Federal Court | Cour fédérale

Date: 20100928

Docket: T-772-09

Citation: 2010 FC 968

Toronto, Ontario, September 28, 2010

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

APOTEX INC.

Plaintiff

and

PFIZER IRELAND PHARMACEUTICALS

Defendant

REASONS FOR ORDER AND ORDER

[1] This is a motion in which the Plaintiff, Apotex Inc., is appealing from a portion of an Order of Prothonotary Aalto dated June 11, 2010 (2010 FC 633) in so far as he refused to strike paragraphs 7, 8, 9, 11-15, 29, 31, 32, 37 (third sentence), 42 (entire paragraph except the first sentence), 44, 45 (the words "and the finding in the T-1314-05 Proceeding"), 46, 49, 50, 53, 56, 59, 61-62, 64 and 75 (last sentence) (collectively, the "Estoppel Allegations") of the Statement of

Defence of Pfizer Ireland Pharmaceuticals ("Pfizer") dated September 25, 2009. For the reasons that follow I will dismiss the motion except to remove the words "*res judicata*" where they may appear in any of those paragraphs, with costs in the cause.

[2] The issue on this appeal concerns the effect, if any, of a final decision in proceedings brought by way of an application under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/83-133 on proceedings brought by way of an action under the *Patent Act* RSC 1985, c. P-4 for a declaration of invalidity of the same patent(s) considered in the NOC application.

[3] In the present case the Plaintiff, Apotex, has instituted an action under the provisions of the *Patent Act* seeking a declaration of invalidity of Canadian Patent No. 2,163,446 (the '466 patent). A number of grounds are pleaded in the Statement of Claim which are said to support a finding of invalidity. The Defendant Pfizer, the owner of the '446 patent, has filed a Statement of Defence which, in addition to addressing the grounds urged for invalidity of the '446 patent, alleges that the same patent was the subject of proceedings taken under the provisions of the *NOC Regulations* between the same parties. It is alleged that many of the same grounds as to invalidity were raised by Apotex in the NOC proceedings (T-1314-05) and, by a final decision of this Court dated September 27, 2007, Pfizer was granted an Order prohibiting Apotex from receiving an NOC in respect of the drug at issue. An appeal from that decision was dismissed by the Federal Court of Appeal on January 16, 2009.

[4] In its Statement of Defence in the present action Pfizer asserts that Apotex is "by reason of *res judicata*, issue estoppel, comity and abuse of process" precluded from challenging the validity of the '446 patent." By way of example I set out paragraphs 12, 13, 14, and part of 15 of the Statement of Defence:

> *12. The T-1314-05 Proceeding:*
>
> *a. involved the same parties that are before the Court in the present action;*
>
> *b. considered the same issues as are before the Court in the present action; and*
>
> *c. resulted in a final decision.*
>
> *13. In the T-1314-05 proceeding, Apotex urged the invalidity of the '446 Patent on the grounds of, inter alia:*
>
> *a. Anticipation;*
>
> *b. Obviousness;*
>
> *c. Claims broader than the invention;*
>
> *d. Insufficient disclosure and ambiguity;*
>
> *e. Lack of utility and sound prediction;*
>
> *f. Lack of inventorship;*
>
> *g. Non-statutory subject matter; and*
>
> *h. Invalid disclaimers*
>
> *14. By reason of reason of res judicata, issue estoppel, collateral estoppel, comity and abuse of process, Apotex is precluded from contesting the validity of the '446 Patent in the present proceeding.*
>
> *15. Further, matters of fact and law that were fully litigated in the T-1314-05 Proceeding are, by reason of res judicata, issue estoppel, collateral estoppel, comity and abuse*

of process, binding in respect of the present action. The findings that are binding in the present proceeding include the following:

a. The invention, as defined in claims 7, 8, 10, 11, 22, and 23 of the '446 Patent, includes the following essential elements: the use of sildenafil (or salt thereof) in the form of an oral medicine for the treatment of erectile dysfunction in man;

(etc.)

