Date: 20080922

Docket: T-1351-07

Citation: 2008 FC 1062

Ottawa, Ontario, September 22, 2008

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

SANOFI-AVENTIS CANADA INC.

Applicant

and

**THE MINISTER OF HEALTH,
THE ATTORNEY GENERAL OF CANADA and
LABORATOIRES RIVA INC.**

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

[1] This application arises from what all parties describe as a unique set of facts. Those facts have been evolving since the application was filed such that, in the absence of certain undertakings by the parties, I would have dismissed the application as moot. I have, however, accepted those undertakings, and exercised my discretion to hear and determine what has evolved as the central issue in the application. The central issue is: can a generic pharmaceutical organization which has applied to the Minister of Health (the Minister) for approval, a Notice of Compliance (NOC), to sell a generic version of a drug on the basis of a cross-reference to another generic's application acquire such a Notice of Compliance where that other, cross

referenced generic has been precluded from doing so as a result of proceedings in this Court under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended (*PMNOC Regulations*).

[2] In the circumstances of the present case, I have concluded that the generic, the Respondent Laboratoires Riva Inc. (Riva), is not so precluded and this application is to be dismissed with costs.

DRUG AND PATENTS AT ISSUE - RAMIPRIL

[3] The drug at issue is known commonly as ramipril and is sold in Canada by the Applicant, Sanofi-Aventis Canada Inc., under the name ALTACE. Sanofi-Aventis Canada, together with others including Sanofi-Aventis Deutchland GmbH and Schering Corporation, appear to own, control, or have some kind of licence or permission to exploit a number of patents directed in some way to ramipril. Sanofi-Aventis Canada, as a "first person" as described in the *PMNOC Regulations*, has listed a number of those patents with the Minister. Some of these patents relate to the chemistry and formulation of the drug while others have expired. Some patents relate to the drug's different uses: an "old" use is the treatment of hypertension while a "newer" use is the treatment of cardiovascular conditions and is sometimes referred to by the acronym HOPE.

[4] One of these patents, Canadian Patent 1,341,206 ('206), relates to chemistry and is of particular importance here.

OBTAINING APPROVAL TO SELL A DRUG IN CANADA

[5] Before a drug can be sold in Canada, except in circumstances not important here, the Respondent Minister of Health must, under the provision of the *Food and Drug Act*, R.S.C. 1985, c. F-27 and associated *Regulations*, be satisfied that the proposed drug is safe and effective for the stated use. An originator (innovator-brand or first person, there are a variety of descriptions) will file a New Drug Submission (NDS), which is an extensive and expensive package of data supporting the safety and efficacy of the drug. It is not unusual for such data, if in print form, to fill rooms and for the cost of the relevant testing to be in the millions. If the Minister is satisfied, after a review of the data and any follow-up, the originator is given a Notice of Compliance to sell its drug in Canada subject to any conditions as the Minister may impose. An approved drug gets a Drug Identification Number (DIN) which appears on the drug's packaging and labelling. Each DIN is unique to each drug, dosage form and strength as approved. These activities are carried out under the provisions of the *Food and Drug Act* and *Regulations*.

[6] Canada has provided that generic copies of approved drugs may be offered for sale in Canada, whether or not the originator consents. This happens provided that the Minister is satisfied that the copies are equally safe and effective as the original as per the *Food and Drug Act* and *Regulations*. The generic does not, however, need to provide the extensive data provided by the originator. It can simply tell the Minister that it relies upon or "references" the originator data by filing an Abbreviated New Drug Submission (ANDS). The generic must submit data on its product, largely directed to satisfying the Minister that the product is

pharmalogically equivalent to the original and that the bioavailability of the active ingredient(s) is the same. Thus a generic is required to make some investment of its own in providing data.

[7] There is a third route available to a party seeking to sell a drug in Canada. That route is not explicitly set out in the *Food and Drug Act* or *Regulations* but has been described by this Court and the Federal Court of Appeal as "soundly anchored" in that *Act* and *Regulations* (see Lemieux J. in *GlaxoSmithKline Inc. v. Canada (Attorney General)*, 2004 FC 1302 at para. 59 and Sharlow JA. in *NuPharm Inc. v. Merck & Co.* (2000), 5 C.P.R. (4th) 138 (FCA) at para. 26). This is the practice of cross-referencing (X-REF).

