Federal Court  Cour fédérale

Date: 20100924

Dockets: T-156-05
T-787-05

Citation: 2010 FC 952

Ottawa, Ontario, September 24, 2010

PRESENT: The Honourable Justice Johanne Gauthier

BETWEEN:

ELI LILLY CANADA INC.

Applicant

and

APOTEX INC. and
THE MINISTER OF HEALTH

Respondents

and

ELI LILLY and COMPANY LIMITED

Respondent/Patentee

REASONS FOR ORDER AND ORDER

[1] In its motion made pursuant to Rule 399 of the *Federal Courts Rules*, SOR 98-106, Apotex Inc. (Apotex) asks the Court to set aside its order dated April 27, 2007, granting Eli Lilly Inc.'s (Eli) applications for an Order prohibiting the Minister of Health from issuing a Notice of Compliance (NOC) to Apotex for its olanzaprine products until the expiry of Canadian Letters Patent No.

2,041,113 (‘113 patent). Apotex also seeks an order dismissing the said applications in the above-mentioned files.

[2] This 2007 Order was confirmed by the Federal Court of Appeal on February 4, 2008 and this decision became final on March 4, 2008.

[3] However, Justice James O’Reilly, in the context of an infringement action and cross-claim for a declaration of invalidity of the ‘113 patent (T-1048-07),[1] declared all the claims of the said patent invalid (declaration *in rem*). This is the new matter that, in Apotex’s view, warrants reconsideration of the 2007 Order.[2] Eli says that this motion is moot since Apotex obtained an NOC for its olanzaprine products on or about October 9, 2009.

[4] After the hearing, it was agreed that the Court should wait for the result of the appeal of Justice O’Reilly’s decision for if it were reversed completely Apotex’s motion would become moot (Apotex agreed on this point).

[5] As a matter of fact, the Federal Court of Appeal did allow the appeal and declared that the patent was not anticipated, nor obvious. However, it remitted the matter to the Trial Judge for redetermination of “the utility and sufficiency of disclosure grounds of alleged invalidity” (para. 124). Apotex took the position that this decision did not make its motion moot since Justice O’Reilly could still find the ‘113 patent invalid on the basis of the arguments remaining to be

[1] The decision of the Court of Appeal was issued July 21, 2010: 2010 FCA 197, [2010] F.C.J. No. 951 (QL).
[2] As an alternative, Apotex says that the applications should be dismissed pursuant to subsection 6(5) of the *Patented Medicines (Notice of Compliance) Regulations* (the *NOC Regulations*). This argument will not be further discussed

determined. For Apotex, it would be premature to dismiss the motion and the Court should wait for a final decision to avoid the filing of a new motion and hearing before the Court once this decision and an appeal has taken place. Eli disagrees.

[6] For the following reasons, whatever Justice O'Reilly's decision may be and despite the able arguments of Apotex's counsel, the Court is satisfied that this motion can be dismissed now.

Analysis

[7] Initially, among other things, this motion raised a difficult issue which involves balancing the fundamental doctrine of *res judicata* with the exceptions set out in Rule 399.

[8] In *Jhajj v. Canada (Minister of Employment and Immigration),* [1995] 2 F.C. 369 (T.D.), [1995] F.C.J. No. 499 (T.D.) (paras. 22-23), Justice Marshall Rothstein notes that it is easy to reconcile the principle of *res judicata* with the power of the Court to correct clerical or inadvertent errors. That is because there is no contradiction between such corrections and "the public interest in the finality of litigation, the objective of certainty and the protection of litigants' rights generally". He also says that it is "equally apparent that the objective of finality of judgments cannot stand in the face of fraud" (one of the grounds for reconsideration pursuant to Rule 399[3]).

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given that it is clear that such subsection does not apply to applications which have already been determined on the merits.

[3] Formerly Rule 1733.

[9] However, as mentioned by the learned judge in the said decision (see paras. 23 and 29), the exceptions which are the most difficult to reconcile with the *res judicata* doctrine are the other two grounds provided for in Rule 399 particularly the one dealing with "a matter that arose or was discovered subsequent to the making of the order" (Rule 399(2)(a)). It is on that ground that the present motion is brought.

