Date: 20080529

Docket: T-1566-07

Citation: 2008 FC 674

BETWEEN:

PFIZER CANDA INC.,
PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, and
PFIZER RESEARCH AND DEVELOPMENT COMPANY N.V./S.A.

Applicants

and

NOVOPHARM LIMITED and
THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

TEITELBAUM D.J.

[1] The Applicants (together "Pfizer") bring this motion to set aside the April 18, 2008 Order (the "Order") of Madam Prothonotary Tabib allowing Novopharm Limited's ("Novopharm") motion to dismiss Pfizer's application in part pursuant to subsection 6(5)(*b*) of the *Patented Medicines (Notice of Compliance) Regulations* (the "*NOC Regulations*") on the basis that the application is an abuse of process in relation to Canadian Patent No. 2,044,748 ("748 patent").

[2] The written and oral submissions of both counsel for the Applicants and counsel for the Respondents were very well articulated. For the reasons set out below, I find in favour of the Respondents and agree with the findings contained in Prothonotary Tabib's Order of April 18, 2008, specifically, that Pfizer's application in respect of the 748 patent constitutes an abuse of process. Because of the very thorough written submissions of the Respondents, I have adopted many of their submissions in my reasons below.

Background

[3] The 748 patent is listed on the Patent Register in relation to the drug VIAGRA containing the medicinal ingredient sildenafil citrate. On July 6, 2007, Novopharm served Pfizer Canada Inc. with a notice of allegation ("NOA"), in which it alleged that the 748 patent is invalid on grounds that include lack of utility and lack of sound prediction.

[4] In response to Novopharm's NOA, on August 24, 2007, Pfizer commenced the within application pursuant to section 6 of the *NOC Regulations* for an order prohibiting the Minister of Health (the "Minister") from issuing a notice of compliance ("NOC") to Novopharm for its tablets containing the medicine sildenafil citrate until after the expiry of the 748 patent.

[5] The 748 patent has already been the subject of proceedings pursuant to the *NOC Regulations*, although that case involved a different generic, namely Apotex Inc. (see *Pfizer Canada Inc. v. Apotex Inc.*, (2007) 59 C.P.R. (4th) 183, 2007 FC 26 (F.C.T.D.) (hereinafter *Pfizer v. Apotex*), aff'd (2007), 60 C.P.R. (4th) 177, 2007 FCA 195 (F.C.A.), leave to appeal dismissed [2007]

S.C.C.A. No. 371 (S.C.C.)). At the trial level, Justice O'Reilly dismissed Pfizer's application against Apotex on the basis that Pfizer failed to prove that Apotex's allegation of invalidity of the 748 patent based on lack of utility and sound prediction was not justified. This decision was upheld by the Federal Court of Appeal, and leave to appeal to the Supreme Court of Canada was denied.

[6] It is not contested that Novopharm's NOA contains all of the allegations of invalidity with respect to the 748 patent that were contained in Apotex's successful NOA in *Pfizer v. Apotex*.

Decision Under Review

[7] On November 8, 2007, Novopharm brought a motion, pursuant to subsection 6(5)(*b*) of the *NOC Regulations*, alleging that Pfizer's application to the Minister, dated August 24, 2007, was an abuse of process insofar as it related to the 748 patent. On April 18, 2008, Prothonotary Tabib issued an Order in which she allowed Novopharm's motion to dismiss Pfizer's August 24, 2007 application in part, on the basis that the application as it related to the 748 patent constituted an abuse of process.

[8] Prothonotary Tabib rejected Pfizer's arguments that the circumstances in the proceedings before Justice O'Reilly in *Pfizer v. Apotex* were distinguishable from those in the Federal Court of Appeal's decision in *Sanofi-Aventis Canada Inc. v. Novopharm Limited*, (2007) 59 C.P.R. (4th) 416, 2007 FCA 163 (F.C.A.) [hereinafter *Sanofi-Aventis v. Novopharm*]. Pfizer attempted to distinguish those circumstances on two grounds. First, that the evidence filed in *Sanofi-Aventis v. Novopharm* was rejected whereas in *Pfizer v. Apotex* no evidence had been filed and thus Justice O'Reilly's

decision was made solely on a failure to meet the burden of proof. Second, that Pfizer's failure to bring the required evidence before Justice O'Reilly in *Pfizer v. Apotex* was not a conscious choice by Pfizer (which was specifically held to be insufficient justification in *Sanofi-Aventis v. Novopharm*), but a failure on the part of Pfizer to appreciate the need for that evidence. Prothonotary Tabib concluded that these marginal differences were not sufficient to warrant a non-application of the abuse of process doctrine.