[8] In cross-referencing, a drug company fills out a simple form advising the Minister that it wishes to sell a drug in Canada that is identical to the product of another company that has, or is seeking, a Notice of Compliance. In such a scenario, the company that has cross-referenced does not need to submit any data of its own. There is a catch however, in that the company whose product is cross-referenced must consent to the cross-reference. The Minister's practice is that once the referenced product is approved, the cross-referenced product also gets approval to sell the identical product - some differences include in the name of the product and the name of the company offering it for sale. All of this activity takes place under the provisions of the *Food and Drug Act* and *Regulations*.

[9] The present case deals with a cross-referencing situation where the Respondent Riva applied to the Minister for a Notice of Compliance to sell a ramipril product in Canada by cross-

referencing an application filed by another generic, Pharmascience Inc., with, of course, the approval of Pharmascience.

[10] The Applicant in these proceedings, Sanofi-Aventis Canada, despite representations made otherwise in its written argument filed with the Court, agreed in oral argument that it is not challenging and has no standing to challenge decisions made by the Minister under and in administering provisions of the *Federal Drug Act* and *Regulations*. This is borne out by the decision of this Court in *Merck Frosst Canada Inc. v. Canada* (1997), 80 C.P.R. (3d) 550 (FCT) per Hugessen J. at paras. 10 & 11; affirmed by the Federal Court of Appeal (1999), 3 C.P.R. (4th) 286 (FCA) at para. 2.

[11] Matters do not stop here, however. Once the Minister is satisfied that a drug is safe and effective it must pass through the rigours of the *PMNOC Regulations* if, in its role as first person, the originator has listed one or more patents with the Minister in respect of the drug under those *Regulations*. This is the case if the drug is a generic copy of an originators drug, whether through the ANDS or X-REF route.

[12] While not entirely clear from Sanofi-Aventis Canada's written material, it was made clear by its counsel in oral argument that it is seeking relief only in respect of what has transpired in the application of the *PMNOC Regulations*. The particular circumstance in this case is that the cross-referenced application, that of Pharmascience, was by Order of this Court made under

the *PMNOCRegulations*, prohibited from receiving a Notice of Compliance. The question now is: without more, should Riva, the cross-referencing party, be equally prohibited?

PARTICULAR FACTS OF THIS CASE

[13] The facts of this case are peculiar and unique. To recount briefly:

> 1) At the earlier time not of record but clearly the first event, Pharmascience filed an ANDS with the Minister in respect of a generic version of ramipril.
>
> 2) Riva filed an application with the Minister to sell a generic version of ramipril identical to the Pharmascience product, doing so by way of cross-reference. By letter dated June 21, 2004, the Minister advised Riva that the examination of the submission is complete but that a NOC will not be issued until the requirements of the *PMNOC Regulations* are met.
>
> 3) Pharmascience sends Sanofi-Aventis's predecessor a Notice of Allegation under the *PMNOC Regulations* respecting its generic ramipril. This triggers proceedings under that *Regulations* instituted by Sanofi-Aventis' predecessor,

In Court File No. T-482-03. By an Order of this Court dated March 11, 2005; the Minister was prohibited from issuing a NOC to Pharmascience. Justice Snider's reasons for this decision can be found at 2005 FC 340; the decision was affirmed by the Federal Court of Appeal 2006 FCA 229; and leave to appeal to the Supreme Court of Canada was denied [2006] SCCA No. 362. Among the patents at issue was the '206 patent. Pharmascience had failed to persuade the Court that its allegation of invalidity of the '206 patent was justified.

4) Another generic, Apotex Inc., was also seeking to sell its generic version of ramipril in Canada and became engaged in proceedings of its own in this Court under the *PMNOC Regulations*. It also challenged the validity of the '206 patent but did so on different grounds than those of Pharmascience. Apotex won in respect of its allegations that the '206 patent was invalid (2005 FC 1283). The decision was affirmed by the Federal Court of Appeal, 2006 FCA 64; leave to appeal to the Supreme Court of Canada was denied [2006] SCCA No. 136. Apotex was given a Notice of Compliance and entered the Canadian market with its generic version of ramipril.

5) Riva served Notices of Allegation on Sanofi-Aventis Canada under the provisions of the *PMNOC Regulations*, causing Sanofi-Aventis to institute 3 separate applications for prohibition in this Court: T-1384-04, T-1888-04, and T-127-07. The first application, T-1384-04 involved, among other matters, the issue of validity of this '206 patent. The other applications involved other patents. The first two applications T-1384-04 and T-1888-04 were heard and disposed of by Justice Harrington of this Court while the third was heard and disposed of by Justice Martineau of this Court.