[10] At the time of the hearing, there were only a few decisions from this Court or the Federal Court of Appeal on similar or related issues. Eli relies more particularly on the decision of Justice Russell Zinn in *Sanofi-Aventis v. Pharmascience*, 2009 FC 915 (*Pharmascience*), as well as two decisions of Justice Roger Hughes in *Apotex Inc. v. Syntex Pharmaceutical International*, 2009 FC 494 (*Syntex*) and *Pfizer Canada Inc. v. ratiopharm*, 2009 FC 1165 (*Pfizer*)[4], while Apotex relies on the decision of Justice Barbara Reed in *Hoffmann-La Roche Ltd. v. Canada (Minister of National Health and Welfare),* [1999] F.C.J. No. 662 (T.D.) (*Hoffmann-La Roche*) and on the Federal Court of Appeal's decision in *Mayne Pharma (Canada) Inc. v. Aventis-Pharma Inc.*, 2008 FCA 21, [2008] F.C.J. No. 67 (C.A.) (*Mayne Pharma*).

[11] Although strictly speaking, as mentioned by Apotex, none of these decisions are binding on the Court or directly involve judicial comity, they do contain useful and cogent statements considering particularly that both *Pharmascience* and *Syntex* have since the hearing been confirmed by the Federal Court of Appeal (*Pharmascience* (C.A.) 2010 FCA 153, *Syntex* (C.A.) 2010 FCA 155). They definitely need to be considered here.

[4] No appeal filed.

[12] But before reviewing this case law, it is important to review why the parties debate this issue given that Apotex has by now received its NOC. Clearly, it is not the requested order setting aside the prohibition orders that is of import for this issue is clearly moot. Rather, Apotex insists that the Court must dismiss the applications because to trigger the application of section 8 of the *NOC Regulations* and have the right to claim damages, the innovator's application must be "withdrawn, discontinued or dismissed by the Court hearing the application or on appeal". Hence, at this stage, the generic is not in a position to claim damages.

[13] In *Hoffman-La Roche*, Justice Reed discusses the Court's jurisdiction to set aside or reconsider a prohibition order after a change in circumstances particularly a declaration of invalidity of the patent in suit in the earlier prohibition proceedings. The Minister of Health had submitted that in light of the prohibition order, he needed some clarification from the Court before issuing a NOC to the generic. Justice Reed expressed some uncertainty as to the application of Rule 399 to such a matter. She thus focuses on the Court's inherent jurisdiction to set aside an injunction as well as a prohibition order. Although the Court in granting Apotex's motion ended up issuing an order dismissing the application, there is not one word on that particular point in her reasons. It may well be that this question was not argued before her, considering that it was not even clear at that time what version of section 8 applied.

[14] In fact, it is only several years later in *Syntex* that Justice Hughes had to deal with the issue of which version of section 8 could apply to the application dismissed in *Hoffman-La Roche*, above.

He held that the 1993 version should apply as the application was not pending at the relevant time, within the meaning of subsection 9(6) of the *NOC Regulations* (transitional provisions). The Federal Court of Appeal confirmed his view in that respect. Justice Hughes then goes on to discuss whether or not Apotex had a right to claim under that version of section 8 as well as under the current version of section 8 in the *NOC Regulations*. It is in respect of the latter issue that he noted that in his view a dismissal may well have been unnecessary in that case.

[15] Although the Court of Appeal did not feel that it was necessary to review the part of Justice Hughes' decision dealing with the 1998 version of section 8 as it was superfluous in the circumstances of that case, Justice Eleanor Dawson, writing for the Court, does mention at paragraph 8 that Justice Reed's dismissal of the NOC proceeding was "for greater certainty".

[16] As noted in the Court of Appeal's reasons, fundamental to Justice Hughes' analysis was the meaning of "expire" which was defined at section 2 of the *NOC Regulations* to mean "expire, lapse or terminate by operation of law". This last expression, in the judge's view, included for instance a declaration of invalidity (at para. 16).

[17] It thereby confirmed once again the position taken in earlier cases that there is no need to set aside a prohibition order when same naturally expires with the expiry of the patent, including when the patent is declared invalid.

