Federal Court of Appeal | Cour d'appel fédérale

CANADA

Date: 20110301

Docket: A-371-10

Citation: 2011 FCA 77

CORAM: **SEXTON J.A.**
LAYDEN-STEVENSON J.A.
STRATAS J.A.

BETWEEN:

APOTEX INC.

Appellant

and

PFIZER IRELAND PHARMACEUTICALS

Respondent

Heard at Toronto, Ontario, on February 16, 2011.

Judgment delivered at Ottawa, Ontario, on March 1, 2011.

REASONS FOR JUDGMENT BY: SEXTON J.A.

CONCURRED IN BY: LAYDEN-STEVENSON J.A.
STRATAS J.A.

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REASONS FOR JUDGMENT

SEXTON J.A.

[1] This is an appeal from an order of Justice Hughes (the "Motions Judge"), allowing in part Apotex's motion to strike certain allegations from Pfizer Ireland's (together with its Canadian licensee, "Pfizer") statement of defence in this impeachment action. Apotex now seeks to strike certain defences that the Motions Judge allowed to stand, including issue estoppel, collateral estoppel, comity, and abuse of process.

[2] I believe this appeal should be allowed in part. In summary, the defences purporting to bar relitigation of the issue of the validity of the patent at issue should be struck, but the other impugned

defences relating to subsidiary issues should be allowed to stand, to be dealt with in the discretion of the trial judge.

History of Proceedings

[3] The decision under appeal arises out of continuing litigation in which Apotex seeks authorization to market a generic version of Pfizer's drug VIAGRA (sildenafil citrate). This action concerns Canadian Letters Patent No. 2,163,446 (the "'446 patent"), which was filed by Pfizer on May 13, 1994 and issued on July 7, 1998. The patent will expire on May 13, 2014.

[4] Apotex previously sought to challenge the '446 patent under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133. By notice of allegation dated June 15, 2005, it sought a Notice of Compliance (an "NOC") allowing it to market generic sildenafil citrate. Apotex argued that its generic sildenafil citrate would not infringe the '446 patent, and that the patent was invalid. On September 27, 2007, Justice Mosley granted Pfizer's application for an order prohibiting the Minister of Health from issuing Apotex an NOC until after the expiry of the '446 patent (the "'446 NOC proceedings"). As part of the decision, he rejected Apotex's argument that the patent was invalid (*Pfizer Canada v. Apotex*, 2007 FC 971). An appeal from that decision was dismissed (2009 FCA 8).

[5] Apotex commenced the present action by statement of claim dated May 13, 2009. It seeks a declaration that: (a) the '446 patent is invalid; and (b) Apotex's generic sildenafil citrate would not infringe any valid claim of the '446 patent.

[6] In its statement of defence, Pfizer described the ‘446 NOC proceedings as part of the factual background to this action. It also repeatedly asserted that Apotex is precluded from relitigating certain issues because of “res judicata, issue estoppel, collateral estoppel, comity and abuse of process” as a result of the ‘446 NOC proceedings.

[7] Apotex then moved before the Federal Court pursuant to Rule 221(1)(*a*) of the *Federal Courts Rules*, SOR-08/106, to strike from Pfizer’s statement of defence certain paragraphs referring to the ‘446 NOC proceedings on the grounds that they disclose no reasonable defence.

[8] The motion was dismissed by Prothonotary Aalto, who held that it should be open to the trial judge to determine whether *res judicata* principles are applicable where the same evidence is introduced in NOC proceedings and a subsequent impeachment action. The Motions Judge reviewed the Prothonotary’s decision *de novo*. He struck the defence of *res judicata* on Pfizer’s consent, but declined to strike anything else. Relying on the decisions in *Merck & Co. v. Apotex*, [2004] 2 F.C.R. 459, 2003 FCA 488 [*Merck*] and *Connaught Laboratories v. Medeva Pharma* (1999), 179 F.T.R. 200 (T.D.), he held that Apotex had not met the high standard required for pleadings to be struck.

Analysis

[9] The parties do not dispute that the Motions Judge was correct in approaching the issue *de novo*. This court is therefore reviewing the decision of the Motions Judge rather than that of the Prothonotary. The court may interfere with the Motions Judge’s decision where “the motions judge

had no grounds to interfere with the prothonotary's decision, or in the event such grounds existed, if the decision of the motions judge was arrived at on a wrong basis or was plainly wrong" (*Z.I. Pompey Industrie v. ECU-Line N.V.*, [2003] 1 S.C.R. 450, 2003 SCC 27 at paragraph 18; *Merck* at paragraph 20). In this case, Apotex alleges what amounts to a pure error of law. This constitutes an allegation that the decision of the Motions Judge was arrived at "on a wrong basis", and the standard of review is effectively correctness.

