Federal Court of Appeal

Cour d'appel fédérale

Date: 20100610

Docket: A-238-09

Citation: 2010 FCA 155

CORAM: **EVANS J.A.**
DAWSON J.A.
STRATAS J.A.

BETWEEN:

APOTEX INC.

Appellant

and

SYNTEX PHARMACEUTICALS INTERNATIONAL INC.
and HOFFMANN LAROCHE LIMITED

Respondents

Heard at Ottawa, Ontario, on May 18, 2010.

Judgment delivered at Ottawa, Ontario, on June 10, 2010.

REASONS FOR JUDGMENT BY: DAWSON J.A.

CONCURRED IN BY: EVANS J.A.
STRATAS J.A.

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REASONS FOR JUDGMENT

DAWSON J.A.

[1] The appellant, Apotex Inc. (Apotex), sued the respondents, Syntex Pharmaceuticals International Inc. and Hoffmann LaRoche Limited (together Roche), for damages under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (Regulations). A judge of the Federal Court dismissed the action (2009 FC 494) finding that:

i. In all the circumstances, the 1993 version of the Regulations applied to the action;

ii. However, section 8 of the Regulations as then in force was not triggered by the events in the action.

[2] At issue in this appeal is the correctness of those findings. In my view, the Judge correctly answered the legal questions before him. I would, therefore, dismiss the appeal.

The Facts

[3] The facts are undisputed and were carefully and comprehensively set out in the reasons for the judgment under appeal. A summary of the facts is sufficient for this appeal.

[4] On March 20, 1996, Madam Justice Reed of the Federal Court of Canada Trial Division, as it then was, issued an order under the Regulations in proceedings brought by Hoffmann LaRoche Limited and Syntex Pharmaceuticals International Limited against the Minister of National Health and Welfare (Minister) and Apotex (prohibition proceeding). The order prohibited the Minister from issuing a Notice of Compliance to Apotex with respect to naproxen slow release tablets until after the expiration of Canadian Patent No. 1, 204, 671 (‘671 patent). In the prohibition proceeding, the Court was not required to consider the validity of the ‘671 patent because Apotex had made no allegation of invalidity.

[5] An appeal and cross-appeal of Justice Reed’s decision were dismissed.

[6] Later, Apotex commenced an action seeking a declaration that the ‘671 patent was invalid. On April 19, 1999, Justice Reed pronounced a judgment declaring the Apotex formulation of naproxen slow release tablets to be non-infringing and further declaring the ‘671 patent to be invalid. No appeal was taken from that judgment.

[7] Notwithstanding the April 19, 1999 judgment, the Minister did not issue a Notice of Compliance to Apotex. The Minister took the position the prohibition order continued in effect and prevented her from issuing a Notice of Compliance. Apotex then brought a motion in the prohibition proceeding seeking an order setting aside the prohibition order and dismissing the proceeding.

[8] On April 30, 1999, Justice Reed made an order “for greater certainty” setting aside the March 20, 1996 prohibition order and dismissing the application. No appeal was taken from this decision. This order is the foundation for Apotex’ claim for damages under section 8 of the Regulations.

[9] Following the dismissal of the prohibition proceeding, the Minister issued to Apotex a Notice of Compliance for naproxen slow release tablets. The Minister has certified that, but for the prohibition order, the Notice of Compliance would have issued to Apotex on July 21, 1995.

Decision of the Federal Court

[10] The Judge began by briefly reviewing the history of the Regulations. They were first enacted effective March 12, 1993, and first amended on March 11, 1998 (SOR/98-166). As the Judge did, I will refer to these as the 1993 and 1998 versions of the Regulations.

[11] The 1998 version effected a number of changes to the Regulations, including amendments to section 8 of the Regulations. Subsection 9(6) of the 1998 version was a transitional provision governing the applicability of the amendments to section 8 of the Regulations.

[12] Subsection 9(6) of the 1998 version of the Regulations provided:

TRANSITIONAL PROVISIONS	DISPOSITIONS TRANSITOIRES
9(6) Section 8 of the Regulations, as enacted by section 8, applies to an application pending on the coming into force of these Regulations. [Emphasis added.]	9(6) L'article 8 du même règlement, édicté par l'article 8, s'applique aux demandes qui sont pendantes à la date d'entrée en vigueur du présent règlement. [Non souligné dans l'original.]

[13] To determine whether the 1993 or 1998 version of the Regulations applied to Apotex' damage claim, the Judge began by considering whether the prohibition proceeding was "pending" or, in the French language version, "pendantes" as of March 11, 1998, the date the 1998 version of the Regulations came into force.