[18] In dealing with Apotex's suggested interpretation of "pending", the Court of Appeal noted at paragraph 29 that the Court's inherent jurisdiction to vary or set aside an order on the basis of changed circumstances cannot have been intended "to make prohibition proceedings permanently pending… expos[ing innovators] to unforeseen liability years after successfully prosecuting prohibition proceedings." In the Court of Appeal's view "[c]learer language would be required to effect that result".

[19] At paragraph 36, the Court of Appeal confirmed the analogy between the 1993 version of the *NOC Regulations* and the interlocutory injunction prohibiting the issuance of a Notice of Compliance for up to thirty months. The 1993 version of section 8 was intended to provide redress to the generic in the same manner as an undertaking for damages in the context of an interlocutory injunction. The parties before me agreed that this was exactly the intended purpose of section 8 in the current *NOC Regulations*. Therefore, it is particularly telling that Justice Dawson said:

> In my view, section 8 was not intended to provide redress where the innovator prevailed in the prohibition proceeding, even if the generic was later successful in patent litigation. It follows that I agree with the Judge that Apotex can not "reach back and apply the finding of invalidity in the action so as to argue that the '671 patent had 'expired' within the meaning of section 8" of the 1993 version of the Regulations.

[20] Although the Court of Appeal does not expressly rely on the English authorities referred to in Justice Hughes's decision, it did note that his conclusion was based among other things on such authorities. I find that it is worth reproducing a passage cited from the decision of the English Court

of Appeal in *Unilin Beheer BV v. Berry Floor NV*, [2007] EWCA Civ. 364 (C.A.), for Eli relies on this passage that Apotex seeks to distinguish.

> 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.
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> 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.
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> 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.[5]

[21] In *Pfizer*, Justice Hughes had another opportunity to deal with this issue but this time only *in obiter* given that in the motion before him, the generic was really seeking to vary a prohibition order issued by the Federal Court of Appeal (after reversing the trial decision). Quite clearly the Court had no jurisdiction to do so but Justice Hughes, in an abundance of caution, commented on the underlying issues. Once again, he noted that there was no good reason to vary the prohibition order

given that it had expired with the declaration of invalidity of the patent. Insofar as ratiopharm's request that the application be dismissed, he found that there was no longer any live controversy in the proceedings respecting section 8 and distinguished in that respect the decision of the Federal Court of Appeal in *Apotex Inc. v. Bayer AG*, 2004 FCA 242. As in the present proceedings, the declaration of invalidity was made in the context of an action for impeachment of the patent involved in the proceedings (Canadian Patent No. 1,321,393) pursuant to the *NOC Regulations* but that action was between the same parties as the PMNOC proceedings. That judgment was not appealed.

[22] At paragraph 30 of his reasons, Justice Hughes says:

> 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.

He notes however that he may have exercised his discretion differently had the patent been obtained by fraud and such ground had been raised in the prohibition proceedings. In effect, he indicates that "each proceeding is to be considered on its own 'stand alone' merits[6], without consideration as to what may have happened in, for instance, a fully litigated action respecting the same patent" (para. 46).

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[5] In *Unilin*, the English Court of Appeal was applying a uniform line of jurisprudence including *Coflexip SA v. Stolt offshore MS Ltd.* No. 2, [2004] F.S.R. 708 (C.A.) and *Poulton v. Adjustable Cover and Boiler Block Company* (1908), 24 R.P.C. 661 (C.A.).

[6] To come to that conclusion, he referred to the Federal Court of Appeal's decisions in *Apotex Inc. v. Janssen Ortho Inc.* 2009 FCA 212 and *Sanofi-Aventis Canada Inc. v. Novopharm* 2007 FCA 163 as well as the general jurisprudence discussing the strict and narrow interpretation of the *NOC Regulations* and proceedings under those Regulations.

[23] The situation before Justice Zinn in *Pharmascience*, above, was somewhat different. There, the new matter relied upon by the generic seeking to set aside the prohibition orders and to obtain a dismissal of two related applications was simply that the claims relied upon in those applications had now been invalidated in the context of an infringement action between the patentee and two other generics.