[9] Prothonotary Tabib held that the Court of Appeal's decision in *Sanofi-Aventis v. Novopharm* was not "an isolated exercise of discretion confined to the particular facts" of that case but that:

> [i]t is the expression of a broad policy principle that innovators are required to bring forth all relevant evidence on each ground of invalidity raised by a generic and will not be allowed to supplement that evidence, should it prove insufficient, in subsequent litigations brought on the same issue by another generic.

[10] Prothonotary Tabib also noted that, in *Sanofi-Aventis v. Novopharm*, the reason for failing to file the evidence and whether this failure was total or partial did not appear to matter to the Court of Appeal.

[11] Regarding the second issue raised by Pfizer in that proceeding, Prothonotary Tabib held that even if the Court of Appeal's decision in *Pfizer Canada Inc. v. Minister of Health and Ranbaxy Laboratories Limited*, 2008 FCA 108, advanced or clarified the law as to the disclosure requirements of section 27(3) of the *Patent Act*, the decision was inapplicable to the issues as determined by Justice O'Reilly and did not change the relevant law as applied by him.

Relevant Statutory Provisions

6. (5) In a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application in whole or in part	**6.** (5) Lors de l'instance relative à la demande visée au paragraphe (1), le tribunal peut, sur requête de la seconde personne, rejeter tout ou partie de la demande si, selon le cas :
(*a*) in respect of those patents that are not eligible for inclusion on the register; or	*a*) les brevets en cause ne sont pas admissibles à l'inscription au registre;
(*b*) on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents.	*b*) il conclut qu'elle est inutile, scandaleuse, frivole ou vexatoire ou constitue autrement, à l'égard d'un ou plusieurs brevets, un abus de procédure.

Standard of Review

[12] Discretionary orders of prothonotaries ought not be disturbed on appeal unless:

a) the questions raised in the motion are vital to the final issue of the case; or

b) the orders are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts.

In such circumstances, the reviewing judge ought to exercise her or his own discretion *de novo* (*Canada v. Aqua-Gem Investments Ltd*, [1993] 2 F.C. 425, as reformulated in *Merck & Co. v. Apotex Inc.* (2003), 30 C.P.R. (4th) 40 at para. 19). Since Prothonotary Tabib's Order dismissing Pfizer's application is determinative of this case as it relates to the 748 patent, I shall exercise my discretion *de novo*.

Issue

[13] The sole issue is whether Pfizer's application for an order prohibiting the Minister from issuing a notice of compliance to Novopharm, dated August 24, 2007, is an abuse of process as it relates to the 748 patent.

Analysis

[14] An abuse of process occurs when there has been a misuse of the court's procedure to the detriment of a party to litigation, such as when a party is involved in unnecessary, repetitious litigation. This principle has been applied by the Federal Court in the context of proceedings under the *NOC Regulations* (see *Hoffman-La Roche Ltd. v. Canada (Minister of National Health and Welfare)* (1998), 85 C.P.R. (3d) 50 (F.C.T.D.) *per* Rothstein J. (as he then was)).

[15] Pfizer filed the affidavit of Me Darren Noseworthy. He offers the following reason why Pfizer should be entitled to relitigate the validity of the 748 patent:

> 3. Pfizer accepts Justice O'Reilly's decision that Pfizer had not proven Apotex's allegations to be unjustified in the Apotex 748 application, and the Court of Appeal upheld that decision. Through this application, Pfizer is not attempting to attack that decision. However, Pfizer intends to file evidence in this proceeding that it did not file in the Apotex 748 application, and asks the Court to decide the application against Novopharm on the basis of the record in this case, including Pfizer's new evidence…
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> 4. In the Apotex 748 application, Pfizer did not file any evidence of its internal tests conducted on sildenafil before June 17, 1991. Pfizer did not appreciate that this evidence was necessary to respond to Apotex's allegation, as Justice O'Reilly decided. Indeed, we could have filed evidence regarding Pfizer's internal testing of

> sildenafil for potency and selectivity, if we had appreciated that it was required.

