F ederal Court  Cour fédérale

Date: 20091116

Docket: T-1350-04

Citation: 2009 FC 1165

Toronto, Ontario, November 16, 2009

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

PFIZER CANADA INC. and PFIZER LIMITED

Applicants

and

THE MINISTER OF HEALTH and RATIOPHARM LIMITED

Respondents

REASONS FOR ORDER AND ORDER

[1] These reasons and order deal with a motion and cross-motion brought in the context of Patented Medicines (Notice of Compliance) Regulations SOR/93-133. Proceedings were brought between these parties several years ago and disposed of by this Court as well as the Federal Court of

Appeal. These motions deal with the effect on those earlier dispositions of a subsequent Judgment in a different proceeding, an action respecting validity of the same patent as was involved in the earlier NOC proceedings. This is yet another illustration as to how Byzantine these Regulations are and how badly they are in need of reform.

[2] For the reasons that follow I am dismissing Ratiopharm's motion to amend the Federal Court of Appeal Judgment in the NOC Proceedings as well as Pfizer's cross-motion to adjourn Ratiopharm's motion.

[3] The following is a chronology of relevant events all of which pertain to Canadian Patent 1,321,393 (the '393 Patent) and various Orders and Judgments of this and higher Courts as to its validity in proceedings involving Pfizer and Ratiopharm:

a. February 17, 2006: the Federal Court (von Finckenstein J.) in an NOC application between Pfizer, the Minister of Health and Ratiopharm, T-1350-04, dismissed Pfizer's application for an Order of Prohibition, finding that Ratiopharm's allegations as to invalidity of the '393 Patent were not shown by Pfizer to be not justified (2006 FC 220);
b. June 9, 2006: the Federal Court of Appeal, A-75-06, allowed an appeal from the decision of von Finckenstein J. and issued an Order of Prohibition (2006 FCA 214);
c. August 8, 2006: the Federal Court of Appeal dismissed Ratiopharm's motion for reconsideration of its Judgment of June 9, 2006;

d. February 1, 2007: the Supreme Court of Canada dismissed Ratiopharm's application for leave to appeal from the Federal Court of Appeal's Judgment of June 9, 2006;

e. July 8, 2009: the Federal Court (Hughes J.) in an action for infringement of the '393 Patent brought by Ratiopharm against Pfizer declared the '393 Patent to be invalid (2009 FC 711);

f. July 9, 2009: Pfizer files a Notice of Appeal to the Federal Court of Appeal from the Federal Court Judgment of July 8, 2006. That appeal A-281-09 is currently waiting to be set down for hearing subject to the disposition of several motions;

g. Also on July 9, 2009: Ratiopharm received its Notice of Compliance, the Federal Court of Appeal Prohibition Order was considered to be no longer operative since the prohibition only lasted till the expiry of the '393 Patent and the Patent had been declared invalid on July 8, 2009;

h. August 14, 2009: Ratiopharm filed a Notice of Motion in the present proceedings seeking to set aside the Order of the Federal Court of Appeal dated June 9, 2006 and to dismiss this application;

i. October 9, 2009: Pfizer filed a Notice of Motion to quash or adjourn Ratiopharm's motion pending the determination of the appeal in A-284-09.

[4] Now before me are Ratiopharm's motion of August 14, 2009 and Pfizer's motion of October 9, 2009.

[5] I will deal first with Pfizer's motion of October 9, 2009 which requests the quashing or a stay of Ratiopharm's motion. Essentially the basis of Pfizer's motion is that, since an appeal is pending from the Judgment declaring the '393 Patent to be invalid, Ratiopharm's motion is premature. Ratiopharm resists this motion, saying that the Judgment declaring invalidity is in effect now and Ratiopharm's motion must be dealt with on the basis of matters as they stand now. If matters change after an appeal, Ratiopharm argues, Pfizer can bring its own motion to deal with the changes.