[24] According to Apotex, this is a crucial distinction given that when a declaration of invalidity is made *in rem*, there is no substrate at all to support the decision in the prohibition proceedings. The learned judge found that contrary to the situation in *Hoffman-La Roche* and *Syntex*, for example, the prohibition orders had not become moot given that the patent had not expired. He thus set aside the said prohibition orders for the future. However, he noted that it would be improper to set aside the findings of the Court in respect of the applications and to order the dismissal of these two prohibition applications. In that respect, he mentions that he shared the view of Justice Hughes that Justice Reed did not need to dismiss the application in *Hoffmann-La Roche* and that, in the cases before him, the findings made by the Court were not upset by the Trial Judge's findings in the infringement action which was based on a different ground of invalidity.

[25] The Federal Court of Appeal dismissed the appeal in respect of the judgment setting aside the prohibition orders because it was moot. It noted, however, that the appeal in respect of Justice Zinn's refusal to dismiss the prohibition applications thereby arguably giving rise to a claim for damages under section 8 of the *NOC Regulations* was not moot. Not only did the Court find that it had not been persuaded of an error in the exercise of the judge's discretion but Justice Karen

Sharlow, writing for the Court, expressly stated: "we agree with his decision not to dismiss the prohibition applications, substantially for the reasons he gave" (para. 6).

[26] Finally, the decision of the Federal Court of Appeal in *Mayne-Pharma* is not particularly helpful in that the reasons are very brief and the circumstances quite different from those under review. In that matter, the prohibition order was not final as the Court of Appeal had yet to rule on the appeal. In fact, it was during the hearing that the Court of Appeal learned that the patent in suit had been delisted as a result of a decision in another proceeding. As could be expected, the Court of Appeal dismissed the application and, in the process, noted that "the prohibition order is a remedy that is only available to a patent holder in the context of the [*NOC Regulations*]. If the prohibition order is allowed to stand, the respondent will have the benefit of a remedy which is not available outside of the context of the [*NOC Regulations*] in a case where no basis exists under those Regulations for the remedy" (para. 3). It is clear that in this case there was no issue of *res judicata* and that the questions before the Court related directly to the prohibition proceedings *per se*.

[27] Apotex strongly argues that all of the above are distinguishable[7] and that the Court must follow *Hoffman-La Roche* mainly because:

a. no *res judicata* or collateral attack principles are at play given that Rule 399 applies;
b. thus the English authorities, such as *Unilin*, are not relevant for they are based on commercial certainty principles irrelevant to the exercise of discretion under Rule 399;

c. it would be unfair for the innovator to have had the benefit of an interlocutory injunction on the basis of an invalid patent;

d. contrary to the situation in *Pharmascience*, Justice O'Reilly's decision is based on grounds raised by Apotex in its NOA and discussed by the Court in the reasons for the 2007 Order;

e. the Court should not concern itself with whether Apotex is otherwise entitled to claim damages under section 8. It should only ensure that its discretion is exercised in a way that will not preclude the exercise of such right, if any;

f. as noted by Justice Gibson albeit in a different context in *Smith v. Canada (Minister of Citizenship and Immigration),* 2007 FC 712, [2008] 1 F.C.R. 694 (T.D.) (para. 41), once the prohibition order is set aside, the application is revived and must be dealt with. As it is now moot, it must be dismissed. There is absolutely no substrate to support the application in the 2007 Order;

[28] Having reviewed the decision in *Smith* in the context of more recent case law including, particularly, the recent comments of the Federal Court of Appeal referred to above, the Court is not willing to exercise its discretion to set aside its 2007 decision to grant these applications on the basis that the specific grounds set out in Apotex's NOA were unjustified.

[29] In its decision, the Federal Court of Appeal confirmed, in effect, the findings made in the 2007 Order with respect to obviousness and anticipation. The grounds which are to be redetermined

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[7] During the hearing, Apotex also said that Justice Hughes was wrong in *Syntex*. This obviously was before the decision

by Justice O'Reilly were not grounds raised in Apotex's NOA. The 2007 decision dealt with this expressly; it was confirmed by the Federal Court of Appeal. There is thus no good reason to distinguish the views expressed in *Pharmascience*.

[30] It is now absolutely clear from the pronouncement of the Federal Court of Appeal in *Syntex* that there is no need to set aside the prohibition order when the patent expires through a declaration of invalidity.