6) On April 24, 2007, the Minister's office wrote to Riva's lawyers concerning Riva's application for ramipril. Among other things, the Minister said:

> *In addition, we would note that since Riva's submission has been cross-referenced with another submission, the NOC will not be issued to Riva until the NOC is issued for the cross-referenced submission for pms-ramipril, in accordance with Health Canada's Policy entitled "Filing of Supplemental New Drug Submissions, Supplemental Abbreviated New Drug Submissions, Notifiable Changes and Cross-referenced Submissions."*

Discussions between the lawyers followed. Riva instituted an application to this Court seeking to quash this decision (Court File No. T-896-07).

7) On May 28, 2007, Justice Harrington released his decision in Sanofi-Aventis' applications in Court File Nos. T-1384-04 and T-1888-04. The reasons can be found at 2007 FC 532. He dismissed both applications. Appeals were taken but ultimately dismissed for mootness by the Federal Court of Appeal on June 19, 2008 (A-288-07 and A-289-07). The decision of Justice Harrington will be referred to further in these reasons but, among other things, he held that, even if he would have found otherwise, Sanofi-Aventis could not assert the '206 patent because of the finding as to invalidity in the previous Apotex decision.

8) On June 21, 2007, lawyers for the Minister wrote to Riva's lawyers advising that the Minister had reversed his view as to whether Riva had to await the outcome of Pharmascience's *PMNOC Regulations* proceedings. In part the letter said:

> *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 also advise that Health Canada will soon be providing Riva with a letter confirming that this is so.*

9) On July 6, 2007, the Minister's official sent a letter to Riva's lawyers confirming what was said in the June 21, 2007 letter. In the July 6 letter, the Minister's official stated:

> *Further to the April 24, 2007 letter, I would like to inform you that the Therapeutic Products Directorate ("TPD") has had recent occasion to revisit the practice with regard to cross-referenced submissions, as a result of a number of issues that have arisen to date. The above-noted policy has been cited particularly in support of the TPD's position that a cross-referenced submission is not eligible to receive an NOC unless the NOC is issued for the original submission being cross-referenced in order to ensure that the requirements for safety and effectiveness under the Food and Drug Regulations have been met.*
>
> *However, a cross-referenced submission on patent hold has met the requirements of the Food and Drug Regulations by virtue of the cross-reference and the NOC is considered to be issuable, subject to compliance with the Patented Medicines (Notice of Compliance) Regulations. As such, the TPD is now of the view that an NOC should not be withheld in circumstances where a second person, whose cross-referenced abbreviated new drug submission is on patent hold, has fulfilled all the requirements under the Patented Medicines (Notice of Compliance) Regulations.*

In effect, the July 6 letter simply confirms the June 21 letter.

10) In the meantime, Pharmascience submitted a new Notice of Allegation to Sanofi-Aventis in which it again challenged the validity of the '206 patent. This time Pharmascience asserted the grounds for invalidity upon which Apotex had prevailed in its NOC proceeding. Sanofi-Aventis instituted an application in this

Court alleging, among other things, that Pharmascience had already lost its challenge to the validity of the ’206 patent and could not launch a second attack as to validity.

On October 12, 2007, Justice Mactavish of this Court gave a decision in the matter, cited as 2007 FC 1057. She held that Pharmascience could not serve a second Notice of Allegation challenging the validity of the patent, whatever new grounds as to validity are raised, when it failed to demonstrate invalidity the first time. She said at paragraph 74:

> ***74*** *Pharmascience gambled. It lost. It has to live with the consequences.*

That decision was affirmed by the Federal Court of Appeal on June 12, 2008, cited as 2008 FCA 213.

This decision of Justice Mactavish (and Federal Court of Appeal) was given after the present application before me was filed.

11) In T-127-07, Justice Martineau released his decision on March 4, 2008, cited as 2008 FC 291, in which he dismissed Sanofi-Aventis’ application against Riva in respect of two other patents.

12) Given the decisions of Justices Harrington and Martineau, both in Riva’s favour, there were no further *PMNOC Regulations* proceedings outstanding against Riva.

On March 14, 2008 (that is, several months after the application under consideration here was filed), the Minister issued a NOC to Riva to permit it to sell ramipril in Canada. Certain DIN (numbers) were assigned to Riva in respect of the product.