[6] Ordinarily I would be inclined to agree with Pfizer's position. It would ordinarily be a waste of judicial resources to deal with a matter where an appeal is pending and, as is apparent here, being diligently pursued. However, since Ratiopharm's motion has been fully argued and I have found many reasons to dismiss it, the best use of judicial resources in this case is to deal with that motion. Therefore, I have heard and will dispose of Ratiopharm's motion.

[7] Turning to Ratiopharm's motion, it seeks an Order of this Court setting aside the order of the Federal Court of Appeal dated June 9, 2006 in A-75-06, an Order dismissing Pfizer's application in this proceeding T-1350-04, as well as costs of the application and appeal on a solicitor-client basis as well as costs of the motion. I am dismissing that motion on three grounds:

i. I find that this Court has no jurisdiction to set aside the Order of the Federal Court of Appeal, it is for that Court to do so, if so advised, not this Court;

ii. The matter is moot; and

iii. The Order of the Federal Court of Appeal is dispositive of the matter and no Order of dismissal of this application can now be made.

1. <u>No Jurisdiction</u>

[8] The powers of the Federal Court of Appeal in the case of an appeal from the Federal Court, are set out in section 52(b) of the *Federal Courts Act*, R.S.C. 1985, c. F-2 and include the power to give the judgment and award the process or other proceedings that the Federal Court should have given or awarded:

Powers of Federal Court of Appeal	***Pouvoirs de la Cour d'appel fédérale***
52. *The Federal Court of Appeal may*	***52.*** *La Cour d'appel fédérale peut :*
[…]	*[…]*
(b) in the case of an appeal from the Federal Court,	*b) dans le cas d'un appel d'une décision de la Cour fédérale :*
(i) dismiss the appeal or give the judgment and award the process or other proceedings that the Federal Court should have given or awarded,	*(i) soit rejeter l'appel ou rendre le jugement que la Cour fédérale aurait dû rendre et prendre toutes mesures d'exécution ou autres que celle-ci aurait dû prendre,*

[9] This statutory provision does not say that the Federal Court of Appeal judgment is a judgment of the Federal Court, it says that it is a judgment that the Federal Court should have given. The judgment remains that of the Federal Court of Appeal. The Federal Court of Appeal per Trudel J.A., in *Grenier v. The Queen*, 2008 FCA 63 wrote at paragraph 6 (in part):

> *a. the trial court cannot correct a judgment it has rendered if the judgment has been the subject of a Court of Appeal judgment, and I would add, still less if it is being implemented or has been implemented, and the conclusions sought were included in those considered by the appeal (see Rule 399 of the Federal Courts Rules; Déziel v. Canada, 2005 TCC 70);*

[10] While I appreciate that G*renier* was addressing a situation where a trial court was attempting to correct its own judgment, not that of a court of appeal, this principle is clear, once the Court of Appeal has disposed of the matter, it is for that Court not this one, to deal with that disposition.

[11] Ratiopharm's Counsel has cited a number of decisions of this Court and the Federal Court of Appeal none of which stand for the proposition that an Order or Judgment of the Federal Court of Appeal rendered after the hearing of the appeal on the merits can be varied or set aside by the Federal Court. In my opinion the Federal Court does not have the power to do so.

[12] In particular Ratiopharm's Counsel relied on a decision of Strayer J.A. as he then was, sitting as a Judge of the Federal Court of Appeal in *Allied Signal Inc. v. DuPont Canada Inc.* (1996), 65 C.P.R. (3d) 230 (FCA. In that case, DuPont, which had been found by the Trial Division to have infringed a patent, sought to introduce an assertion that a new, allegedly different, product,

did not infringe in the Court of Appeal. Strayer J.A. found that such an allegation required new evidence and findings of fact therefore should be heard by the Trial Division. He said at page 231:

> *In my view, that application should be heard in the Trial Division. As a matter of law the Court of Appeal, in issuing the injunction, acted under s.52(b)(i) of the Federal Court Act, R.S.C. 1985, c. F-7, in giving the judgment that it considered the Trial Division should have given. The injunction therefore is in effect an injunction of the Trial Division. Further, in both law and practice it is appropriate that the application for a declaration be heard in the Trial Division. There are obviously some contested matters which will require the consideration of new evidence and findings of fact. These are normally matters for the Trial Division.*