[5] Apotex brought a motion to strike these and similar paragraphs from the Statement of Defence. That motion was heard by Prothonotary Aalto. He declined to strike these paragraphs. In so doing he said, *inter alia*, at paragraphs 22 to 25 of his reasons:

> **22** *In this case it can hardly be said that alleging abuse of process and res judicata given the extensive history of proceedings between Pfizer and Apotex that these allegations do not have some relevance to the issues in play. While the doctrine of res judicata does not render this proceeding moot or previously decided, to the extent that evidence from prior proceedings is identical to the evidence to be lead in this case, that will have some relevance but not necessarily be determinative of the issue on which that evidence is lead. At the very least it may go to the issue of costs.*
>
> **23** *It must also be remembered that res judicata is a short form of res judicata pro veritate accipitur or a "thing adjudicated is received as the truth" [see, Osborn, P.G., A Concise Law Dictionary (1964, 5th Ed.) at p. 278]. Pfizer is not pleading that this proceeding should be determined solely on the basis of the application of the res judicata doctrine. Rather, it raises all of its substantive defences and additionally seeks relief "[b]y reason of res judicata, issue estoppel, collateral estoppel, comity and abuse of process Apotex should be precluded from contesting the validity of the '446 Patent in the present proceeding". To the extent a witness' evidence is identical to evidence given in prior proceedings why should it not be left open to the trial judge's discretion whether there is any applicability of the pleaded principles and whether to assess and weigh that evidence in the context of the prior proceedings.*

> *24 While the Regulations are designed to be a summary process which is the rationale for not strictly applying the res judicata doctrine to subsequent impeachment proceedings such as this, parties ought not to be able to have endless "kicks at the can" and use up more and more judicial resources because they do not like the prior result and are sufficiently well-heeled to pursue more and more litigation.*
>
> *25 The Court has an obligation to control its own process to ensure that judicial resources are available to all. While the policy articulated by the Federal Court of Appeal regarding the application* of *res judicata to proceedings under the Regulations is to be followed, the current pleading is one that should be permitted to stand as the prior proceedings may have some relevance in the context of this proceeding. Further, to the extent that the evidence adduced by Apotex at trial is the same evidence on the same issues as in prior proceedings this too may have some relevance and at a minimum may affect the disposition of costs. This is particularly so given the many similarities between this proceeding and the prior proceedings as described above. The motion insofar as it seeks to strike this part of the pleading is dismissed.*

Apotex challenges this disposition of the matter in this appeal.

APPEALS FROM PROTHONOTARIES

[6] It is common ground that discretionary orders of prothonotaries (associate judges) should not be disturbed on appeal unless the matters are vital to the final issues or the decision was clearly wrong in that it was based on a wrong principle or misapprehension of the facts *(Merck & Co v. Apotex Inc.* (2003), 30 C.P.R. (4th) 40 (FCA)). However, in the present case Apotex argues that the basis upon which it seeks to strike the pleadings is a principle of law, thus the prothonotary's decision must be assessed on the basis of correctness. If that is the basis of this appeal, I agree and will proceed to address the matter *de novo*.

PRINCIPLES FOR STRIKING A PLEADING

[7] The basis upon which Apotex seeks to strike the portions of the Statement of defence in question is as set out in Rule 221(1)(a) of this Court namely that no reasonable defence is disclosed. Counsel are agreed that the jurisprudence, including *Inuit Tapirisat of Canada v. Canada (Attorney General)*, [1980] 2 S.C.R. 735 and *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959, makes it clear that in order to succeed a high threshold must be met. It must be "plain and obvious" that the pleading cannot succeed before a party is denied its right to have the matter fully litigated. The point was succinctly made by Sharpe J.A. for the panel of the Ontario Court of Appeal *in Eliopoulous v. Her Majesty* (2006), 82 O.R. (3rd) 321 at paragraph 8 where Rule 21.01(1)(b) of the Ontario Rules, similar to Federal Court Rule 221(1)(a), was considered:

> *[8] It is common ground that the test for striking a statement of claim at the pleadings stage is a stringent one with a difficult burden for defendants to meet. The allegations of fact in the statement of claim, unless patently ridiculous or incapable of proof, must be accepted as proven. In order to succeed, rule 21.01(1)(b) requires the moving party to show "that it is plain, obvious, and beyond doubt that the plaintiff could not succeed". Moreover, the claim "must be read generously with allowance for inadequacies due to drafting deficiencies" and should "not be dismissed simply because it is novel": see Hunt v. Carey Canada Inc., [1990] 2 S.C.R. 959, [1990] S.C.J. No. 93, at p. 980 S.C.R.*

THE PLEADINGS AT ISSUE

[8] Apotex argues that the pleading at issue must be struck out, given the jurisprudence which it puts forward as, it is plain and obvious that the Defences cannot succeed.