[10] According to the Supreme Court, the power to strike a pleading should be exercised with restraint. A pleading should only be struck on the grounds that it discloses no reasonable defence where it is "plain and obvious" that it is certain to fail (*Hunt v. Carey Canada*, [1990] 2 S.C.R. 959 at 980; *Apotex v. Syntex Pharmaceuticals International*, 2005 FC 1310 at paragraph 31, affirmed 2006 FCA 60).

[11] Apotex argues that this court's jurisprudence makes it plain and obvious that no findings in an NOC proceeding can preclude relitigation in a subsequent infringement and impeachment proceeding. Pfizer responds that this jurisprudence is premised on the fact that parties have broader opportunities to gather and present evidence in actions than they do in NOC proceedings. In NOC proceedings, there is no right of discovery and no opportunity to present *viva voce* evidence. According to Pfizer, issue estoppel and related doctrines may apply where a party seeks to relitigate an issue decided in NOC proceedings on the same evidence, with the same arguments. It argues that it would be inappropriate to strike the defences at least until Apotex introduces new evidence or new argumentation.

[12] Apotex is correct that this court has taken a dim view of attempts to prevent relitigation of issues decided in NOC proceedings in subsequent actions. Because of the extent to which Apotex relies on the prior jurisprudence, it is worth reviewing it in some detail.

[13] This court first dealt with the issue in two early cases. In *Merck Frosst Canada v. Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302 (C.A.) [*Merck 1994*], Justice Hugessen wrote:

> The proceedings are not an action and their object is solely to prohibit the issuance of a notice of compliance under the Food and Drug Regulations. Manifestly, they do not constitute "an action for infringement of a patent"
>
> …
>
> In this connection, it may be noted that, while subparagraph 7(2)(*b*) seems to envisage the Court making a declaration of invalidity or non-infringement, it is clear to me that such declaration could not be given in the course of the section 6 proceedings themselves. Those proceedings, after all, are instituted by the patentee and seek a prohibition against the Minister; since they take the form of a summary application for judicial review, it is impossible to conceive of them giving rise to a counter-claim by the respondent seeking such a declaration. Patent invalidity, like patent infringement, cannot be litigated in this kind of proceeding. I can only think that the draftsperson had in mind the possibility of there being parallel proceedings instituted by the second person which might give rise to such a declaration and be binding on the parties (at paragraphs 23 and 25).

[14] The issue arose again later that year in *Pharmacia v. Canada (Minister of Health and Welfare)* (1994), [1995] 1 F.C. 588 (C.A.). Justice Strayer quoted at length from the decision in *Merck 1994*, and added the following comments:

> If the Governor in Council had intended by these Regulations to provide for a final determination of the issues of validity or infringement, a determination which would be binding on all private parties and preclude future litigation of the same issues, it

> surely would have said so. This Court is not prepared to accept that patentees and generic companies alike have been forced to make their sole assertion of their private rights through the summary procedure of a judicial review application. As the Regulations direct that such issues as may be adjudicated at this time must be addressed through such a process, this is a fairly clear indication that these issues must be of a limited or preliminary nature. If a full trial of validity or infringement issues is required this can be obtained in the usual way by commencing an action (at paragraph 14).

[15] In *Pfizer Canada v. Apotex* (2001), 11 C.P.R. (4th) 245 (C.A.), the issue arose in the context of whether an appeal from an order dismissing an application for a prohibition order was moot after the NOC was issued. Justice Isaac wrote:

> It should be noticed that a decision by this Court that the appeals are moot does not mean that the appellants are without remedies. They may commence actions for infringement if so advised and the facts warrant. This Court has been very clear on the fact that section 6 proceedings are not adjudicative of the rights of the patentee…In these circumstances, it is idle to suggest that any decision that this Court makes in these appeals could be used to attack collaterally a judgment in an infringement action (at paragraph 25).

[16] Justice Strayer dealt with the issue again in *Novartis v. Apotex* (2002), 22 C.P.R. (4th) 450 (C.A.). He wrote:

> The basic principle is that the extraordinary procedures provided by the Regulations are for the public law purpose of enabling the Trial Division to prevent a public officer from issuing a Notice of Compliance, designed for the protection of the public's health, if the patentee can show that the patents, as referred to by a generic company in its notice of allegation seeking a Notice of Compliance, are owned by the applicant "first person" and that the relevant claims are not invalid and would be infringed. This is a finding of the Court for the limited purpose of deciding whether or not the Minister can issue a Notice of Compliance: no one could suppose that this is a scheme designed for res judicata determinations of the scope or validity of patents (at paragraph 9).