[13] Ratiopharm's Counsel emphasises the statement that the injunction is *"in effect an injunction of the Trial Division"* and urges that this means that the Court of Appeal judgment is, in reality, a Trial Division judgment. I do not think that this statement can be pushed that far. In my opinion Strayer J.A. was simply reinforcing his view that, given that new evidence and factual findings were required, the Trial Division should deal with the matter.

[14] Ratiopharm's Counsel also relies upon the decision of the Federal Court of Appeal in *Nu-Pharm Inc. v. Canada (Attorney General)* (1999), 2 C.P.R. (4th) 49 at paragraph 21 where that Court said that where there is a remedy in the Trial Division that remedy should be addressed first. Decary J.A. for the Court wrote at paragraph 21:

> ***21*** *In the instant case, were the appeal allowed to proceed, the Court of Appeal would be asked to rule on issues not raised in the Trial Division and to do so on the basis of evidence not adduced below. It would make more practical sense in such circumstances to have the application re-heard by the Trial Division. Where there is a remedy available in the Trial Division, litigants should normally be addressing themselves to the Trial Division first. I note that in Société des Acadiens the existence of an alternate remedy does not*

> *appear to have been raised, the interest of the parents in the proceedings were not in issue - by contrast in the present case, whether or not the applicants have an interest in the original proceeding is the very issue this Court would be called upon to decide without having the benefit of the opinion of the Trial Judge on it - and the absent party had agreed to be bound in appeal by the record in the Trial Division (see Re Association of Parents for Fairness in Education, Grand Falls District 50 Branch and Société des Acadiens du Nouveau-Brunswick Inc. et al (1984), 8 D.L.R. (4th) 238 at 246 (N.B.C.A.)).*

[15] I view this paragraph as saying that <u>if</u> there is a remedy in the Trial Division that remedy should be pursued first. I do not view this paragraph as saying that a remedy lies first in the Trial Division to revise a Federal Court of Appeal judgment.

[16] Therefore, I find that Ratiopharm's remedy, if any, lies with the Federal Court of Appeal thus its motion must be dismissed. However, if I am wrong in this finding, I will address the other matters that arise.

2. <u>Mootness</u>

[17] In the present proceedings the Prohibition Order given by the Federal Court of Appeal has been rendered moot since the Notice of Compliance, which would have been prohibited by that Order, has now been given to Ratiopharm.

[18] Ratiopharm argues that there is a second matter still outstanding which is whether the application should be dismissed, thus, presumably opening the gateway to Ratiopharm under section 8 of the *NOC Regulations* to make a claim for monetary recovery.

[19] The well known decision of the Supreme Court of Canada in *Borowski v. Canada (Attorney General)* [1989], 1 S.C.R. 342 advises that while a Court ordinarily should not hear a case that has become moot, it has a discretion to hear the case where there may still be some live controversy or where some other particular reason dictates that the matter be heard. Ratiopharm relies on a decision of the Federal Court of Appeal *in Apotex Inc. v. Bayer AG*, 2004 FCA 242 at paras. 14 and 17 where, notwithstanding that a Notice of Compliance had issued immediately following a decision of the Federal Court dismissing an application for prohibition, the Federal Court of Appeal decided to hear the appeal since the Federal Court Order dismissing the application would trigger a section 8 claim for compensation.

[20] I distinguish the *Apotex* case. It was one where the Court of Appeal had not yet heard the appeal on its merits. Here the Court of Appeal has heard the case on its merits and made a decision to order prohibition. The matter was finally determined. For the reasons that follow in respect of the third issue here, there is no longer any live controversy in these proceedings respecting section 8. All matters are now moot. There is no reason to hear the motion by Ratiopharm.