[16] The law is clear, as established in *Glaxo Group Ltd. v. Canada (Minister of Health)*, 2001 FCT 16 (F.C.T.D.), that litigants who have already litigated a matter and lost, are not permitted to relitigate merely because they have acquired new evidence:

> [16] In *Hoffman-LaRoche, supra*, the factors that led Rothstein J. to conclude there was an abuse of process are analogous to the facts before me. The applicants and the patents are the same in both proceedings, the Notices of Allegation are in all material respects identical, and the issues were fully litigated in the first proceeding. The only distinguishing aspect between the first and current applications is that Glaxo believes it has a better evidentiary basis on which to litigate the issues. Litigants who have already litigated a matter, but lost, should not be permitted to relitigate because they have acquired new evidence. This, in my view, is an abuse of the Court's process.

[17] This principle was applied by the Federal Court of Appeal in *Sanofi-Aventis v. Novopharm* at paragraphs 47 and 50, wherein the circumstances were virtually identical to those of the present proceeding:

> [47] In any event, the additional evidence adduced by Sanofi-Aventis and Schering in these proceedings does not change the fact that in the circumstances, they cannot attempt to relitigate a claim they have already made. Sanofi-Aventis and Schering were required to put their best foot forward in the earlier proceedings. They can have no relief in these new proceedings for having failed to do so. The doctrine of abuse of process calls for the innovator to bring forth all its evidence on each ground of invalidity raised. It should not be allowed to hold back evidence and then use that as a ground for allowing a second application to proceed. Even though in *Glaxo Group Ltd. v. Canada (Minister of Health)*, [2001] F.C.J. No. 159, 2001 FCT 16 at paragraph 16 (F.C.T.D.) the two cases involved the same parties, nevertheless the quote of Hansen J. is apposite. . . .

> […]
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> [50] . . . 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.

[18] The Federal Court of Appeal's decision in *Sanofi-Aventis v. Novopharm* was subsequently followed by Justice Harrington in *Sanofi-Aventis v. Laboratoire Riva Inc.* (2007), 58 C.P.R. (4th) 109 (F.C.T.D.) [hereinafter *Sanofi-Aventis v. Riva*]:

> [12] However, after I had taken these matters under reserve, the Federal Court of Appeal handed down its decision in *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, [2007] F.C.J. No. 548, 2007 FCA 163 [*Novopharm*]. Mr. Justice Sexton found it to be an abuse of process within the meaning of the PM (NOC) Regulations for a patent holder to relitigate an allegation of invalidity against a generic, if the allegation had been held to be well founded in an earlier proceeding against a different generic. Madam Justice Sharlow concurred, but Mr. Justice Nadon dissented. The patent at issue was the very same as in this case -- patent '206.
>
> [13] I am bound by that decision, and in light thereof, I will maintain Riva's motion and dismiss Sanofi-Aventis' applications without issuing prohibition orders.
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> […]
>
> [75] Although it may have been better to have Apotex's NOA formally before me, I think this is an unduly technical point. A comparison of Riva's NOA against what Madam Justice Mactavish took to be the relevant portions of Apotex's NOA on the lack of sound prediction point shows no material difference between them. With respect to claim 12, both allege that apart from Ramipril, the other seven compounds lack the requisite level of activity to inhibit ACE or the requisite pharmacological and toxicological properties to have utility, or to be suitable for the treatment of high blood pressure. Consequently, there is sufficient information to allow me to conclude that the same point is being litigated.