[9] Apotex begins with the decision of the Federal Court of Appeal in *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, (1994), 55 C.P.R. (3d) 302 the relevant portions of which were cited with approval by Strayer J.A. for the Federal Court of Appeal panel in *Pharmacia Inc. v. Canada (Minister of National Health and Welfare)* (1994), 58 C.P.R. (3d) 209 at pages 216-217:

> *Given the multitude of interlocutory proceedings now outstanding in the Trial Division of this nature, it is apparent that in many cases the parties have indeed tried to treat such proceedings as actions for infringement or declarations of validity of patents. As a result they have tried to have the court strike out or order amendments to notices of allegation. Parties have as in the present case sought to strike out originating notices of motion and have sought the equivalent of discovery of the opposing party. However, this court made clear in Merck Frosst v. Canada, supra, that these proceedings are not actions for determining validity or infringement: rather they are proceedings to determine whether the Minister may issue a notice of compliance. That decision must turn on whether there are allegations by the generic company sufficiently substantiated to support a conclusion for administrative purposes (the issue of a notice of compliance) that the applicant's patent would not be infringed if the generic's product is put on the market. It is useful to reiterate what the court said in the Merck case [at pp. 319-20].*
>
> > *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".*
> > . . . .
> >
> > *Furthermore, since the regulations clearly allow the Minister, absent a timely application under s.6, to issue a notice of compliance on the basis of the allegations in the notice of allegation, it would seem that on the hearing of such an application, at least where the notice has alleged non-infringement, the court should start from the proposition that the allegations of fact in the notice of allegation are true except to the extent that the contrary has been shown*

> *by the applicant. In determining whether or not the allegations are "justified" (s. 6(2)), the court must then decide whether, on the basis of such facts as have been assumed or proven, the allegations would give rise in law to the conclusion that the patent would not be infringed by the respondent.*
>
> *In this connection, it may be noted that, while s. 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 s.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 counterclaim 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 thee being parallel proceedings instituted by the second person which might give rise to such a declaration and be binding on the parties. It is, in any event, evident that the declaration referred to in s.7(2)(b) is not a precondition to the ultimate dismissal of the s. 6 application, the consequences of which are separately dealt with in s.7(4).*

It will be noted that the regulations nowhere create or abolish any rights of action between the parties; instead they confer a right on the patentee to bring an application for prohibition against the Minister of National Health and Welfare. That is, the regulations pertain to public law, not private rights of action. Of course the real adversary in such a prohibition proceeding is the generic company which served the notice of allegation.

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.*

[10] Apotex's Counsel then moved to the very strong statement of Isaac C.J. for the panel of the Federal Court of Appeal in *Pfizer Canada Inc. v. Nu-Pharm Inc.* (2001), 11 C.P.R. (4th) 245 at paragraph 25 where he said that NOC proceedings were not adjudicative of the rights:

> ***25*** *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 Merck Frosst Canada, supra at 319, Hugessen J.A. rejected the notion that prohibition proceedings could be assimilated to an action of any kind:*
>
> > *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 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.*

[11] This decision was cited with approval by the Federal Court of Appeal in *Novartis A.G. v. Apotex Inc.* (2002), 22 C.P.R. (4th) 450 where Strayer J.A. for the Court wrote at paragraph 9:

> ***9*** *I believe that the fundamental principles applicable are those stated in the reasons of Isaac J.A. in the Pfizer case, as approved and followed by another panel of this Court in the Rhoxalpharma case less than one year ago. 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. As Isaac J.A. said at 253-54 of the Pfizer case:

> *[25] 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 s. 6 proceedings are not adjudicative of the rights of the patentee. In Merck Frosst Canada, [1994] F.C.J. No. 662, supra, at 319, Hugessen J.A. rejected the notion that prohibition proceedings could be assimilated to an action of any kind:*
>
> *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 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.*

As Isaac J.A. also pointed out in Pfizer at 252, by subsection 7(4) of the Regulations the period of automatic stay of the issue of an NOC expires when, inter alia, the application for prohibition is "dismissed by the court". This has been interpreted by this Court to mean "dismissed by the Trial Division", given the special and self-contained scheme of the Regulations. (Hoffman-LaRoche Ltd. v.

> *Canada (1996), 70 C.P.R. (3d) 206). It does not mean "dismissed by the Federal Court of Appeal".*

[12] I relied on this decision in *Janssen-Ortho Inc. v. Novopharm Ltd.* (2006), 57 C.P.R. (4th) 6 at paragraph 74.

> *74 These parties have previously been engaged in litigation in Canada involving this Patent. That litigation was pursuant to the Patented Medicines (Notice of Compliance) Regulations (S.O.R./93-133) [Regulations]. In that litigation, the Court found that Novopharm's allegation that the relevant claims of the patent were invalid was "justified" pursuant to section 6(2) of those* Regulations. *In that case, Janssen-Ortho Inc. v. Novopharm Ltd. (2005), 35 C.P.R. (4th) 353, 2004 FC 1631), Justice Mosley of this Court held, at paragraph 29 of his Reasons, that the discovery of the beneficial properties of the S(-) optical isomer (of Ofloxacin) was the object and usefulness of this Patent. He found, at paragraph 85, that Novopharm had established, on a balance of probabilities, that a technician skilled in the art would have come directly and without difficulty to the solution taught by the patent simply by conducting known, routine experiments with racemic Ofloxacin. Accordingly, at paragraph 87, he found the Patent to be invalid for obviousness, that is, that Janssen had not demonstrated on a balance of probabilities that Novopharm's allegation of invalidity on this ground was not justified. The Federal Court of Appeal dismissed the appeal on the ground of mootness as the Notice of Compliance had already been issued (2005), 40 C.P.R. (4th) 1, 2005 FCA 6. Leave to appeal to the Supreme Court of Canada was dismissed, [2005] 1 S.C.R. 776, 2005 S.C.C.A No. 189. Those findings do not constitute* res judicata *in this case (Novartis AG v. Apotex Inc. (2002), 22 C.P.R. (4th) 450 at para. 9 (F.C.A.), 2002 FCA 440).*

[13] Lastly, Apotex's Counsel referred to the recent decision of the Federal Court of Appeal in *Pfizer Limited v. Ratiopharm Inc.*, 2010 FCA 204 where Layden-Stevenson J.A., for the panel, wrote at paragraph 25:

> *25 First, Pfizer grounds its position on a factual conclusion from* Pfizer NOC, *a case arising out of the Patented Medicine Notice of Compliance Regulations, S.O.R./93-133 (NOC Regulations). This*

> *Court has repeatedly stated that what I will refer to as "NOC proceedings" do not operate* as *res judicata. 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. Factual findings are derived from the evidence that is before the court in the particular proceeding.*

[14] Pfizer's counsel acknowledged that the Statement of Defence, in as much as it pleaded the words *res judicata*, was wrong and consented to the removal of those words from that pleading. However, Pfizer's Counsel argued, issues as to issue estoppel, collateral estoppel, comity and abuse of process had not been raised or fully argued in any previous case, particularly as they relate to evidentiary findings and findings as to legal issues that were fully argued.