3. Can an Order for Dismissal be Made Now?

[21] Ratiopharm's Counsel argues for a dismissal for the NOC proceedings on three grounds:

1. The inherent jurisdiction of the Court over its own processes and orders;
2. Rule 399(2)(a), a new matter arising subsequent to the Order, namely the Judgment as to invalidity, and
3. Rule 399(2)(b) that the Order was obtained by fraud.

First I will address the matter generally.

[22] Section 8 of the *NOC Regulations* triggers a liability for compensation of a respondent such as Ratiopharm by an applicant such as Pfizer if the application to this Court has been withdrawn or discontinued or dismissed. Thus a respondent such as Ratiopharm is understandably desirous of an Order that dismisses the application.

[23] Here the application was dismissed in the first instance by this Court, however that Order was reversed by the Federal Court of Appeal, hence not dismissed. This Court in a different proceeding, an action for impeachment of the '363 Patent brought by the Respondent, Ratiopharm against Pfizer, declared that Patent to be invalid. There is a pending appeal. The patent has been impeached, thus the patent has "expired", the Prohibition Order of the Federal Court of Appeal is no longer effective. The operative part of the Judgment of the Federal Court of Appeal dated June 9, 2009 reads:

JUDGMENT

> *[1] The appeal is allowed with costs and the Order of the Applications Judge, dated February 17, 2006, is set aside.*

> *[2] The appellants' application is allowed with costs and an Order is issued prohibiting the Minister from providing an NOC to Ratiopharm in respect of its proposed amlodipine besylate products until the expiry of the '393 patent.* (Emphasis added).

[24] There are several reasons for which a patent may be said to "expire"; its full term (17 or 20 years) could have come to an end; the patentee may have stopped or neglected to pay maintenance fees; the patent may have been declared to be invalid. The last of these is the case here. The NOC Prohibition Order has come to an end not because the proceedings were dismissed, rather it is because the patent has expired, (at least unless a higher Court on appeal holds otherwise).

1. Inherent Jurisdiction

[25] Ratiopharm's Counsel says that the Court has inherent jurisdiction over its own Orders, including Prohibition Orders in an NOC proceeding, such that when events change, the Order may be revisited. Reliance is placed on the decision of the Federal Court of Appeal in *Apotex Inc. v. AB Hassle*, 2008 FCA 416 and in particular paragraph 30 where Sharlow J.A., for the Court wrote:

> ***30*** *As mentioned above, it has been established that a final determination by the Federal Court that a patent is invalid will prevail over a prohibition order relating to that patent, justifying the setting aside of the prohibition order (*Hoffmann-La Roche, *cited above). By the same reasoning, the prohibition orders in Case 1 or Case 2 may be set aside if it is determined in an action that the Apotex product will not infringe any of the patents in issue in those cases. I understand from the submissions of Astrazeneca in this appeal that the question of infringement is to be determined in an action in the Federal Court (File T-1409-04). Nothing in these reasons will prejudice the right of Apotex to seek to set aside the prohibition orders in Case 1 or Case 2, if it is successful in that case.*

[26] I view this case as saying that a Prohibition Order may be vacated if, as is the case here, in an action the patent is held to be invalid or that the generic does not infringe. I do not view this statement as saying that the application for prohibition will subsequently be dismissed notwithstanding that the Prohibition Order is no longer effective.

[27] An NOC proceeding does not constitute an *in rem* proceeding as to the validity of a patent. It is a "special purpose" proceeding for the determination as to whether the Minister should be prohibited from issuing an NOC to a generic (*Eli Lilly Canada Inc. v. Novopharm Limited*, 2007 FCA 359 at para. 40). NOC proceedings are a unique, self-contained proceeding, designed to determine whether or not the Minister of Health should issue a Notice of Compliance to a generic based on a determination by the Court as to whether or not the allegations made by the generic in its Notice of Allegations are justified or not. No decision *in rem* is made.