[17] In *Sanofi-Aventis Canada v. Novopharm*, [2008] 1 F.C.R. 174, 2007 FCA 163 [*Sanofi-Aventis*], this court noted that "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" (at paragraph 36). In *Eli Lilly Canada v. Novopharm*, [2008] 3 F.C.R. 449, 2007 FCA 359, another mootness case, the court wrote:

> It is settled law that decisions under the NOC Regulations cannot be taken as an *in rem* determination of the validity of patents.
>
> …
>
> NOC proceedings were never intended to be substitutes for an infringement action (at paragraphs 40 and 41).

[18] Each of the above cases dealt only with whether decisions as to validity or infringement made in an NOC proceeding were binding in a subsequent action. When it denied the application of *res judicata* in these cases, the courts meant the term in the sense of cause of action estoppel, the doctrine that a party cannot relitigate a cause of action that has already been dealt with. Though Pfizer initially pleaded this as a defence in this case, it conceded the inapplicability of *res judicata* before the Prothonotary, and *res judicata* was struck by Justice Hughes on consent.

[19] *Res judicata* in the sense of cause of action estoppel is inapplicable because the subject matter of an infringement or impeachment action is very different from that of an NOC proceeding. The question before a judge in NOC proceedings is simply whether the allegations of invalidity or non-infringement contained in a notice of allegation are justified. This narrow determination is relevant only to whether the court should prohibit the Minister of Health from issuing a NOC. It

cannot be seen as a definitive answer to the very different question of whether the patent at issue is valid or infringed. For the same reason, issue estoppel, abuse of process and the other defences pleaded by Merck also cannot apply to the question of a patent's validity. Simply put, the issues of validity and infringement are not before the court in an NOC proceeding. However, this principle does not extend as far as Apotex suggests. Even where a later proceeding involves issues quite different from an earlier proceeding, it may be open to a judge to apply the doctrines of issue estoppel or abuse of process in the later proceeding to prevent a party from relitigating certain factual and legal issues decided in the earlier proceeding: *Danyluk v. Ainsworth Technologies Inc.*, [2001] 2 S.C.R. 460, 2001 SCC 44 [*Danyluk*] (involving issue estoppel) and *Toronto (City) v. Canadian Union of Public Employees (C.U.P.E.), Local 79*, [2003] 3 S.C.R. 77, 2003 SCC 63 [*C.U.P.E.*] (involving abuse of process). *Danyluk* and *C.U.P.E.* both emphasize that these bars against relitigation are discretionary and that the discretion must be exercised taking into account a wide variety of circumstances. Normally, as here, these circumstances are not before the court on a pleadings motion.

[20] In *C.U.P.E.*, the Supreme Court of Canada explored the rationales underlying issue estoppel and abuse of process. According to Justice Arbour, writing for the majority, relitigation of an issue can undermine the integrity of the adjudicative process:

> The policy grounds supporting abuse of process by relitigation are the same as the essential policy grounds supporting issue estoppel (Lange, *supra*, at pp. 347-48):
>
> > The two policy grounds, namely, that there be an end to litigation and that no one should be twice vexed by the same cause, have been cited as policies in the application of abuse of process by relitigation. Other policy grounds have also been cited, namely, to

> preserve the courts' and the litigants' resources, to uphold the integrity of the legal system in order to avoid inconsistent results, and to protect the principle of finality so crucial to the proper administration of justice (*C.U.P.E.* at paragraph 38).

[21] Justice Arbour also noted that relitigation might be permitted in certain circumstances, including where fresh evidence becomes available. However, she emphasized that the application of abuse of process or issue estoppel in individual cases to bar relitigation is a discretionary matter for the trial judge:

> 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.
>
> 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 (*C.U.P.E.* at paragraphs 52-53).

[22] In *Sanofi-Aventis*, this court recognized that an abuse of process could arise as a result of an earlier NOC proceeding. Although the question in that case was whether it could be abusive for an innovator to relitigate issues decided in one NOC proceeding in a subsequent NOC proceeding, the same principles apply here. In following *C.U.P.E.*, the court wrote:

> 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 (at paragraph 49).