[14] The Judge considered the meaning of the words "pending" and "pendantes" in light of several legal dictionary definitions and found that their plain and ordinary meaning "is a proceeding

that is not yet finished, one in which there is no final judgment." He acknowledged there were unusual situations where a final judgment could be varied or set aside and referred to this Court's decision in *AB Hassle v. Apotex Inc.*, 2008 FCA 416 at paragraph 30 which confirmed that a prohibition order can be set aside if an action determines invalidity or non-infringement. In light of a line of English cases dealing with patent infringement and the finality of damage awards even where the patent is later invalidated, and the final quality of Justice Reed's decision and the appeal therefrom, the Judge determined the prohibition proceeding was not pending at the relevant time within the meaning of the transitional provisions. Therefore, it followed that the 1993 Regulations applied.

[15] The Judge went on to examine and interpret section 8 of the 1993 version of the Regulations which provided:

8(1) The first person is liable to the second person for all damage suffered by the second person where, because of an application of paragraph 7(1)(*e*), the Minister delays issuing a notice of compliance beyond the expiration of all patents that are the subject of an order pursuant to subsection 6(1).	8(1) La première personne est responsable envers la seconde personne de tout préjudice subi par cette dernière lorsque, en application de l'alinéa 7(1)*e*), le ministre reporte la délivrance de l'avis de conformité au-delà de la date d'expiration de tous les brevets visés par une ordonnance rendue aux termes du paragraphe 6(1).
(2) The court may make such order for relief by way of damages or profits as the circumstances require in respect of any damage referred to in subsection (1).	(2) Le tribunal peut rendre toute ordonnance de redressement par voie de dommages-intérêts ou de profits que les circonstances exigent à l'égard de tout préjudice subi du fait de l'application du paragraphe (1).

[16] Fundamental to the Judge's analysis was the meaning of "expire" which was defined at section 2 of the Regulations to mean to "expire, lapse or terminate by operation of law". The Judge observed that a patent could expire by the natural end of its term, lapse due to the failure to pay maintenance fees or terminate by operation of law, for instance, by a declaration of invalidity. He noted that paragraph 7(1)(*e*) of the Regulations required the Minister to wait 30 months before issuing a Notice of Compliance if an application for prohibition had been made. The Judge found the Minister, because of paragraph 7(1)(*f*) and subsection 7(2) of the Regulations, did not have to delay in granting a Notice of Compliance where a patent had expired.

[17] Then, turning to section 8 of the 1993 version of the Regulations, the Judge had regard to principles of statutory interpretation. These he articulated as requiring him to make sense of the provision by reading it in context. He also suggested he should not necessarily be distracted by the ambiguities and absurdities suggested by the parties.

[18] He went on to reason at paragraphs 71 to 73 and 76 that:

> 71. A reasonable interpretation of section 8 would be to impose a liability on a first person if the cause of the delay in issuing a Notice of Compliance to a second person was that the patent that was the subject of the proceeding had "expired", that is by the natural end of its term, or by lapse such as failure to pay maintenance fees, or by operation of law such as a declaration of invalidity. If, for instance, the patent was declared invalid in the context of the relevant NOC application itself, then it can be said that the Minister had delayed in issuing the Notice of Compliance because the patent must be considered to have "expired". The extent of the delay could reasonably be considered to be the later of the day upon which the Minister says that the Notice of Compliance would otherwise have been issued if it were not for the application of the Court, or the filing date of that application with the Court. The end date would be the date that the Notice of Compliance was actually issued. In the present case the Minister has provided a letter (Trial Exhibit 2-13) stating that the

> Notice of Compliance would have issued on July 21, 1995 were it not for the application in this Court which was filed August 3, 1993 (Trial Exhibit 2-5). The Notice of Compliance was actually issued May 4, 1999 (Trial Exhibit 2-12). Thus the period would be between July 21, 1995 and May 4, 1999.
>
> 72. However, in this case the Judgment holding the '671 patent to be invalid did not occur in the context of the *PMNOC Regulations* application but in the context of a separate action. That Judgment issued on April 23, 1999, only a few days before May 4, 1999. The Order varying the prohibition Order and dismissing the *PMNOC* application was made April 30, 1999. There is no evidence as to the dates when the Minister was actually made aware of the Judgment or the Order. I find that there was no unreasonable delay by the Minister in issuing a Notice of Compliance to Apotex.
>
> 73. Given the circumstances Apotex was, as of May 4, 1999, free to sell the drug in question. Can it also 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 *PMNOC Regulations* such that it can make a claim under that provision? I find that Apotex cannot.
>
> […]
>
> 76. At no time during the period when the prohibition Order was made, including the period where that Order was affirmed on appeal, was the '671 patent held to be invalid by the Court in that proceeding or any other Court in any other proceeding. The patent had not "expired" when the Order was made or affirmed on appeal. Immediately upon the "expiry" of the patent by a finding of invalidity in another proceeding the Minister issued a Notice of Compliance. There was no delay. I find, therefore, that section 8 of the 1993 version of the *PMNOC Regulations* is not triggered in the circumstances of this action. [Underlining added.]