13) On April 11, 2008, Sanofi-Aventis filed an application for judicial review with the Court in T-584-08 to set aside the NOC granted to Riva. Prothonotary Aalto, by an Order dated May 26, 2008, stayed this proceeding pending the disposition of this trial.

14) In August 2008, Sanofi-Aventis noticed that Pharmascience is offering a ramipril product for sale in Canada which bears the DIN (numbers) assigned to Riva.

15) On August 1, 2008, Sanofi-Aventis filed a regular-type patent infringement action against Riva asserting the ’206 patent. No defence has yet been filed. The action is being case managed.

16) This Court was advised that there are two other regular patent actions commenced by Sanofi-Aventis in which the ’206 patent is asserted. One is against Apotex, the other against another generic, Novopharm. These actions are apparently scheduled to be heard at trial commencing in January 2009.

RELIEF SOUGHT – MOOTNESS

[14] The present application, filed July 23, 2007, requests, in addition to costs and "other relief", the following:

> *(a) an Order quashing the Decision;*
>
> *(b) an Order requiring the Minister to advise Riva that a NOC will not issue to Riva in respect of its ANDS for ramipril 2.5, 5 and 10mg capsules until such time as the requirements of the Regulations are met and Pharmascience receives a NOC in respect of its ANDS for ramipril 2.5, 5, and 5mg capsules; and*
>
> *(c) an Order prohibiting the Minister from issuing a NOC to Riva in respect of its ANDS for ramipril 2.5, 5 and 10 mg capsules, and/or quashing any such NOC issued to Riva pending the determination of this application, until such time as the requirement of the Regulations are met and Pharmascience receives a NOC in respect of its ANDS for ramipril 2.5, 5, and 5mg capsules; and*
>
> *(d) an interim Order, pursuant to sections 18.2 of the Federal Courts Act, including staying the effect of the Decision, and prohibiting the grant of a NOC to Riva for its ramipril capsules, pending final determination of this application;*

[15] As set out in the recital of facts above, a NOC was issued to Riva on March 14, 2007. I invited the parties to make submissions as to whether this application was moot in view of the NOC having been granted and in view of the fact that Sanofi-Aventis has brought other proceedings (T-584-08) challenging the grant of that NOC.

[16] Riva takes the position that the present application is moot. Counsel for the Minister provided a letter to the Court dated September 12, 2008, stating *inter alia*:

> *The position of the Crown Respondents, without acknowledging that the Application has any merit whatever, is that new evidence does not render it moot. That is, to the extent that the Application has any merit, the fact that a Notice of Compliance has now issued does not appear to give rise to a mootness issue.*
>
> *In essence, a proceeding will be dismissed for mootness primarily if the circumstances are or have become such that the Court cannot make an order having a practical effect. Here, it would seem that hearing the application could have such an effect.*
>
> *First, the Applicant has sought, by way of alternative relief, an Order quashing any Notice of Compliance issued in the interim. (Note that the Application is, of course, made under section 18 of the Federal Courts Act, rather than under the Patented Medicines (Notice of Compliance) Regulations.) Whether the Court ought to grant such relief on the grounds alleged remains at issue, but if it did, the Order would have practical effect.*
>
> *Second (or alternatively), if the Court were somehow to find that at law, Riva was not entitled to be issued a Notice of Compliance before Pharmascience received on (as argued by the Applicant), the Minister would consider the Notice of Compliance to have been invalidly issued to Riva and would revoke it. The proceeding would have a practical effect.*
>
> *Finally, on the other hand, if the Applicant's grounds are found by this Court to be without merit, to the extent that those grounds are also raised in the Applicant's subsequent application in T-584-08, that application might be dismissed as moot or an abuse of process. Thus, again, the proceeding would have a practical effect.*

[17] In oral argument at the hearing, Sanofi-Aventis' counsel agreed that the relief seeking to prevent the issuance of a NOC could no longer be pursued but asserted that the relief sought in paragraph a) of its prayer for relief:

> *(a) an Order quashing the Decision (of June 21, 2007 affirmed July 6, 2007)*

and part of (c):

> *(c) …quashing any such NOC issued to Riva…*

was still viable. Counsel, on behalf of Sanofi-Aventis, undertook to withdraw its application T-584-08 if it did not receive the relief requested in a) or part of c) as set out above.

