmascience to proceed with its allegations of invalidity.

[8] Accordingly, an order will go declaring that Pharmascience cannot rely on the allegations of invalidity asserted in its second Notice of Allegation relating to Canadian patent No. 1,341,206 (the "'206 patent").

The Parties

[9] Schering Corporation is the owner of the '206 patent. Under the terms of 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.

[10] Pharmascience is a manufacturer of generic drug products. Pharmascience wants to enter the market with its own ramipril product.

Background

[11] In order to understand the parties' arguments in this case, it is necessary to have an appreciation of the sequence of events leading up to this hearing.

[12] In previous *PM(NOC)* proceedings involving these same parties or their predecessors, Pharmascience alleged that the '206 patent was invalid due to double patenting.

[13] In March of 2005, Justice Snider found that Pharmascience's allegation of invalidity was not justified. As a result, she issued a prohibition order preventing the Minister of Health from issuing a Notice of Compliance to Pharmascience in relation to ramipril until after the expiry of the '206 patent: see *Aventis Pharma Inc. v. Pharmascience Inc.*, 2005 FC 340 ("*Aventis Pharma*").

[14] Justice Snider's decision was subsequently affirmed by the Federal Court of Appeal (2006 FCA 229), and leave to appeal to the Supreme Court of Canada was denied ([2006] S.C.C.A. No. 362).

[15] Several months after Justice Snider rendered her decision in *Aventis Pharma*, in prohibition proceedings involving a different generic, I concluded 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. As a consequence, I dismissed Aventis' application for prohibition in that case, allowing for a Notice of Compliance to issue to Apotex with respect to ramipril: see *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283 ("*Apotex*").

[16] My decision was subsequently upheld by the Federal Court of Appeal: see *Aventis Pharma Inc. v. Apotex Inc.*, 2006 FCA 64. Leave to appeal to the Supreme Court of Canada was sought by Sanofi-Aventis (Aventis' successor), and was denied by the Supreme Court in April of 2006 ([2006] S.C.C.A. 136).

[17] After I rendered my decision in *Apotex*, and before the appeal of Justice Snider's decision in *Aventis Pharma* was heard, Pharmascience moved for an order from the Federal Court of Appeal barring Sanofi-Aventis from asserting that the '206 patent was valid, in light of my decision in *Apotex*.

[18] The Federal Court of Appeal dismissed Pharmascience's motion. In so doing, the Federal Court of Appeal observed that my decision in *Apotex* did not amount to a final determination of the validity of the '206 patent. Rather, I simply determined whether the Apotex's Notice of Allegation was justified, and thus whether an order of prohibition should issue: see *Pharmascience Inc. v. Sanofi-Aventis Canada Inc.*, 2006 FCA 210.

[19] Allegations as to the invalidity of the '206 patent made in *PM(NOC)* proceedings involving a third generic manufacturer then entered the picture. In September of 2006, in *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2006 FC 1135, Justice Tremblay-Lamer summarily dismissed Sanofi-Aventis' application for an order of prohibition against Novopharm in relation to the '206 patent for the drug ramipril.

[20] Justice Tremblay-Lamer found that Sanofi-Aventis' application for prohibition amounted to an abuse of process, given that Novopharm's allegations regarding lack of sound prediction were very similar to those that had successfully been advanced by Apotex in the prior proceeding before me.

[21] On November 15, 2006 Pharmascience served its second Notice of Allegation in relation to the '206 patent. In this NOA, Pharmascience asserted that the 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.

[22] Sanofi-Aventis then 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".

[23] In this regard, Sanofi-Aventis asserted that in light of Justice Snider's decision in Aventis Pharma rejecting Pharmascience's earlier allegations of invalidity, Pharmascience was barred 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.

[24] In April of this year, the Federal Court of Appeal released its decisions in *Abbott* and *Novopharm*. The Court's findings in these two cases have been summarized in the introduction to

this decision, and the implications of those findings for this litigation will be discussed further on in these reasons.

[25] In response to Sanofi-Aventis' Notice of Application, Pharmascience asserts that it is 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 *Apotex*. In support of this contention, Pharmascience relies on subsection 6(5) of the *PM(NOC) Regulations* and the Federal Court of Appeal's decision in *Novopharm*. Accordingly, Pharmascience asked that the portion of Sanofi-Aventis' application seeking such a determination be struck.