> [76] I am not tempted by the timing point. The main distinction between the Novopharm and the Riva proceedings is that Madam Justice Mactavish's decision had already been rendered when Sanofi-Aventis instituted its proceedings against Novopharm. The proceedings against Riva were already well advanced when that judgment came out. As I understand it, once a specific allegation of patent invalidity has been finally found to be justified in the NOC context, as long as the same allegation and the same patent are in issue in another NOC proceeding, that is the end of it. It does not matter what the experts said in their affidavits, or what they might have admitted in cross-examination. The integrity of the judicial process takes precedence.
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> […]
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> [82] I do not think it can be said that the situation is unfair, notwithstanding that the Minister has been prohibited from issuing Pharmascience an NOA, but not prohibited from issuing ones to Apotex and Riva (subject to Sanofi-Aventis' right of appeal). It is likely that new generics coming along in their wake will simply have to allege that they will not infringe patent '206, because it has already been held within the NOC context that allegations of invalidity on the ground of lack of sound prediction were justified. As noted by Mr. Justice Sexton, Sanofi-Aventis' obvious remedy would be *in rem* patent proceedings. [Emphasis in original.]

[19] Contrary to the submissions made by Pfizer, I do not think this case is distinguishable from *Sanofi-Aventis v. Novopharm* or *Sanofi-Aventis v. Riva*. In light of the previous jurisprudence referenced above and the facts before me, I am convinced that Pfizer's application in respect of the 748 patent constitutes an abuse of process and, as such, Prothonotary Tabib was correct in concluding as she did in the August 18, 2008 Order. In reference to the above case-law, however, I note that the evidence that Pfizer failed to submit in the previous proceeding and upon which it wishes to rely regarding the 748 patent is not new evidence. Indeed, Pfizer admits that the evidence at issue was available at the time of the proceedings in *Pfizer v. Apotex* but that it did not file this evidence because it "did not appreciate that this evidence was necessary to respond to Apotex's

allegation" and that Pfizer "could have filed evidence regarding Pfizer's internal testing of sildenafil for potency and selectivity, if [it] had appreciated that it was required."

[20] Pfizer seeks to distinguish the present case on the ground that, in *Sanofi-Aventis v. Novopharm*, "Sanofi was aware of the basis on which Apotex was alleging the invalidity of the…patent," whereas in the present case "Pfizer simply did not appreciate that this evidence was necessary to respond to Apotex's allegation."

[21] However, in the Supreme Court of Canada's decision in *Toronto (City) v. C.U.P.E., Local 79*, [2003] 3 S.C.R. 77, 2003 SCC 63 at para. 51 (hereinafter *C.U.P.E.*), Justice Arbour stressed that the key concern motivating the doctrine of abuse of process is preserving the integrity of the adjudicative process, and not the motive of the parties.

[22] Accordingly, Prothonotary Tabib was correct in holding that "[n]either the reasons for the innovator's failure to lead the evidence in the earlier proceeding, nor the question of whether its initial failure to lead evidence was total or partial would appear to matter in the reasoning adopted by the Court of Appeal" in *Sanofi-Aventis v. Novopharm*. Notwithstanding the explanation offered by Pfizer, it was incumbent upon it to put its best foot forward in the *Pfizer v. Apotex*. Having failed to do so, Pfizer is disentitled to relief in the present application.

[23] Further, Pfizer states that it accepts Justice O'Reilly's decision in *Pfizer v. Apotex* and claims that it is not attempting to attack that decision. However, Pfizer's submission that it did not appreciate that the evidence at issue was necessary to respond to Apotex's allegation is tantamount

to an argument that Apotex's NOA was insufficient to put Pfizer on notice that Apotex would be challenging whether Pfizer had carried out the tests necessary to demonstrate utility. Apotex's NOA contained the following allegations:

> Somewhat surprisingly none of the purported tests identify any particular compound as having been tested nor are the purported identity of "both cGMP PDEs" and the purportedly 'determined' IC_{50} values provided in the disclosure of the '748 patent…
>
> Apotex further alleges that by June 6, 1990, the purported inventors had not demonstrated the selectivity of the purported "compounds of the invention," including sildenafil, for inhibition of cGMP PDEs rather than cAMP PDEs.