[18] The fundamental case dealing with the issue of mootness is the decision of the Supreme Court of Canada in *Borowski v. Canada (Attorney General)*, [1989] 1 S.C.R. 342. This decision was revisited by that Court in *Doucet-Boudreau v. Nova Scotia (Minister of Education)*, [2003] 3 S.C.R. 3, in which that Court summarized the three factors to be considered by a Court in deciding whether to exercise its discretion to hear a matter even if moot (at paragraph 18):

> ***18*** *Although this appeal is moot, the considerations in Borowski, supra, suggest that it should be heard. Writing for the Court, Sopinka J. outlined the following criteria for courts to consider in exercising discretion to hear a moot case (at pp. 358-63):*
>
> *(1) the presence of an adversarial context;*
>
> *(2) the concern for judicial economy; and*
>
> *(3) the need for the Court to be sensitive to its role as the adjudicative branch in our political framework.*

[19] These factors are not to be applied in a mechanistic manner (*Borowski*, *supra*, paragraph 42).

[20] In the present application there is still an adversarial context in which the matter arises and the issues have been argued such that a judicial determination of relevant issues can be made.

[21] In the interests of judicial economy, given the undertakings of the Minister as set out in letter above and the undertakings Sanofi-Aventis made in oral argument at the hearing, I will proceed to make a determination of the issues still in play: (a) above and part of (c) above.

STANDING

[22] A threshold argument was raised in the written arguments of the Minister and Riva as to whether Sanofi-Aventis has standing to seek the relief sought either in quashing the decision of June 21, 2007 (July 6, 2007) to permit Riva's application for an NOC to proceed, regardless as to Pharmascience's cross-referenced application or to set aside the NOC ultimately granted to Riva. Much of this argument arose because Sanofi-Aventis' written argument was directed in part to Ministerial decisions made under the *Food and Drug Act* and *Regulations.*

[23] The parties are now all agreed that Sanofi-Aventis has no standing to challenge decisions of the Minister in as much as they arise under the *Food and Drug Act* and *Regulations.*

[24] In respect of the decision of the Minister as recited in the letter of June 21, 2007, and confirmed in the letter of July 6, 2007, what the Minister did was reverse an earlier position and permit Riva's application to proceed to be challenged under the *PMNOC Regulations*, whether by Sanofi-Aventis or whoever else may have relevant listed patents, regardless as to the fate of the cross-referenced Pharmascience application. As such the Minister was taking a final step under the *Food and Drug Act* and *Regulations* and not a step under the *PMNOC Regulations*. The *PMNOC Regulations* were about to be, but has not yet been, engaged. Sanofi-Aventis has

no status to challenge this decision. Sanofi-Aventis argued, not very seriously, that it has a public interest standing to challenge that decision. They did not press the point and neither will I. The relief requested in (a) of the Prayer for Relief will be denied.

[25] The relief requested in (c), as confirmed by the undertakings of the Minister and Sanofi-Aventis, is to quash the subsequently issued NOC. This clearly concerns the *PMNOC Regulations* in respect of ramipril. Sanofi-Aventis clearly has standing to seek a determination in respect of this matter (*Ferring Inc. v. Canada (Minister of Health)*, 2007 FCA 276 at para. 5).

QUASHING THE NOC (RELIEF (C))

[26] Having determined that I will exercise my discretion as to mootness, and that Sanofi-Aventis has standing in respect of challenging the issuance of a NOC to Riva; I will turn to the determination of that issue.

[27] In a nutshell, Sanofi-Aventis' position is that it would be absurd to grant a NOC to Riva when all it did was cross-reference Pharmascience's application and Pharmascience has been precluded from getting a NOC. Sanofi-Aventis characterizes the situation as that of an "end run" and points out that the evidence shows that the practical result of granting a NOC to Riva is that Pharmascience is now on the market with a generic version of ramipril. They argue that this is something the Order of Justice Snider prohibited and Justice Mactavish affirmed.

[28] Riva, on the other hand, says it was perfectly proper to consider its application for a NOC independently from that of Pharmascience and that Sanofi-Aventis had opportunities before Justice Harrington, in particular, as well as Justice Martineau to make arguments as to preclusion because of Pharmascience. Riva says that Justice Harrington in fact heard and determined such arguments in Riva's favour. Further, Riva argues, the preclusion against Pharmascience is a result of unique circumstances where it could not re-argue the validity of the '206 patent. Others, such as Apotex, did persuade the Court as to such invalidity and are marketing generic ramipril in Canada. Sanofi-Aventis, Riva argues, is trying to assert an invalid patent against Riva simply because of the unique Pharmascience preclusion.