[26] In an Order dated July 25, 2007, Prothonotary Tabib found that the two 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 are the issues before me.

Issues

[27] The parties' competing positions raise the following issues:

1. Which issue has to be determined first? 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? Or Pharmascience’s contention that it is an abuse of process for Sanofi-Aventis and Schering to argue the validity of the ‘206 patent?

2. Is Pharmascience 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?

3. Is it an abuse of process for Sanofi-Aventis and Schering to argue the validity of the ’206 patent?

Which Issue Has To Be Determined First?

[28] The parties made only brief submissions on this point. Given that Sanofi-Aventis’ application for prohibition was triggered by Pharmascience’s Notice of Allegation, the scope of Pharmascience’s NOA has to be determined first. Sanofi-Aventis’ need to assert the validity of the ’206 patent only arises if Pharmascience is in a position to raise the invalidity of the patent. If Pharmascience is precluded from raising the issue of invalidity in its NOA, the scope of Sanofi-Aventis and Schering’s ability to defend the validity of the ’206 patent becomes irrelevant.

Is Pharmascience Precluded From Making Further Allegations of Invalidity?

[29] In determining Pharmascience is precluded from making further allegations of invalidity in relation to the ’206 patent, the first question that I will address is whether the doctrine of issue estoppel is engaged in this proceeding, in light of Justice Snider’s decision in *Aventis Pharma Inc. v. Pharmascience Inc.*.

[30] Issue estoppel is a public policy doctrine designed to advance the interests of justice: *Danyluk v. Ainsworth Technologies Inc.*, [2001] S.C.R. 460, 2001 SCC 44. Its object is to prevent parties from re-litigating issues that have already been decided in other proceedings.

[31] The policy considerations underlying the doctrine of issue estoppel include the need to have an end to litigation, as well as the desire to protect individuals from having to defend multiple legal proceedings arising out of the same set of circumstances: *Angle v. Canada (Minister of National Revenue)*, [1975] 2 S.C.R. 248, at p.267, per Laskin J. (dissenting).

[32] Concerns have also been expressed about the cost of duplicative proceedings, as well as the risk of inconsistent results if the same issue is pursued in multiple fora: *Rasanen v. Rosemount Instruments Ltd. (1994)*, 17 O.R. (3d) 267 (Ont. C.A.).

[33] As the Supreme Court of Canada noted in *Angle*, there are three elements that must be established to engage the doctrine of issue estoppel:

i) The same issue is being decided in each proceeding;

ii) The decision which raises the issue estoppel is a final decision; and

iii) The parties to the two proceedings are the same parties, or are their privies.

[34] It is clear from the Supreme Court of Canada's decision in *Maynard v. Maynard*, [1951] S.C.R. 346, that even if the precise issue before the Court has not previously been litigated, issue estoppel will operate to preclude a party from litigating a new issue, where that issue could have

been raised in the earlier proceeding by the exercise of reasonable diligence, but was not: see also *Apotex Inc. v. Merck & Co.*, 19 C.P.R. (4th) 163, at ¶26, *Fidelitas Shipping Co. v. V/O Exportchleb*, [1966] 1 Q.B. 630 (C.A.) and *Apotex Inc. v. Merck & Co. et al.* (1999), 5 C.P.R. (4th) 363.

[35] Even if all three elements necessary to engage the doctrine of issue estoppel are present, the Court still has the residual discretion to refuse to apply issue estoppel in "special circumstances": see, for example, *Arnold v. National Westminster Bank, PLC*, [1991] 2 A.C. 93 at 110-11 and *Doering v. Grandview (Town)* [1976]] 2 S.C.R. 621.

[36] Pharmascience acknowledges that this proceeding involves the same parties as were before Justice Snider in *Aventis Pharma*, or their privies, and further accepts that as a result of the Supreme Court of Canada denying leave in that case, Justice Snider's decision is now final. Pharmascience also acknowledges that its NOA in this case raises the same issue – that is, the validity of the '206 patent – as was in dispute before Justice Snider.

[37] As a consequence, Pharmascience concedes that all three of the requirements for the establishment of issue estoppel are present in this case.