[15] Pfizer's Counsel points out that the Federal Court of Appeal in *Merck & co. v. Apotex Inc.* (2003), 30 C.P.R. (4th) 40 refused to allow an amendment to be made by Apotex to its pleading in an action, where the matter had been fully litigated in a previous NOC proceeding. Décary J.A. for the majority wrote at paragraph 47:

> *47 Assuming, for the sake of discussion, that there is a triable issue, I still would not allow the proposed amendments. They represent, as already noted, a radical departure from the position held by Apotex during the past ten years in proceedings before this Court. It repudiates admissions made in the pleadings of the present proceedings and during discovery as well as admissions made by counsel in the course of a previous proceeding closely associated with the present one. It casts a shadow on the integrity of the process through which Apotex obtained its NOC in 1996, a process which necessitated by section 5(1) of the NOC Regulations, inter alia, a demonstration of "bioequivalence" in order to obtain the NOC and which permitted Apotex to market a product for the past seven years. It questions for the first time the construction of a patent upon which Apotex itself has relied to gain favour with this Court. It questions the construction of the patent six years after the commencement of the proceedings and once the discovery process has been completed,*

> *therefore rendering the trial more complex and presumably lengthier. All of this has been on the basis of allegations supported solely by an affidavit deposed by a counsel for Apotex. This is indeed a very unique situation which should be examined very carefully.*

[16] In *Connaught Laboratories Ltd. v. Medeva Pharma Ltd.*, (1999), 4 C.P.R. (4th) 508 Sharlow J., as she then was in the Federal Court, considered a pleading very much like that at issue here. She wrote at paragraph 12:

> ***12*** *The broad principle underlying the prothonotary's decision is that a claim should be struck only if it is plain and obvious that the claim will fail: Hunt v. Carey Canada Inc., [1990] 2 S.C.R. 959. The first step in the analysis is to examine the proposed legal arguments as set out in paragraph 25, which are based on one or more of "res judicata, issue estoppel, collateral estoppel, comity, abuse of process." These are different expressions of the general principle that judicial proceedings must at some point be conclusive, that an issue of fact need only be decided once.*

[17] In the following paragraphs Sharlow J. reviewed each of *res judicata*, issue estoppel, collateral estoppel and comity in the context as to whether they could apply in respect of findings made by a foreign court in respect of a patent similar to that at issue in Canada. She held that the matter was arguable and the pleading should stand. At paragraphs 26, 27 and 31 she wrote:

> ***26*** *However, I do not understand why inconsistencies in findings of fact made by different tribunals should be tolerated if they can be avoided without offending the substantive law or procedural norms. Connaught is simply attempting to argue in this case that it is wrong in principle for Medeva to be permitted to take inconsistent positions on specific questions of fact that are in issue in this case and that have already been litigated elsewhere.*
>
> ***27*** *I have been referred to no case law that persuades me that the arguments Connaught would make based on res judicata, issue estoppel and related arguments cannot succeed. Therefore, I conclude that the Associate Senior Prothonotary erred in ordering that they be struck out.*
>
> . . .

> ***31*** *It is also worth noting that the problem of complexity may be viewed in different ways. Patent litigation is already complex, in this Court and in every court that deals with patents. Ultimately, patent litigation may be simplified by principles that permit or require, in appropriate cases, the adoption of findings of fact in foreign proceedings. But that will never happen unless, in this case or another one, the Court undertakes an examination of the arguments that would open the door for establishing such a principle.*

[18] I find, as Sharlow J. did, that the matters raised in the Statement of Defence at issue here have not been squarely raised previously and that the matter is not sufficiently "plain and obvious" as would warrant that they be struck out. It may be that Apotex is ultimately successful on the issue in which case there may be cost implications. I invited the parties to consider expeditious ways that the matter could be put to the Court such as a summary trial under Rule 216 or a question of law under Rule 220. The reception of counsel to these suggestions was not entirely enthusiastic. Given that the issue has been framed before me as a motion to strike under Rule 221(1)(a) I find that the "plain and obvious" considerations must prevail and that the pleadings remain as they are, other than striking "*res judicata*" on consent.

[19] It is appropriate that costs should be in the cause.

ORDER

FOR THE REASONS PROVIDED

THIS COURT ORDERS that:

1. The motion is dismissed with the exception that the words "*res judicata*" as they may appear in any of the paragraphs 14, 15, 29, 31, 44, 46, 49, 50, 53, 56, 61, 64, and 75 of the Statement of Defence shall be struck out;

2. The Defendant shall file an Amended Statement of Defence giving effect to this Order within ten (10) days;

3. Costs in the cause.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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