[19] In view of his findings, it was unnecessary for the Judge to rule on the other issues raised by Apotex. He did so for the “almost inevitable” appeal. One such issue was whether Roche would be liable for damages if the 1998 version of the Regulations applied. On this appeal it is not necessary to consider the Judge’s interpretation of section 8 of the 1998 version of the Regulations. Therefore, no comment is made about the correctness of that interpretation.

The Asserted Errors

[20] Apotex asserts the Judge erred as follows in reaching the above conclusions:

1. Given Justice Reed's order of April 30, 1999 dismissing the prohibition proceeding, the Judge erred by failing to find that Roche was estopped from arguing the prohibition proceeding was not pending as at March 11, 1998.
2. If Roche was not estopped, the Judge nonetheless erred by finding the prohibition proceeding was not pending as at March 11, 1998.
3. The Judge erred by construing the 1993 version of the Regulations to prevent it from recovering damages.

The Standard of Appellate Review

[21] The parties agree the questions raised on this appeal are questions of law the Judge was required to answer correctly. I agree.

Analysis

Did the Judge err by failing to find that Roche was estopped from arguing the prohibition proceeding was not pending as at March 11, 1998?

[22] Apotex argues that, in her 1999 decision to set aside the prohibition order, Justice Reed heard submissions that she had no jurisdiction to grant the requested order because the proceeding was no longer extant. Justice Reed disagreed, and found the Court had continuing jurisdiction over a prohibition order made under the Regulations. Since this decision was not appealed, Apotex says

the matter is *res judicata* and Roche is estopped by the principles of issue estoppel from reopening the issue.

[23] In my respectful view, there is no merit in this submission. As a matter of law, issue estoppel only operates where the same question has been conclusively determined between the parties. The estoppel extends to the material facts and the conclusions of law or of mixed fact and law that were necessarily, even if not explicitly, determined in the earlier proceedings. See: *Danyluk v. Ainsworth Technologies Inc.*, [2001] 2 S.C.R. 460 at page 481. Justice Reed neither explicitly nor necessarily decided whether the prohibition proceeding was pending for the purpose of subsection 9(6) of the 1998 version of the Regulations. Rather, Justice Reed based her decision on the Court's inherent continuing jurisdiction to amend or annul the prohibition order in response to changed circumstances. She also expressed the view the prohibition order had, by its own terms, ceased to have any operative effect with the issuance of the April 19, 1999 order that had declared the '671 patent to be invalid. Thus, she granted the order dismissing the prohibition proceeding "for greater certainty." See: (1999) 167 F.T.R. 111 at paragraphs 8, 14 and 15.

[24] Without a prior determination of whether the prohibition proceeding was pending for the purpose of subsection 9(6) of the 1998 version of the Regulations, Apotex' argument of issue estoppel must fail.

Did the Judge err by finding the prohibition proceeding was not pending as at March 11, 1998?

[25] Apotex argues that to properly interpret the word "pending" as used in subsection 9(6) of the 1998 version of the Regulations, it is necessary to consider the context in which it is used. This includes the scheme and object of the 1998 version of the Regulations, the purpose of the 1993 amendments to the *Patent Act*, R.S.C. 1985, c. P-4, the Regulations as enacted and the 1998 amendments to the Regulations. Apotex notes the Regulatory Impact Analysis Statement (RIAS) which accompanied the original version of the Regulations showed an intention to mitigate the automatic stay under the Regulations through the mechanism of section 8. This is said to evidence an attempt to balance the rights of the patentee with the generic. The purpose of the 1998 amendments was to clarify and streamline the Regulations. The RIAS accompanying the 1998 amendments also commented on the need for balance between the patentee's rights and the public interest in ensuring that generic drug products enter the market as soon as possible. The RIAS stated that a clearer indication was given to the Court about the circumstances where damages could be awarded. The transitional provision showed the intent that the new regulations were to apply to applications commenced prior to the coming into force of the amendments: applications that were still pending.

[26] Apotex relies on *Stroud's Judicial Dictionary of Words and Phrases* for the proposition that a proceeding is pending "so long as the Court having original cognizance of it can make an order on the matters in issue, or to be dealt with, therein." It also relies on a statement of Jessel M.R. from an 1882 insolvency case (*In re Clagett's Estate*; *Fordham v. Clagett* (1882), 20 Ch D 637 at 653) that a

pending insolvency "includes every insolvency in which any proceeding can by any possibility be taken. […] A cause is said to be pending in a Court of justice when any proceeding can be taken in it." Apotex also points out that in a fraudulent conveyance action, litigation remains pending after judgment until all acts necessary to make assets available to creditors have been performed.