[38] Pharmascience also acknowledges that in *Abbott*, the Federal Court of Appeal has held that in circumstances such as this, issue estoppel will ordinarily operate to preclude a generic from raising allegations of invalidity based on different grounds in a second Notice of Allegation.

[39] However, Pharmascience submits that “special circumstances” exist in this case, with the result that it should not be precluded from challenging the validity of the ’206 patent. According to Pharmascience, there has been a change in the law since Justice Snider rendered her decision, such that it would be unfair to preclude Pharmascience from raising new grounds of invalidity in relation to the ’206 patent.

[40] Pharmascience identifies this change in the law as being the combined effect of my finding in *Apotex* that Schering did not have a sound basis for predicting the utility of the invention claimed in the ’206 patent at the time it applied for the patent, and the Federal Court of Appeal’s decision in *Novopharm* allowing generics to “piggy-back” onto invalidity findings made in the context of *PM(NOC)* proceedings involving other generics.

[41] Thus the question for determination is whether there are “special circumstances” in this case such that I should exercise my discretion and allow Pharmascience to challenge the validity of the ’206 patent on new grounds.

Analysis

[42] The starting point for my analysis must be a consideration of the scope of the Court’s discretion not to apply the doctrine of issue estoppel in proceedings that involve the same issue being litigated by the same parties, where another judge has already finally determined the issue.

[43] Citing the Supreme Court in *Danyluk*, the Federal Court of Appeal observed in *Abbott* that while there is no doubt that such a discretion exists, this discretion must be very limited in its application: see *Abbott* at ¶51.

[44] The Federal Court of Appeal also noted that the Court's discretion is intended to ensure that issue estoppel is not applied unfairly in the circumstances of a given case: *Abbott*, at ¶53.

[45] That is, the Federal Court of Appeal observed that the purpose of this overriding discretion was to "ensure that the operation of issue estoppel promotes the orderly administration of justice but not at the cost of real injustice in the particular case": *Abbott* at ¶53, quoting *Danyluk.*

[46] It is also clear from the jurisprudence that the factors which may be relevant in deciding whether to exercise this discretion will differ from case to case: *Danyluk*, at ¶67.

[47] There is, however, some dispute in the jurisprudence as to whether a change in the law is a factor that would warrant the exercise of the Court's discretion not to apply the doctrine of issue estoppel.

[48] Some Canadian jurisdictions have recognized a change in the law as a relevant factor (see, for example, *Hockin v. Bank of British Columbia* (1995), 123 D.L.R. (4th) 538 (B.C.C.A.)). However, in *Apotex Inc. v. Merck & Co.*, 19 C.P.R. (4th) 163, Justice Malone observed that neither

the Federal Court of Appeal or the Supreme Court of Canada has ever found that a change in the law would justify relaxing the application of issue estoppel: *Merck*, at ¶35.

[49] If I assume, as Justice Malone did, that a change in the law can indeed constitute a special circumstance in the appropriate case, the next question is whether there has indeed been a change in the law relating to *PM(NOC)* proceedings.

[50] Pharmascience asserts that my decision in *Apotex* and the Federal Court of Appeal's decision in *Novopharm*, when taken together, amount to just such a change in the law.

[51] I do not agree.

[52] According to Pharmascience, my decision in *Apotex* represents "a new and definitive decision as to the validity of the '206 patent, namely that for the purposes of the [*PM*] *(NOC) Regulations* an allegation is justified that the '206 patent lacks a sound basis for predicting the alleged utility of the invention claimed therein".

[53] This is clearly not the case.

[54] The Federal Court of Appeal has already commented on the significance of my decision in *Apotex* in the context of the appeal of Justice Snider's decision in *Pharmascience*. As the Court noted, my decision in that case involved the factual determination, based upon the evidentiary

record before me in that case, that Apotex was justified in asserting 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 filed its application for the patent: see *Pharmascience Inc. v. Sanofi-Aventis Canada Inc.*, 2006 FCA 210.

[55] In *Apotex*, I decided that Aventis had not demonstrated that Apotex’ allegation as to invalidity was not justified. Decisions made under the *PM(NOC) Regulations* are not *in rem* decisions, do not decide the question of validity, and are not binding on other judges in subsequent NOC proceedings: see *Novopharm*, at ¶30.