[29] The Minister asserts that it was completely proper to grant a NOC to Riva once Justices Harrington and Martineau had made their determinations and that the preclusion of Pharmascience must be limited to that company alone.

[30] An analysis of the situation must start with an acknowledgement that nothing in the *PMNOC Regulations* or in any other statute or regulation is directed to the particular circumstances of this case which arise because of cross-referencing and the finding of invalidity of the '206 patent in the context of one NOC proceeding and not in another.

[31] This matter must be considered in light of decisions of the Federal Court of Appeal and this Court, including that of Justice Mactavish previously referred to, concerned with *res judicata*, abuse of process and issue estoppel. The Courts are concerned with the proliferation of NOC proceedings, particularly where the same patents and parties are concerned, and whether repeated proceedings constitute an abuse or otherwise should not be permitted to continue.

[32] The Courts have approached the situation by considering issue estoppel and whether the three preconditions have been established:

1. Has the same question been decided in the previous proceeding?

2. Is that previous decision final?

3. Were the parties to the previous and present decision the same or privies of such parties?

[33] These tests are not to be mechanically applied. I repeat what Sexton JA. of the Federal Court of Appeal said for that Court in *Abbott Laboratories v. Canada (Minister of Health)*, 2007 FCA 140 at paragraphs 26 to 29:

> ***26*** *On a number of occasions the Supreme Court of Canada has had the opportunity to explain the doctrine of issue estoppel. In Toronto (City) v. Canadian Union of Public Employees (C.U.P.E.), Local 79, [2003] 3 S.C.R. 77 at paragraph 23, Arbour J. described issue estoppel as "a branch of res judicata (the other branch being cause of action estoppel), which precludes the relitigation of issues previously decided in court in another proceeding."*

> ***27*** *In Danyluk v. Ainsworth Technologies Inc., [2001] 2 S.C.R. 460 at paragraph 33 ("Danyluk"), Binnie J. explained that there is a two-step analysis governing issue estoppel:*
>
> > *The first step is to determine whether the moving party (in this case the respondent) has established the preconditions to the operation of issue estoppel set out by Dickson J. in Angle, supra. If successful, the court must still determine whether, as a matter of discretion, issue estoppel ought to be applied.*
>
> ***28*** *The pre-conditions to the operation of issue estoppel referred to in Danyluk are those from Lord Guest's decision in Carl Zeiss Stiftung v. Rayner & Keeler Ltd. (No. 2), [1967] 1 A.C. 853, which were cited with approval by a majority of the Supreme Court of Canada in Angle v. Canada (Minister of National Revenue), [1975] 2 S.C.R. 248 at 254 ("Angle"):*
>
> > *...(1) that the same question has been decided; (2) that the judicial decision which is said to create the estoppel was final; and, (3) that the parties to the judicial decision or their privies were the same persons as the parties to the proceedings in which the estoppel is raised or their privies...*
>
> ***29*** *In Danyluk at paragraph 33, Binnie J. stressed that this test is not to be mechanically applied:*
>
> > *The rules governing issue estoppel should not be mechanically applied. The underlying purpose 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. (There are corresponding private interests.)*

[34] As stated in the *Danyluk* case and by Sexton JA. in *Abbott, supra*, at paragraph 51, any judicial discretion to be applied must be of very limited application. In *Abbott*, the Federal Court of Appeal expressly rejected an argument that a generic could serve multiple Notices of Allegation raising grounds as to invalidity of a patent different from those asserted in an earlier

Notice of Allegation and which had failed earlier in Court proceedings. The overriding issue is validity, not the grounds. If you fail once, that is the end of the matter. He said at paragraph 41:

> ***41*** *What the NOC Regulations require the second person to establish is, inter alia, that the patent is invalid or that it would not be infringed. In other words, the "issue" to be addressed is invalidity or non-infringement. The specific grounds on which the second person wishes to demonstrate invalidity, whether that be by obviousness, anticipation, overbreadth or lack of sound prediction, do not constitute separate issues for the purpose of issue estoppel but are merely different bases on which the second person may address the issue of invalidity. Consequently, multiple NOAs from the same generic relating to a particular pharmaceutical and alleging invalidity of a particular patent will generally not be permitted, even if different grounds for establishing invalidity are put forward in each. As a majority of this Court identified in P&G at paragraph 22, an exception to the application of this rule might be made in cases where facts material to the issue could not have been discovered with reasonable diligence at the time of the first litigation. No such exception applies in the present case, however. Pharmascience does not deny that it could have raised additional grounds of invalidity in the first NOA, but merely contends that splitting its claims is permissible within the scheme of the regulations.*