[31] With respect to fairness, the statements of the Federal Court of Appeal in *Syntex*, although made in respect of the 1993 version of section 8, are quite applicable here. It is perfectly understandable when one looks at the analogy upon which even Apotex relies, ***i.e.*** the filing of an application is like a motion for an interim injunction and section 8 exists in lieu of an undertaking for damages, that it would make little sense for such a guarantee against damages to apply in respect of another action or proceeding and even less sense where the parties involved are different. The Court is not aware that an undertaking for damages was ever given to guarantee against damages flowing from an injunction if the patent is later invalidated in the context of an expungement action between different parties.

[32] It is undisputable that the current version of section 8 was meant to clarify the legislator's intent. When it was adopted after full consultation, it would have been easy to add − had this been Parliament's intent − that the generic was to be indemnified if the patent listed was ever declared

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of the Federal Court of Appeal.

invalid. Instead, Parliament chose to focus on all possibilities that could happen in the normal course of a prohibition proceeding (dismissed, discontinued, reversed in appeal, *etc*.).

[33] The Court sees no good reason for changing the *status quo* by giving Apotex an opportunity that had ceased to exist when the Federal Court of Appeal confirmed the 2007 order. Apotex had a full opportunity to raise all possible allegations in respect of the invalidity of the '113 patent in its NOA. It also had the right to seek expungement from day one. In balancing the issue of fairness, I do not believe that the balance is in favour of Apotex here.

[34] Finally, as noted by Justice Rothstein in *Jhajj*, the public interest in the finality of litigation (including in that public interest, commercial interests) is one of the ingredients or principles that the Court must balance, albeit not the only one, when exercising its discretion pursuant to the exceptions to the principle of *res judicata* set out in Rule 399. Also, as indicated by Eli in its supplementary submissions, there is no doubt that the English Court of Appeal like the Federal Court has jurisdiction to vary its own judgments.

[35] As noted by Justice Rothstein (see *Jhajj* at para. 21), the discretion given to the Court in Rule 399(2) is exceptional. The Court should thus exercise such discretion with great care. Here, this is even more so when one considers, as noted in *Unilin*, that the validity of a patent is always at risk during the whole life of the patent.

[36] Having considered all the circumstances, the Court concludes that the motion must be dismissed with costs.

ORDER

THIS COURT ORDERS that the application is dismissed with costs.

"Johanne Gauthier"

Judge

ANNEX A

Patented Medicines (Notice of Compliance Regulations, SOR/93-13

6(5) Subject to subsection (5.1), 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) Sous réserve du paragraphe (5.1), 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

Federal Courts Rules, SOR/98-106

399 (1) On motion, the Court may set aside or vary an order that was made (a) ex parte; or (b) in the absence of a party who failed to appear by accident or mistake or by reason of insufficient notice of the proceeding, if the party against whom the order is made discloses a prima facie case why the order should not have been made. Setting aside or variance	399 (1) La Cour peut, sur requête, annuler ou modifier l'une des ordonnances suivantes, si la partie contre laquelle elle a été rendue présente une preuve prima facie démontrant pourquoi elle n'aurait pas dû être rendue : a) toute ordonnance rendue sur requête ex parte; b) toute ordonnance rendue en l'absence d'une partie qui n'a pas comparu par suite d'un événement fortuit ou d'une erreur ou à cause d'un avis

insuffisant de l'instance.
Annulation

(2) On motion, 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 the order; or
(b) where the order was obtained by fraud.
Effect of order

(2) La Cour peut, sur requête, annuler ou modifier une ordonnance dans l'un ou l'autre des cas suivants :
a) des faits nouveaux sont survenus ou ont été découverts après que l'ordonnance a été rendue;
b) l'ordonnance a été obtenue par fraude.
Effet de l'ordonnance

(3) Unless the Court orders otherwise, the setting aside or variance of an order under subsection (1) or (2) does not affect the validity or character of anything done or not done before the order was set aside or varied.

(3) Sauf ordonnance contraire de la Cour, l'annulation ou la modification d'une ordonnance en vertu des paragraphes (1) ou (2) ne porte pas atteinte à la validité ou à la nature des actes ou omissions antérieurs à cette annulation ou modification

FEDERAL COURT

SOLICITORS OF RECORD

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