[56] My decision in *Apotex* does not, therefore, amount to a change in the law.

[57] Insofar as the *Novopharm* decision is concerned, Pharmascience points to the following statement by Justice Harrington in *Sanofi-Aventis Inc. v. Laboratoire Riva Inc.*, 2007 FC 532, at ¶68:

> Mr. Justice Sexton's decision in *Novopharm* […] drives home the point that mere litigation, with another party, of a point already decided, can constitute, without more, an abuse of process, even if it is not clear and obvious that the application would have failed on the merits. *This decision marks a clear development in the law as applicable in NOC proceedings*. [emphasis added]

[58] Does this mean that there has therefore been a change in the law of the type that has been found in the jurisprudence to amount to “special circumstances” justifying the exercise of the Court’s discretion? I think not.

[59] First of all, in *Novopharm*, Justice Sexton simply applied the existing law relating to abuse of process to the facts before the Court in that case. As Justice Sexton himself noted in *Abbott*¸ the fact that no decision may have previously considered the specific question at issue in a given case does not mean that the decision changes the applicable law: see *Abbott* at ¶60-61.

[60] Moreover, my review of the cases relied upon by Pharmascience in this regard demonstrates that the type of 'change in the law' that has been found to justify relief from the application of the doctrine of issue estoppel occurs when the result in a later decision dictates that the findings in an earlier decision were clearly wrong.

[61] In such cases, courts have held that it would be unfair not to allow a party to derive the benefit of the later decision, notwithstanding the fact that the party may have previously litigated the point and lost: see, for example, *Hockin*, previously cited, and *Arnold v. National Westminster Bank, PLC*, [1991] 2 A.C. 93, as well as *Minott v. O'Shanter Development Co.* (1999), 42 O.R. (3d) 321 (Ont. C.A.)).

[62] This is not the situation that we have here. There is no suggestion that Justice Snider's decision in *Aventis Pharma Inc. v. Pharmascience Inc.* was made in error, such that it would be unfair to deny Pharmascience the right to re-litigate the issue of the validity of the '206 patent. Indeed, Pharmascience concedes that Justice Snider's decision was not clearly wrong.

[63] Moreover, even if the Federal Court of Appeal's decision in *Novopharm* had been released prior to the hearing before Justice Snider, it would not have assisted *Pharmascience*. Having been the first generic to challenge the '206 patent, there was no earlier decision involving a successful invalidity challenge by another generic that Pharmascience could have relied on. That is, *Novopharm* could not have affected the outcome of the case before Justice Snider.

[64] As a consequence, I am not persuaded that there has been a change in the law that would warrant the exercise of my discretion in Pharmascience's favour.

[65] The question still remains as to whether there are other bases on which I should exercise my discretion in Pharmascience's favour in this case.

[66] In this regard, I note that issue estoppel is an equitable doctrine, and, as the Supreme Court of Canada has stated, the rules governing issue estoppel should not be mechanically applied. Rather, the task for the Court is to balance the public interest in the finality of litigation with the public interest in ensuring that justice is done on the facts of a particular case: *Danyluk*, at ¶33.

[67] Moreover, *Danyluk* teaches that the exercise of the Court's discretion is necessarily case-specific, and will depend on all of the circumstances in a particular case. That is, the Court must ask whether, in the context of the case in issue, the application of the doctrine of issue estoppel would work an injustice: *Danyluk*, at ¶63.

[68] Pharmascience says that it would be unfair if it were the only generic that was unable to benefit from the combined effect of my decision in *Apotex* and the Federal Court of Appeal decision in *Novopharm*.

[69] I am not persuaded that this is an unfair result, in the circumstances.

[70] Pharmascience made the strategic decision to move quickly, in order to be the first generic to take a run at the ’206 patent by means of the *PM(NOC) Regulations*. The company made a further tactical decision not to ‘put its best foot forward’, but to allege invalidity only on the ground of double patenting in its first NOA.

[71] Pharmascience concedes that there was nothing preventing it from alleging that the ’206 patent was invalid for lack of sound prediction at the time that it served its first NOA.