[24] I note that in *Pfizer v. Apotex*, Pfizer argued that it bore the onus to respond to Apotex's NOA by adducing evidence to prove that sildenafil had utility as a potent and selective cGMP PDE inhibitor. This is evident from Justice O'Reilly's reasons wherein he stated at paragraph 42:

> [42] Much of Apotex's argument relates to the lack of demonstrated utility or sound prediction in relation to the compounds' use in treating the conditions named in the patent. However, I agree with Pfizer that, at least for its Claim 6 (which is a claim for the compound sildenafil alone) it is enough if Pfizer can prove that sildenafil had a useful property (*i.e.* potent and selective cGMP PDE inhibition) that may make it suitable for use in the treatment of certain diseases or conditions, or for use in the laboratory. In doing so, Pfizer would show that its product met the definition of an "invention" set out in the Act. I am satisfied from the evidence that, at the priority date of the patent, it was expected that PDE inhibitors could be useful in the treatment of certain conditions. Scientists were looking for compounds that were more potent and selective cGMP inhibitors than were currently available. Accordingly, for Claim 6, Pfizer merely has to show that sildenafil had been demonstrated, or soundly predicted, to be useful simply by virtue of its capacity to act as a potent and selective cGMP PDE inhibitor. [Emphasis added.]

[25] On appeal from the decision of Justice O'Reilly, Pfizer argued that the use of utility had not been raised in Apotex's NOA. This argument was rejected by the Federal Court of Appeal at paragraph 2 of its decision in *Pfizer v. Apotex*, *supra*:

> [2] The first issue is whether the Judge misinterpreted the notice of allegation, leading him to reach a conclusion on the utility of claim 6 of the 748 patent that was not raised in the notice of allegation. We are not persuaded that the Judge made an error in his interpretation of the notice of allegation. In our view, the notice of allegation did allege that the compounds of the 748 patent including sildenafil had not, in the words of paragraph 65 of the Judge's reasons, been "shown, or soundly predicted, to be potent and selective cGMP PDE inhibitors".

[26] Thus, Pfizer's argument in the present application that it did not appreciate that the evidence was necessary to respond to Apotex's allegation can simply be seen as a thinly-veiled collateral attack on the decision of the Federal Court of Appeal holding that the Apotex NOA did allege the compounds had not been shown to have the described utility.

[27] A closely similar argument was made in *Sanofi-Aventis v. Novopharm* involving the drug ramipril. The Federal Court of Appeal rejected this argument, stating:

> [44] . . . Sanofi-Aventis and Schering say that in the previous proceeding, they were not put on notice that Apotex would be challenging the predictability of the chirality of the bridgehead carbons in the compounds covered by the '206 patent, an issue that became a critical factor in Mactavish J.'s conclusion that the compounds disclosed in the '206 patent were not soundly predicted. Consequently, they say it would be unjust to prevent them from tendering additional evidence on that issue in the present proceedings. In their view, the additional evidence adduced in these proceedings establishes that the chirality of the bridgehead carbons was soundly predicted and accordingly, the patent is not invalid for lack of sound prediction.

> [45] This argument is itself a collateral attack on Justice Mactavish's decision. In the Apotex case, the parties fully argued whether the Apotex NOA was sufficient with respect to the issue of sound prediction. Mactavish J. concluded that it was and went on to dispose of the case based on the allegations made in the NOA. Sanofi-Aventis and Schering attempted to challenge Mactavish J.'s conclusion as to the sufficiency of the Apotex NOA on appeal to this Court and their argument was rejected.

[28] In the present circumstances, Pfizer cannot be permitted to mount a collateral attack on the finding of the Federal Court of Appeal that Apotex's NOA was sufficient by couching the issue as one of a failure to appreciate the evidence required to respond to the NOA.

[29] Pfizer further contends that "the circumstances of this case do not engage the policy rationales underlying the doctrine of abuse of process" as articulated by the Supreme Court of Canada in *C.U.P.E., supra*. Pfizer argues that if the application in relation to the 748 patent is allowed to proceed, it will lead to a more accurate result, it will not undermine the justice system, it will not waste judicial resources, is not a relitigation of the *Pfizer v. Apotex* proceeding, and its dismissal will cause unfairness to Pfizer.