[35] In a decision released a few weeks later, *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 163, Sexton JA. again addressed the matter for the Federal Court of Appeal. In this case, the issue was whether an innovator, Sanofi-Aventis, could assert a patent against a generic where, in other earlier NOC proceedings involving a different generic, that patent had been determined to be invalid. The Court of Appeal held that it would be an abuse of process for Sanofi-Aventis to assert the patent, even if a different generic was involved. Not surprisingly, the patent was the very ’206 patent involved here and the earlier invalidity decision was the Apotex decision previously discussed. Sexton JA. said at paragraph 50:

> ***50*** *Finally, Sanofi-Aventis and Schering argue that a finding of abuse of process in this case will lead to unfairness. They say that while first persons will not be permitted to defend against allegations by subsequent generics after the same allegation made by an earlier generic has been found to be justified, subsequent generics will be permitted to repeat allegations already made earlier by other generics even if the earlier allegations were found to be unjustified. However, there is no unfairness in this scenario. All parties are held to the same standard: they must each put forward their entire case, complete with all relevant evidence, at first instance. The innovator is prevented from relitigating an issue already decided in a proceeding to which it was a party with the aid of additional evidence it chose not to adduce in the earlier proceedings. Generics likewise must put forward their full case at the first opportunity. Multiple NOAs issued by the same generic relating to a particular drug and alleging invalidity of a particular patent will generally not be permitted, even if different grounds for establishing invalidity are put forward in each. However, where one generic has made an allegation but has failed to put forward the requisite evidence and argument to illustrate the allegation is justified, it would be unjust to preclude a subsequent generic, who is apprised of better evidence or a more appropriate legal argument, from introducing it. Although this situation may give rise to the possibility of an inconsistent result, this concern is overridden by the potential for unfairness to the generic that is barred from bringing forward its case simply because another generic's approach was inadequate. In each situation, it is necessary to balance the effect of a proceeding on the administration of justice against the unfairness to a party from precluding it from bringing forward its case.*

[36] In her decision previously referred to, *Sanofi-Aventis Inc. v. Pharmascience Inc.*, 2007 FC 1057; aff'd 2006 FCA 229, Justice Mactavish was required to consider whether Pharmascience, having previously failed in its NOC challenge to validity of the '206 patent, could make a fresh challenge asserting grounds for invalidity in respect of which another generic had been successful. Pharmascience acknowledged that its first proceeding involved the same patent and same parties and validity of the '206 patent. At paragraph 36, she said:

> ***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] Pharmascience argued that the *Apotex* decision, *supra*, coupled with other decisions, created new law and that, as a matter of judicial discretion, it should be allowed to make these arguments. It also argued that it was unfair that it was the only generic unable to take advantage of the benefit of these decisions. Justice Mactavish rejected these arguments and at paragraphs 69 to 74 and said:

> ***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 para. 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.*

[38] In the present case, consideration must be given as to whether Riva is in any way a "privy" of Pharmascience. There is absolutely no evidence in the record of the present proceeding to indicate that it is. The only evidence is that Riva has cross-referenced Pharmascience's application, implying that Pharmascience has given its consent to such cross-reference. The other piece of evidence is that since Riva obtained its NOC, including certain DIN (numbers), Pharmascience is now offering a ramipril product for sale in Canada using identical DIN (numbers). The implication is that some commercial arrangement has been struck between Riva and Pharmascience.

[39] In his decision previously referred to, Justice Harrington was asked to consider the relationship between Riva and Pharmascience. In the present case, Riva has filed pieces of Sanofi-Aventis' written argument submitted to Justice Harrington where Sanofi-Aventis describes such an issue as a "threshold" issue. Justice Harrington did consider the issue on the basis of the evidence before him. At paragraphs 21 to 27 of his decision, 2007 FC 532, he said:

> ***21*** *The concept of parties being privy to each other is an offshoot of the principle of res judicata. The authorities, as they then were, were reviewed by Mr. Justice Richard, as he then was, in Hoffman-La Roche Ltd. v. Canada (Minister of National Health and Welfare), [1997] 2 F.C. 681, 72 C.P.R. (3d) 362. Mr. Justice Richard, deciding in the context of the PM (NOC) Regulations, referred to the decision of Mr. Justice Dickson, as he was, in Angle v. Minister of National Revenue, [1975] 2 S.C.R. 248, 47 D.L.R. (3d) 544, a tax case, wherein he said that res judicata, a form of*

estoppel, had two species. The first, "cause of action estoppel", precludes a person from bringing an action against another when that cause of action has already been decided. The second, "estoppel per rem judicatam", or "issue estoppel", is where, although the cause of action is different, the same point or issue of fact has already been decided.