[28] This to be contrasted with an action for impeachment of a patent, which is a different sort of proceeding. If the Court decides that the patent is invalid, it is impeached, that is, declared invalid and void. The judgment affects the patent itself and not just the parties (*Patent Act*, section 60). I repeat what I said in *Apotex Inc. v. Syntex Pharmaceuticals International Ltd.*, 2009 FC 494 at paragraph 41 in citing Sir Robin Jacob in *Unilin* for the proposition that a subsequent proceeding invalidating a patent should not affect an earlier judgment in which the patent was considered to be valid:

> *41 The English Courts have in a series of cases, Poulton v. Adjustable Cover and Boiler Block Company (1908), 25 R.P.C. 661 (CA); Coflexip SA v. Stolt Offshore MS Ltd. (No. 2), [2004] F.S.R. 708 (CA); and Unilin Beheer BV v. Beerry Floor NV, [2007] EWCA*

> *Civ. 364 (CA), considered the situation where a party was found to infringe a patent and, subsequently, that patent was found to be invalid in other proceedings. The result has been that the award of damages and costs remains but the injunction is terminated. The position of the English Court of Appeal was nicely put by Lord Justice Jacob in the recent Unilin decision at paragraphs 44 to 46:*
>
> > *44. Now a purist may say: it is a nonsense, and moreover an unjust nonsense, for a man to have to pay for doing what, with hindsight, we know to have been lawful. The purist might, I suppose, also say that a licensee who has paid royalties under a patent subsequently revoked ex tunc should get his money back. He might even say that a man who lost profits by refraining from some commercial activity by reason of a fear, now known to be groundless, of infringing the patent should have some remedy.*
> >
> > *45. But I think there are good and pragmatic reasons why the purist approach makes bad business sense. You cannot unravel everything without creating uncertainty. And where a final decision has been made on a fair contest between the parties, that should stand as the final answer between them.*
> >
> > *46. In a sense a patent is always potentially at risk - someone may come up with a bang on but obscure piece of prior art (my favourite pretend example is an anticipation written in Sanskrit wrongly placed in the children's section of Alice Springs public library), or simply with better evidence on known prior art. That is no reason for undoing what has been done or regarding a final decision as merely provisional. After a final decision businessmen should be able to get on with their businesses, knowing what the position is.*

[29] In the present case Ratiopharm had its day in Court in the NOC proceedings, it raised the issues that it believed to be important, adduced the evidence that it chose and, made the arguments that it wished. The result was a Prohibition Order valid until the “expiry” of the patent.

[30] The Judgment given in the impeachment action which is a different proceeding has caused the patent to "expire" but it does not "dismiss" the NOC proceedings.

2. Rule 399(2)(a)

[31] Rule 399(2)(a) of the *Federal Courts Rules* states that the Court may set aside or vary an order:

> *(a) by reason of a matter that arose or was discovered subsequent to the making of that order*

[32] The issue here is the same as that discussed with respect to inherent jurisdiction. There has been a separate proceeding, an action for impeachment of the '393 Patent, which has caused that Patent to "expire". The Prohibition Order is no longer operative by its very terms. That does not mean that the NOC application proceedings must therefore be dismissed.

3. Rule 399(2)(b)

[33] Rule 399(2)(b) of the *Federal Courts Rules* states that the Court may set aside or vary an order:

> *(b) where the order was obtained by fraud*

[34] This issue has caused me considerable difficulty. In the impeachment action respecting the '363 Patent, *Ratiopharm Inc. v. Pfizer Limited*, 2009 FC 711 I found that section 53 of the *Patent Act*, R.S.C. 1985, c. P-5, came close to being directed to issues of fraud and that Pfizer had breached the provisions of that section in at least three respects. I wrote at paragraphs 196, 197 and 204:

> ***196*** *Canada, unlike other jurisdictions such as the United States, does not have an explicit statutory provision directed to issues of fraud. However, Section 53 comes close. In so doing, I agree with the submissions of Pfizer's counsel that allegations directed to this section must be pleaded with particularity and a party alleged to have breached the provisions of that section should have ample opportunity to know what is alleged and prepare its defences.*
>
> ***197*** *Ratiopharm has alleged that Pfizer has breached section 53 in three aspects having regard to the Amended Statement of Claim, October 20, 2008, paragraphs 63 to 78:*
>
> *i) omitting to mention the stability of the mesylate monohydrate and adding that it was unsuitable for tablet formulations;*
> *ii) omitting the sulphonic acid test data showing mesylate, napsylate and tosylate to be stable, non-hygroscopic hydrates; and*
> *iii) adding a statement that none of the salts outlined in EP167 had been found to satisfy the four criteria for pharmaceutically acceptable salts.*
>
> …
>
> ***204*** *Here I find that the three pleaded matters were misstatements, they were misleading and, sufficient intent to make such statements has been made out in the evidence. The '393 Patent is invalid for this reason as well, it cannot be saved under section 53(2) of the Patent Act.*

[35] In the NOC application proceedings which ultimately resulted in the Federal Court of Appeal Judgment now under consideration, Ratiopharm did not raise in its Notice of Allegations

any allegation or issue as to fraud or as to section 53 of the *Patent Act*. As a result neither the Federal Court nor the Federal Court of Appeal had to address those issues. There was, to use the NOC proceeding vocabulary, no issue as to "justification" of any allegation respecting fraud or section 53.

[36] Ratiopharm, however, asks that this Court take a broader view of the matter. Its Counsel urges that Pfizer has been found to have knowingly drafted, applied for and received a grant for a patent that has been found to have contained false statements. It put that patent on the list under the NOC Regulations and brought an application for prohibition which it subsequently won. It is argued that given the nature of Notice of Application proceedings in which there is no discovery, Ratiopharm had no way of knowing what went on behind closed doors at Pfizer thus it could not have any basis for making allegations as to fraud or breach of section 53.

[37] I drew to the attention of both Counsel the decision of Justice McGillis of this Court in *SmithKline Beecham Inc. v. Apotex Inc.* (1999), 1 C.P.R. (4th) 99 where she was dealing with a situation where the generic was alleging that its medicine would not infringe the patent at issue on the basis that it would not convert to a hemihydrate. This was knowledge unique to the generic. McGillis J. found for the generic but concluded that there would be "very grave" consequences if the generic's representations to the Court did not prove to be correct. She wrote at paragraph 40:

> ***40*** *I have therefore concluded that Apotex should not be prevented from taking its anhydrate tablets to market on the basis of a potential conversion to hemihydrate at some undisclosed and imprecise time in the future. In the event that Apotex's anhydrate tablets do convert to hemihydrate, in whole or in part, it will face "very grave" consequences at that point in time. [See Hoffman-LaRoche Ltd. v.*

> *Canada (Minister of National Health and Welfare) (1996), 70 C.P.R. (3d) 206 at 213 (F.C.A.); Zeneca Pharma Inc. v. Canada (Minister of National Health and Welfare) (1996), 69 C.P.R. (3d) 451 at 452 (F.C.A.)]*.

[38] McGillis J. did not elaborate as to what those "very grave" consequences might be nor do the cases that she cited serve to amplify the point. Counsel for the innovator drug company applicants in many subsequent NOC Proceedings have made ominous references to this statement of McGillis J. but no Court has elaborated upon these words.

[39] On the other hand, Pfizer's Counsel argues that the fraud as contemplated by Rule 399(2)(b) must be related to the issues that were before the Court that made the Order under consideration. There was, it is argued, no issue as to section 53 or fraud before this Court or the Court of Appeal in the NOC proceedings. The matters determined by the NOC proceedings did not implicate section 53 or fraud. Further, Pfizer's Counsel argues, Pfizer was quite entitled to rely on the presumption of validity afforded by the *Patent Act*, a validity that was sustained by the Federal Court of Appeal in the circumstances of the allegations raised by Ratiopharm in its Notice of Allegations and the evidence lead in that proceeding.