[30] Pfizer's submissions fail to recognize that all of the discretionary factors that it now cites as being relevant to the present case were equally applicable to *Sanofi-Aventis v. Novopharm*. After detailed consideration of the discretionary factors recited in the *C.U.P.E.* decision, the Federal Court of Appeal in *Sanofi-Aventis v. Novopharm* exercised its discretion to dismiss the application as an abuse of process.

[31] In support of its submission that the possibility of inconsistent decisions does not lead to a finding of abuse where the second result will be "more accurate," Pfizer argues that:

> The possibility of two courts reaching different decisions on similar questions is not an abuse of process. Rather, the potential for inconsistency is only an abuse when there is no compelling reason to believe that the second result will be more accurate than the first, or in those rare circumstances where the mere reconsideration of an issue may undermine the integrity of the justice system. Where, as in this case, neither of these circumstances exists, the possibility of different results does not lead to a finding of abuse.

[32] The issue of inconsistent decisions was fully considered by the Federal Court of Appeal in *Sanofi-Aventis v. Novopharm*. In that case, Sanofi-Aventis made the same argument that Pfizer makes in the present case, namely that the evidence that it failed to file in the earlier proceeding would lead to a more accurate result:

> [44] In oral argument, Schering counsel stressed that Sanofi-Aventis' application was not an abuse of process because in these proceedings Sanofi-Aventis and Schering have tendered evidence that was not before Mactavish J. in the Apotex proceeding and that would lead a trier of fact to reach the opposite conclusion on the issue of sound prediction....In their view, the additional evidence adduced in these proceedings establishes that the chirality of the bridgehead carbons was soundly predicted and accordingly, the patent is not invalid for lack of sound prediction.

[33] However, the suggestion of a more accurate result in *Sanofi-Aventis v. Novopharm* did not prevent the dismissal of the application based on the relevant *C.U.P.E.* factors:

> [36] . . . Allowing Sanofi-Aventis to proceed with its application will give rise to the possibility of inconsistent judicial decisions, with one judge holding that the inventors of the '206 patent lacked a sound basis for predicting the utility of their invention and another holding that there was sound prediction. Thus one generic would receive an NOC because of invalidity based on lack of sound prediction while

> another would be refused an NOC even though its NOA raised the same allegation. As Arbour J. identified, permitting that type of inconsistency would threaten the credibility of the adjudicative process. . . .
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> [...]
>
> [49] Sanofi-Aventis and Schering also emphasize that proceedings under the *NOC Regulations* are of a preliminary nature and are accompanied by limited procedural safeguards. While this argument may be sufficient to establish that decisions made in the context of the *NOC Regulations* should not be binding on judges adjudicating actions for patent infringement or declarations of patent invalidity, it does not change the fact that relitigation by a first person of an issue already decided against it within the context of the *NOC Regulations* is generally not permissible. As I have already said, the possibility of different judges adjudicating equivalent proceedings concerning the same issue reaching different results threatens the integrity of the adjudicative process. The nature of the proceedings does not change this reality.

[34] Moreover, contrary to Pfizer's submissions, the newly filed evidence that Pfizer seeks to rely on will not necessarily produce a different result, let alone a more accurate result. The accuracy of the result must be considered in the context of the issue to be decided. Proceedings under the *NOC Regulations* do not determine patent validity, but instead only decide whether the second person's allegations are justified for the purposes of granting regulatory approval to market a drug. As stated by the Federal Court of Appeal in *Sanofi-Aventis v. Novopharm*, *supra*, at paragraph 36:

> [36] . . . there is no reason to think that a second proceeding under section 6 of the *NOC Regulations* will lead to a more accurate result than the first. This scenario is in contrast to an action for a declaration of patent invalidity, where because the parties have the benefit of a full trial and all the attendant procedural safeguards, a more accurate result may arise. That is why the courts have on numerous occasions stated the principle that decisions rendered under the *NOC Regulations* are not binding on actions for patent infringement or to declare a patent invalid [citations omitted].