[27] Apotex asserts that a broad interpretation of "pending" is consistent with Justice Reed's finding that the Court has continuing jurisdiction in prohibition proceedings and with the intent behind the remedial amendments. Refusing to apply the 1998 Regulations would, it argues, defeat that remedial intent.

[28] In my view, the Judge correctly interpreted the transitional provision. In the context of a legal proceeding, the plain and ordinary meaning of the words "pending" or "pendantes" is a proceeding that is not yet finished. Here, at the time of the 1998 amendments a final order had been pronounced in the prohibition proceeding. Apotex had made two allegations in respect of the '671 patent. They were, first, that the patent did not fall within the scope of the Regulations and, second, that its product would not infringe the patent. The Court had found both allegations to be unjustified. That decision was affirmed on appeal. The Judge's decision properly gives effect to the dismissal on the merits of the prohibition proceeding.

[29] With respect to the definitions relied upon by Apotex, 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. This would mean that all prohibition proceedings

brought under the Regulations would be perpetually pending under the transitional provision, with the consequence that an innovator would be exposed to unforeseen liability years after successfully prosecuting prohibition proceedings. Clearer language would be required to effect that result.

Did the Judge err by construing the 1993 version of the Regulations to prevent Apotex from recovering damages?

[30] Apotex does not take issue with the Judge's synthesis of the applicable principles of statutory interpretation. It says, however, that his interpretation was faulty for the following reasons.

[31] First, Apotex argues there are several issues the Judge's interpretation fails to resolve. They are:

- He recognized the Minister need not delay in granting a Notice of Compliance if the patent has expired, but he did not resolve the quandary created by the fact that section 8 appears to impose liability only where the minister delays in issuing a Notice of Compliance "beyond the expiration of all patents".
- He did not resolve why there would be liability if a prohibition order has been issued (as section 8 incorporates subsection 6(1)). This leads to the absurd result that a generic could only recover damages if it fails in a prohibition application.
- The Judge's interpretation only allows liability where there is an inexplicable delay by the Minister after the expiry of a patent. The Judge did not explain why the first person and not the Minister would be liable for such a delay.

[32] Beyond this, Apotex argues the Judge also found that “expiry” of a patent could include a declaration of invalidity in the context of prohibition proceedings. However, summary proceedings under the Regulations cannot result in a finding of invalidity. This also leads to an inconsistency whereby damages would be available for invalidity, but not for non-infringement.

[33] Apotex submits that its own interpretation of section 8 avoids these absurdities. It says the language in section 8 of the 1993 Regulations refers to a situation in which more than one patent is on the patent list and prohibition orders have issued for one or more of the other patents, not the one in which the generic brings the section 8 action. In the present case, since there are no other relevant patents or prohibition orders, the Notice of Compliance would have issued on July 21, 1995 had the statutory freeze not been in effect at that point. Until April 30, 1999, the Minister was prevented from issuing a Notice of Compliance by the prohibition proceeding. Apotex therefore states that it is entitled to damages throughout that period.

[34] This Court has previously observed that section 8 as contained in the 1993 version of the Regulations is particularly obscure in its meaning. See: *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1994), 169 N.R. 342 (F.C.A.). It may well not be possible to find an interpretation that resolves all the contingencies that may be posed.

[35] I agree with Apotex that the Judge’s reference to a patent being “declared invalid in the context of the relevant NOC application itself” was not an accurate statement because no such declaration may be made in a prohibition proceeding. That said, I am satisfied the Judge’s language

was inadvertent and not a material error. The situation the Judge was addressing was where, in a prohibition proceeding under the Regulations, the Court found an allegation of invalidity to be justified. With that clarification, in my view, the Judge correctly interpreted section 8 of the 1993 version of the Regulations in the context of the unique facts before him.

[36] Under the 1993 version of the Regulations, when an innovator commenced a proceeding seeking a prohibition order it obtained the equivalent of an interlocutory injunction prohibiting the issuance of a notice of compliance for up to 30 months. The innovator need not have satisfied the criteria for obtaining injunctive relief and no undertaking for damages was required. In that circumstance, section 8 of the Regulations was intended to provide redress to the generic where the innovator failed to establish that the generic's allegations of invalidity or non-infringement were not justified. 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.

[37] I do not find the interpretation of the Regulations advanced by Apotex to be correct because it would require extensive judicial re-writing of section 8. Further, as noted by Apotex at paragraph 62 of its memorandum of fact and law, Apotex' interpretation requires that no prohibition order issue on the patent in respect of which the section 8 action is brought. Here a prohibition order did issue with respect to the patent which forms the basis of the section 8 action.

Conclusion

[38] For these reasons, I would dismiss the appeal with costs payable by Apotex to Roche.

"Eleanor R. Dawson"

J.A.

"I agree.
John M. Evans J.A."

"I agree.
David Stratas J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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