22 *There are three identities that must be present in res judicata: the object, the action and the parties. The notion of "privies" deals with identity of parties. The question is whether two persons legally distinct should be treated as one. Call one the alter ego or "prête nom" of the other, or call it piercing the corporate veil; for two corporations to be treated as one there must be a relevant community or privity of interest between them.*

23 *Riva filed its Abbreviated New Drug Submission (ANDS) with Health Canada in the spring of 2004. It cross-referenced its regulatory submission to an earlier one submitted by Pharmascience, who neither then nor even now has received an NOC (see the decision of Madam Justice Snider in Aventis, above). Since Pharmascience did not have an NOC it follows that its version of Ramipril and the product monograph were not publicly available. This means, as was admitted on cross-examination, that Riva and Pharmascience had a trade relationship.*

24 *Mostafa Akbarieh, Riva's vice-president of Research and Development and Regulatory Affairs, admitted that its ANDS for Ramipril was not the first submission it filed which cross-referenced Pharmascience's submissions. Riva relies on the information found in the Pharmascience submission and its product monograph was, and had to be, identical.*

25 *Although Riva obviously had to have Pharmascience's permission, Mr. Akbarieh was not involved in negotiations. He did not know if there was a written agreement in place with respect to the cross-reference. Although he knew the two corporations did not have any common employees, he knew nothing of common shareholding or any other matter which might make the companies related. Riva's solicitor refused to undertake to make that information available.*

26 *It is clear that if the respondent in these applications were Pharmascience, it would be precluded by "issue estoppel" from relying on the allegations in its NOA. Indeed, Pharmascience*

> *unsuccessfully sought an order that it would be an abuse of process for Sanofi-Aventis to continue to argue that the '206 patent was valid in the light of the decision of Madam Justice Mactavish in Apotex, above. In Pharmascience Inc. v. Sanofi-Aventis Canada Inc., 2006 FCA 210, [2006] F.C.J. No. 933 (QL), Madam Justice Sharlow gave short shrift to that argument. She pointed out that all Madam Justice Mactavish did was dismiss Sanofi-Aventis' application for a prohibition order. That was not a final determination as to the validity of the'206 patent. Pharmascience had not made an allegation of invalidity on the basis of lack of sound prediction and so Sanofi-Aventis could hardly be faulted for failing to respond to an allegation which had not been made. See also the recent decision of the Federal Court of Appeal in Abbott Laboratories v. Canada (Minister of Health), [2007] F.C.J. No. 506, 2007 FCA 140.*
>
> ***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 parties were privies. All that has been established is that they have a trade relationship, and that is not enough (Hoffman-La Roche, above).*

[40] At paragraph 30, Justice Harrington dealt with the cross-referencing issue. He did not determine it, indicating that a separate judicial review would be more appropriate:

> ***30*** *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.*

[41] What the Court is left with in the present proceedings is very little evidence as to the relationship between Riva and Pharmascience. Additionally, the Court has a determination by Justice Harrington on the evidence before him, as summarized in paragraph 27 of his decision,

that there is no satisfactory evidence that the parties Riva and Pharmascience are privies and, at most, they have some sort of trade relationship.

[42] Thus, I am left with a question as to whether the mere fact that one party has cross-referenced a drug application of another party under the provisions of the *Food and Drug Act* and *Regulations* is enough to burden the cross-referencing party (Riva) with the judicial preclusions against challenging validity of a patent visited by the Courts against the other party (Pharmascience). I find that, without more, it is not sufficient simply to rely on the fact of cross-referencing so as to invoke preclusion. There must be more evidence than the Court has here such as would establish that one party is a privy of the other or that some other situation existed that would require that Court intervene to prevent an abuse.

[43] I find that Sanofi-Aventis fails in its application to set aside the ramipril NOC granted to Riva.

COSTS

[44] Costs are awarded to the Respondents at the usual level, middle of Column III.

JUDGMENT

For the Reasons provided herein;

THE COURT ADJUDGES that:

1. This application is dismissed; and

2. The Respondents are entitled to their costs to be taxed at the middle of Column III.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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