[35] In short, because proceedings under the *NOC Regulations* do not result in a binding determination of the validity or invalidity of the patent, one cannot say *a priori* that any result is or is not more accurate unless and until validity is determined at trial.

[36] In support of its argument that the application, as it relates to the 748 patent, is not an abuse of process, Pfizer also submits that "there is nothing about this case to spark moral outrage" because a "reasonable observer would recognize Pfizer's uncontradicted evidence that it did not appreciate that testing evidence was needed in the case against Apotex."

[37] In my view, it cannot be reasonably contended that the present case is distinguishable from *Sanofi-Aventis v. Novopharm* on the basis of the extent to which it might or might not spark moral outrage. A suggested lack of moral outrage can no more dictate the outcome in the present case than it did in *Sanofi-Aventis v. Novopharm*. Moreover, Pfizer has submitted no authority for the proposition that abuse of process only applies in cases of "moral outrage" and its absence is not a determining factor.

[38] Regardless, the reasonable observer, in my view, would not understand how or why Pfizer would be allowed to proceed with an otherwise abusive proceeding solely on the alleged and subjective failure to appreciate the scope of Apotex's NOA when the Federal Court of Appeal has found this very NOA to be sufficient to put Pfizer on notice of the case that it was required to meet.

[39] Pfizer also argues that letting this application proceed will not waste judicial resources. In particular, Pfizer submits that "[t]here can be no waste of judicial resources in allowing the Court to

assess, for the first time, Pfizer's case in respect of sildenafil's utility" which was previously "determined by the absence of any evidence."

[40] The law is clear that litigants who have already litigated a matter but were unsuccessful are not to be permitted to relitigate because they have evidence that was previously omitted through negligence, inadvertence, or even accident. Further, I am of the view that a waste of judicial resources would arise in allowing Pfizer to relitigate this matter in a separate application under the *NOC Regulations* in order to obtain a non-binding finding of patent validity.

[41] Pfizer further submits that because it did not appreciate the evidence it was required to adduce in the *Pfizer v. Apotex* proceeding, the issues were not fully litigated in that case. This argument was not accepted by the Federal Court of Appeal in *Sanofi-Aventis v. Novopharm* and was correctly rejected by Madam Prothonotary Tabib in the decision under appeal. In particular, Prothonotary Tabib correctly concluded that the application of the principles set down in *Sanofi-Aventis v. Novopharm* were unaffected by the question of whether the issue of validity was fully or partially litigated in the earlier proceeding.

[42] Pfizer further attempted to distinguish the present proceeding from that in *Sanofi-Aventis v. Novopharm* by asserting:

> The Court of Appeal in *Sanofi-Aventis* did not suggest that in proceedings under the *Regulations* a patentee must "put its best foot forward" in respect of the validity of a patent generally. Rather, due to the summary nature of the proceedings, the patentee must put forth all of this evidence in respect of the allegations as it understands them.

This assertion finds no support in *Sanofi-Aventis v. Novopharm*. The requirement to put one's best foot forward is unqualified:

> [47] In any event, the additional evidence adduced by Sanofi-Aventis and Schering in these proceedings does not change the fact that in the circumstances, they cannot attempt to relitigate a claim they have already made. Sanofi-Aventis and Schering were required to put their best foot forward in the earlier proceedings. They can have no relief in these new proceedings for having failed to do so. The doctrine of abuse of process calls for the innovator to bring forth all its evidence on each ground of invalidity raised. It should not be allowed to hold back evidence and then use that as a ground for allowing a second application to proceed.

[43] There is simply no suggestion by the Federal Court of Appeal, in my reading of *Sanofi-Aventis v. Novopharm*, that a litigant may excuse a failure to file evidence on the basis of a subjective lack of understanding of the allegations of invalidity.

[44] Lastly, Pfizer argues that:

> It is simply unfair to refuse to permit Pfizer to lead its evidence of internal testing in this case...It is no answer to Pfizer that it can still sue Novopharm for patent infringement...In contrast, there is nothing unfair to Novopharm in permitting this application to proceed.