[40] There has been since 1993, the year that the *NOC Regulations* were introduced, considerable jurisprudence developed as to how these proceedings are to be conducted. Canada is alone in this respect since only the United States has anything similar, the Hatch-Waxman Act (Orange Book) proceedings. The United States procedure is quite different from Canada's. Canada's jurisprudence has developed along what I believe to be an unfortunate and narrowly

construed path. For instance a Notice of Allegation cannot be amended, prior art cited as a Notice of Allegation for one purpose cannot be relied upon in argument at the hearing for another purpose and so forth. My personal view however will not colour or influence my decision here.

[41] Recently, the Federal Court of Appeal has provided two decisions that are difficult to reconcile. The first is a 2007 majority decision of that Court in *Sanofi Aventis Canada Inc. v. Novopharm Limited*, 2007 FCA 163 where Sexton J.A., with whom Sharlow J.A. concurred, wrote 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.*

[42] This decision was seen by many to be of great assistance in dealing with the multiples of cases before the Court in NOC proceedings involving the same patent which different parties were litigating over and over.

[43] In the summer of 2009, the Federal Court of Appeal in *Apotex Inc. v. Janssen Ortho Inc.*, 2009 FCA 212 revisited the *Sanofi* case. The majority decision in *Apotex*, was written by one of the Judges who was on the panel in *Sanofi*. At paragraphs 44 and 45 Nadon J.A., with whom Trudel J.A. concurred, wrote:

> ***44*** *In my view, a fair reading of paragraph 50 of Sexton J.A.'s Reasons in Sanofi-Aventis, supra, does not lead to the conclusion that a second person can only put forward a NOA on grounds similar to those put forward by a different generic in other proceedings when it has better evidence to offer or better legal arguments to make. I believe that at paragraph 50 of his Reasons, Sexton J.A. was simply attempting to explain his view that notwithstanding the possibility that different judgments might be rendered with respect to identical or similar NOAs, fairness required that a generic, such as Apotex in the present case, which had not yet litigated the issues which it raised in its NOA, be allowed to have its day in court. In my view, it cannot be seriously argued that Sexton J.A. was advocating that an assessment of the second generic's evidence and legal arguments had to be made before it could send its NOA and respond to the application for prohibition.*
>
> ***45*** *I am therefore satisfied that nothing said in our decision in Sanofi-Aventis, supra, supports the Judge's conclusion that a second person, unless it is in a position to show that it has "better evidence or a more appropriate legal argument", cannot send a NOA to a patentee and, hence, respond to the patentee's application for prohibition on grounds similar to those put forward by a different generic in other proceedings with the same patentee. I therefore*

> *conclude that the Judge erred in concluding as he did on the issue of abuse of process.*

[44] Layden-Stevenson J.A. who wrote a separate decision in *Apotex* wrote at paragraph 81:

> ***81*** *LAYDEN-STEVENSON J.A. (dissenting reasons):-- I have read the reasons of my colleague and I agree, for the reasons given by him, this Court's decision in Sanofi-Aventis does not stand for the proposition that, unless a second person is in a position to show it has "better evidence or a more appropriate legal argument", it cannot send a NOA to a patentee and respond to the patentee's application for prohibition on grounds similar to those put forward by a different generic in other proceedings with the same patentee. It necessarily follows that the applications judge erred in concluding as he did on the issue of abuse of process.*

[45] A narrow distinction between the *Apotex* and *Sanofi* decisions can be made on the basis that in *Apotex* the Court of Appeal is saying that a generic cannot be precluded from alleging something that was dealt with in a prior proceeding whereas *Sanofi* is saying that a Court in considering the matter at the hearing should be cautious about making a determination different from an earlier determination unless there is better evidence or more appropriate argument. If this is not the difference, then it is difficult to discern any difference other than that the decisions are contradictory.