[72] As a consequence, I do not accept Pharmascience’s contention that my decision in *Apotex* amounts to “relevant new material” not otherwise discoverable by the exercise of due diligence.

[73] Moreover, as the Federal Court of Appeal made clear in the *Abbott* decision (at ¶60), the law has always been that generics are precluded from bringing multiple NOAs asserting invalidity on different grounds. As a result, at the time that it served its first NOA, Pharmascience knew, or should have known, that if it was unsuccessful in its attack on the ’206 patent based on double

patenting, it would be precluded from advancing other grounds of invalidity in the future. For whatever reason, it chose to put all of its eggs in one basket.

[74] Pharmascience gambled. It lost. It has to live with the consequences.

[75] In addition, Pharmascience is not without a remedy. If Pharmascience wants to be in a position to market ramipril, it remains open to it to bring an impeachment action in relation to the '206 patent.

[76] There is a further reason for declining to exercise my discretion in Pharmascience's favour. The situation in which Pharmascience finds itself in this case is precisely the situation that Pharmascience faced in the *Abbott* case. Nevertheless, the Federal Court of Appeal felt it appropriate to apply issue estoppel against Pharmascience in that case.

[77] That is, in *Abbott*, Pharmascience had alleged in an NOA that a patent owned by an innovator company was invalid on the basis that the claims were broader than the invention disclosed. Following *PM(NOC)* proceedings in this Court, Pharmascience's allegations were not found to be justified, and a writ of prohibition was issued against the company.

[78] However, in subsequent NOC proceedings involving the same patent but other generics, this Court found other companies' allegations of invalidity to be justified.

[79] Pharmascience then served a second NOA, asserting different allegations of invalidity. The Federal Court of Appeal found that the doctrine of issue estoppel operated in those circumstances to preclude Pharmascience from making further allegations of invalidity. Clearly the Federal Court of Appeal did not consider this to be an unjust result.

[80] It is true that the Federal Court of Appeal had not yet rendered its decision in *Novopharm* at the time that the *Abbott* decision was issued. However, *Novopharm* was under reserve, and the decision in *Novopharm* was released just a few days after that in *Abbott*. Justice Sexton wrote both decisions. The cases are clearly intended to establish policy regarding proceedings under the *PM (NOC) Regulations*, and have to be read together.

[81] It is, therefore, reasonable to conclude that Justice Sexton was aware of the fact that his decision in *Abbott* would preclude Pharmascience from being able to "piggy-back" onto the findings in other NOC proceedings in the same way that other generics could. He did not find this to be an unjust result in that case, and I do not do so here.

[82] In this regard it does bear noting that there is one very material difference between the position of the generic in *Novopharm* as compared to that of Pharmascience in this case. That is, at the time that Novopharm sought to rely on invalidity findings made in prohibition proceedings involving another generic, Novopharm had not previously challenged the validity of the patent in question by means of a Notice of Allegation.

[83] In other words, Novopharm was not endeavouring to re-litigate a battle that it had already fought and lost.

[84] For all of these reasons, I therefore decline to exercise my discretion in Pharmascience's favour. In accordance with the decision of the Federal Court of Appeal in *Abbott*, I find that the doctrine of issue estoppel should apply to preclude Pharmascience from raising further allegations of invalidity based on new grounds in its second Notice of Allegation.

[85] As a consequence, an order will issue declaring that Pharmascience cannot rely on allegations of invalidity in its second Notice of Allegation relating to the '206 patent.

Other Issues

[86] In light of my conclusion in relation to the question of issue estoppel, it is unnecessary to address the parties' arguments in relation to Pharmascience's second NOA based upon cause of action estoppel or abuse of process.

[87] Moreover, given that I have found that Pharmascience is precluded from relying on allegations of invalidity in its second Notice of Allegation relating to the '206 patent, the question of the scope of Sanofi-Aventis's ability to assert the validity of the '206 patent in its Notice of Application does not arise.

Costs

[88] Each party shall have two weeks to serve and file submissions in writing regarding costs, which are not to exceed five pages in length. The parties will each then have one further week in which to serve and file any reply submissions, not to exceed two pages in length.

"Anne Mactavish"
Judge

Ottawa, Ontario
October 17, 2007

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

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