[23] Only one case decided by this court deals specifically with whether subsidiary findings in an NOC proceeding can have binding effect in a subsequent action. In *Ratiopharm v. Pfizer*, 87 C.P.R. (4th) 185, 2010 FCA 204 [*Ratiopharm*], Pfizer argued that a factual conclusion from an NOC proceeding should bind the court in a subsequent impeachment action. Writing for the court, Justice Layden-Stevenson rejected that argument:

> This Court has repeatedly stated that what I will refer to as "NOC proceedings" do not operate as res judicata. <u>While Pfizer may be correct that the factual basis in the NOC proceeding is the same as that in this action, it does not follow that the evidentiary basis is the same</u>. Factual findings are derived from the evidence that is before the court in the particular proceeding.
>
> The trial judge was aware of the previous NOC proceedings in relation to the '393 Patent and considered them to be instructive (reasons at para. 18). However, he was not and could not be bound by the factual determinations in a prior NOC proceeding. Rather, it was incumbent upon the judge to arrive at his findings on the basis of the evidence that was before him (at paragraphs 25 and 26, emphasis added).

Justice Layden-Stevenson implicitly left open the possibility that issue estoppel or abuse of process could apply to prevent relitigation of the factual issue where the evidentiary record at trial was identical to that of the NOC proceeding. It is also significant that she considered the applicability of those defences after trial and on a full factual record, rather than at a preliminary stage.

[24] This court has repeatedly said that NOC proceedings are quite different from subsequent infringement or impeachment actions. In my view, there is scope for applying the bars of issue estoppel and abuse of process in the later proceedings to prevent the relitigation of subsidiary factual and legal issues in order to preserve judicial resources, promote the integrity of the justice system, prevent inconsistent findings, and prevent abuse. The difference between the NOC proceeding and later proceedings is an important consideration for the judge in the later proceedings, along with all of the other discretionary considerations discussed in *Danyluk* and *C.U.P.E.* Simply put, *Danyluk* and *C.U.P.E.* can apply in proceedings such as these.

[25] Given the foregoing analysis to the effect that *res judicata* does not apply to the determination of validity and infringement, the parties remain free to launch proceedings on those issues in other fora. Where a party introduces significant and important new evidence or raises significant and important new argumentation in the subsequent action, the trial judge should reconsider the issue in light of the full record before him or her (*Ratiopharm* at paragraphs 25 and 26). In applying the rule that issue estoppel generally precludes parties from raising arguments or issues that could have been raised at the original hearing, courts should be cognisant of the summary nature of NOC proceedings and the fact that no discoveries or live evidence are permissible.

[26] Specific applications of the principles in *Danyluk* and *C.U.P.E.* should await later cases. But, for clarity, I offer one illustration. If a witness gives exactly the same evidence in both proceedings, and the judge found the witness not to be credible in the NOC proceedings, it may be open to the trial judge in the action to bar relitigation of the witness's credibility through issue estoppel or abuse of process. On the other hand, if the witness gives different or additional evidence at the action, the trial judge may be justified in reconsidering the witness's credibility. There may of course be other considerations as well. Obviously, this is a discretionary matter. Suffice to say, the facts that will inform the discretion are not known in a pleadings motion.

[27] I acknowledge a risk that parties may be tempted to make submissions concerning issue estoppel and abuse of process witness by witness, document by document, thereby prolonging proceedings. It must be remembered that issue estoppel and abuse of process exist primarily as pragmatic rules intended to promote judicial economy and efficiency. Those who act in a way such that pragmatism, judicial economy and efficiency are adversely affected, may find that the judge exercises his or her discretion in order to prevent such conduct. Danyluk and C.U.P.E. empower the judge to prevent abuses from happening. Thus the manner in which parties litigate questions of issue estoppel and abuse of process in the proceedings may well affect the judge's discretion, alongside the other Danyluk and C.U.P.E. factors, regarding whether relitigation should be permitted.

[28] In any event it is evident that at this stage, in this pleadings motion, it is not possible to determine one way or the other whether the discretionary bars of issue estoppel and abuse of process apply.

Conclusion

[29] For those reasons, this appeal is allowed in part. It is plain and obvious that Pfizer's defences of issue estoppel, collateral estoppel, comity, and abuse of process cannot apply to bar litigation of the validity issue. Paragraphs 11, 14, and 44, along with the third sentence in paragraph 37 and the words "and the finding in the T-1314-05 Proceedings" in paragraph 45, will be struck from its statement of defence. The other paragraphs at issue, however, relate to distinct subsidiary findings of Justice Moseley. These will be allowed to stand, as the trial judge retains the discretion to evaluate whether these findings may be relitigated in light of the evidence and arguments introduced at trial. In light of its substantial success, Pfizer is entitled to its costs.

"J. Edgar Sexton"
J.A.

"I agree
Carolyn Layden-Stevenson J.A."

"I agree
David Stratas J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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DATED:	MARCH 1, 2011

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