[46] The point that I draw from these two decisions and the general jurisprudence is that the Courts have adopted a strict and narrow interpretation of the *NOC Regulations* and proceedings under those *Regulations*. The position taken by Pfizer's Counsel here is more consistent with that view and the recently expressed view of the Federal Court of Appeal in *Apotex, supra*, that each proceeding is to be considered on its own "stand alone" merits, without consideration as to what

may have happened in, for instance, a fully litigated action respecting the same patent. Nadon J.A. wrote in *Apotex, supra*, at paragraphs 38, 47, 48 and 70:

> ***38*** *In my view, the learned Judge clearly erred in concluding, as he does at paragraph 205 of his Reasons, that "the Court does agree with the applicants' argument on the abuse of process". Specifically, the Judge agreed with the respondents' submissions that because the validity of the '080 patent had already been determined by the Federal Court in the Novopharm trial and by this Court in the Novopharm appeal, Apotex's attempt in these proceedings to contest the validity of the patent as a selection patent was simply an attempt, under the guise of differently-cloaked arguments, to relitigate the issues which had been litigated in the Novopharm trial and in the Novopharm appeal. Since most, if not all, of the arguments made by Apotex in these proceedings had been considered and dealt with by the Federal Court and this Court, there was simply no basis for allowing Apotex to contest the validity of the '080 patent unless it had either "better evidence or a more appropriate legal argument".*
>
> …
>
> ***47*** *Because there was no abuse of process on the part of Apotex, the Judge was required to assess the evidence put before him by both parties independently of the findings made by Hughes J. in the Novopharm trial. I therefore turn to that question. Before answering it, however, it is worth repeating the arguments which Apotex makes in support of its assertion that the Judge erred in applying the test for abuse of process and that, as a result, this Court must intervene.*
>
> ***48*** *Reduced to its essentials, Apotex's position is that this was the first time that it raised the issues which are now before the Court and that, as a result, it was entitled to a fresh determination by the Judge of these issues on the evidence before him, which determination had to be made irrespective of the findings made and conclusions reached by Hughes J. in the Novopharm trial. Thus, it submits that it did not have a fair hearing and that its fate was determined by the Novopharm trial.*
>
> …
>
> ***70*** *To sum up, I have read the Judge's Reasons on numerous occasions. On each occasion, I have attempted to understand the rationale behind his Reasons so as to determine whether he conducted an assessment of the evidence independent of that made by Hughes J. in the Novopharm trial. As I am unable to so conclude,*

> *I am inevitably led to the view that the Judge's misunderstanding of the principles set out in Sanofi-Aventis, supra, has tainted his assessment of the evidence before him. Formulated in another way, it is my view that the Judge did not conduct a parallel enquiry, but an enquiry which co-mingled the evidence before him and the findings made by Hughes J. in the Novopharm trial.*

Thus I find that I am to consider the NOC application proceedings in isolation from the impeachment action. In other words the findings and Judgment in the impeachment action, are not to affect the finding and Judgment in the NOC proceedings. This is particularly so since in the NOC proceedings no section 53 or fraud allegations were raised.

[47] Therefore I find that Rule 399(1)(b) cannot apply in the present circumstances since there was no fraud, or section 53 violation, at issue in the NOC proceeding.

Conclusion and Costs

[48] I have heard the matter on its merits having dismissed Pfizer's matter to adjourn. I have not "quashed" Ratiopharm's motion as Pfizer requests and I have dismissed Ratiopharm's motion.

[49] Pfizer is entitled to costs of this motion. I invited the parties to make submissions as to quantum. I will reserve on the quantum until I receive those submissions which I expect to receive in one week.

ORDER

For the reasons provided:

THIS COURT ORDERS that:

1. Pfizer's motion to quash or adjourn Ratiopharm's motion is dismissed;
2. Ratiopharm's motion to dismiss the NOC proceedings is dismissed; and
3. Pfizer is entitled to costs to be fixed after receipt of submissions from Counsel within one week.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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PLACE OF HEARING:	Toronto, Ontario
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REASONS FOR ORDER AND ORDER:	Hughes J.
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APPEARANCES:

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