[45] The Federal Court of Appeal, in *Sanofi-Aventis v. Novopharm*, considered and rejected such an argument and held:

> [40] While it is important in each case to ensure the application of the doctrine of abuse of process does not give rise to unfairness in the circumstances, in my view, no such unfairness would result in the present case. Prohibition proceedings under the *NOC Regulations* do not prevent patentees from enforcing their patent rights through actions for patent infringement in accordance with the *Patent Act*.

> Moreover, the findings from any such prohibition proceedings have no bearing on patent infringement actions.
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> [...]
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> [50] . . . [T]here 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.

[46] I am not satisfied that the circumstances in this case are such that would warrant a finding that the abuse of process doctrine should not apply. In the Supreme Court of Canada's decision in *C.U.P.E., supra* at paras. 52-53, the Court outlined circumstances where a court should exercise its discretion not to dismiss duplicitous proceedings on the ground of abuse of process:

> [52] In contrast, proper review by way of appeal increases confidence in the ultimate result and affirms both the authority of the process as well as the finality of the result. It is therefore apparent that from the system's point of view, relitigation carries serious detrimental effects and should be avoided unless the circumstances dictate that relitigation is in fact necessary to enhance the credibility and the effectiveness of the adjudicative process as a whole. There

> may be instances where relitigation will enhance, rather than impeach, the integrity of the judicial system, for example: (1) when the first proceeding is tainted by fraud or dishonesty; (2) when fresh, new evidence, previously unavailable, conclusively impeaches the original results; or (3) when fairness dictates that the original result should not be binding in the new context. This was stated unequivocally by this Court in *Danyluk*, *supra*, at para. 80.
>
> [53] The discretionary factors that apply to prevent the doctrine of issue estoppel from operating in an unjust or unfair way are equally available to prevent the doctrine of abuse of process from achieving a similar undesirable result. There are many circumstances in which the bar against relitigation, either through the doctrine of *res judicata* or that of abuse of process, would create unfairness. If, for instance, the stakes in the original proceeding were too minor to generate a full and robust response, while the subsequent stakes were considerable, fairness would dictate that the administration of justice would be better served by permitting the second proceeding to go forward than by insisting that finality should prevail. An inadequate incentive to defend, the discovery of new evidence in appropriate circumstances, or a tainted original process may all overcome the interest in maintaining the finality of the original decision (*Danyluk*, *supra*, at para. 51; *Franco*, *supra*, at para. 55).

[47] None of the discretionary factors referred to in *C.U.P.E.* apply in the present application. There is no suggestion that the proceeding in *Pfizer v. Apotex* was tainted by fraud. The evidence that Pfizer now seeks to introduce is not "fresh, new evidence, previously unavailable." Rather, as Me Noseworthy confirms in paragraph 4 of his affidavit, Pfizer "could have filed evidence regarding Pfizer's internal testing of sildenafil for potency and selectivity, if [Pfizer] had appreciated that it was required." Further, there are no circumstances that create any unfairness in barring relitigation of the validity of the 748 patent. In this regard, there is no suggestion that the stakes in the *Pfizer v. Apotex* proceeding were "too minor to generate a full and robust response" or that Pfizer had "an inadequate incentive to defend Apotex's allegations of invalidity."

[48] For the reasons above, I conclude that Madam Prothonotary Tabib was correct in concluding that Pfizer's application, as it relates to the 748 patent, constitutes an abuse of process as it is an improper attempt to relitigate the issue of validity of the 748 patent that was lost in *Pfizer v. Apotex*.

ORDER

THIS COURT ORDERS that Pfizer's motion to set aside the Order of Prothonotary Tabib, dated April 18, 2008, is dismissed. Costs are awarded to the Respondents on a party to party basis.

"Max M. Teitelbaum"
Deputy Judge

Ottawa, Ontario
May 29, 2008

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-1566-07
STYLE OF CAUSE:	PFIZER CANADA INC., PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, and PFIZER RESEARCH AND DEVELOPMENT COMPANY N.V./S.A. v. NOVOPHARM LIMITED and THE MINISTER OF HEALTH
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	May 22, 2008
REASONS FOR ORDER AND ORDER:	Teitelbaum D.J.
DATED:	May 29, 2008

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