Federal Court of Appeal | Cour d'appel fédérale

Date: 20110628

Docket: A-75-06

Citation: 2011 FCA 215

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

BETWEEN:

PFIZER CANADA INC. and PFIZER LIMITED

Appellants

and

THE MINISTER OF HEALTH and RATIOPHARM INC.

Respondents

Heard at Toronto, Ontario, on June 9, 2011.

Judgment delivered at Ottawa, Ontario, on June 28, 2011.

REASONS FOR JUDGMENT BY: LÉTOURNEAU J.A.

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

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REASONS FOR JUDGMENT

LÉTOURNEAU J.A.

Issues in these proceedings

[1] Ratiopharm Inc. has filed a motion pursuant to Rule 399 of the *Federal Courts Rules*, SOR/98-106, to set aside an order of this Court in this matter (2006 order) rendered on June 9, 2006 (*Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FCA 214), whereby this Court allowed an appeal from a decision of the Federal Court and issued an order prohibiting the Minister of Health

(Minister) from issuing a Notice of Compliance (NOC) to Ratiopharm Inc. until the expiry of Pfizer Limited's '393 Patent.

[2] Ratiopharm Inc. submits that the 2006 order should be set aside under Rule 399(2)(*a*) and (*b*) by reason of a matter that was discovered subsequent to the making of the order and because the order was obtained by fraud. The Rule reads:

399.	**399.**
…	[…]
(2) On motion, the Court may set aside or vary an order	(2) La Cour peut, sur requête, annuler ou modifier une ordonnance dans l'un ou l'autre des cas suivants :
(*a*) by reason of a matter that arose or was discovered subsequent to the making of the order; or	*a*) des faits nouveaux sont survenus ou ont été découverts après que l'ordonnance a été rendue;
(*b*) where the order was obtained by fraud.	*b*) l'ordonnance a été obtenue par fraude.

[3] Exceptionally, the motion was not dealt with in writing as the parties and the Court felt that the interests of justice would be better served by an oral hearing in view of the fact that the impugned order dates back to 2006 and that two members of the original panel have now retired.

[4] In addition to the setting aside of the 2006 order, Ratiopharm Inc. wants an order dismissing the application for prohibition in Federal Court File No. T-1350-04.

The facts giving rise to the motion to set aside

[5] In File T-1350-04, Pfizer Canada Inc. and Pfizer Limited applied pursuant to the *Patented Medicines Notice of Compliance) Regulations*, SOR/93-133 (NOC Regulations) for an order prohibiting the Minister from issuing a NOC to Ratiopharm. In a decision rendered on February 17, 2006, the Federal Court found for Ratiopharm and dismissed with costs the application for prohibition. Upon appeal to our Court, the decision of the Federal Court was set aside. A prohibition order issued. This is the 2006 order which is now the subject of Ratiopharm's attack.

[6] Subsequent to the 2006 order, Ratiopharm took impeachment proceedings under the *Patent Act*, R.S.C. 1985, c. P-4 (Act) to have Pfizer Limited's '393 Patent declared invalid.

[7] In a judgment rendered on July 8, 2009 (*Ratiopharm Inc. and Pfizer Limited*, 2009 FC 711), affirmed by our Court, 2010 FCA 204, Hughes J. of the Federal Court (judge) found for Ratiopharm and held Pfizer Limited's '393 Patent invalid on all grounds argued at trial, i.e. obviousness, utility, sufficiency, selection patent and section 53 of the Act which prohibits an applicant from willfully making, in his petition in respect of the patent, material allegations that are untrue. Hence, Ratiopharm's motion presently before us to set aside the 2006 order.

[8] In its Notice of Motion, Ratiopharm indicates that, upon the setting aside of our 2006 order, it will be entitled to seek compensation pursuant to section 8 of the NOC Regulations for the losses

incurred during the time it was held off the market because of the NOC proceedings. Section 8 reads:

8. (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period	**8.** (1) Si la demande présentée aux termes du paragraphe 6(1) est retirée ou fait l'objet d'un désistement par la première personne ou est rejetée par le tribunal qui en est saisi, ou si l'ordonnance interdisant au ministre de délivrer un avis de conformité, rendue aux termes de ce paragraphe, est annulée lors d'un appel, la première personne est responsable envers la seconde personne de toute perte subie au cours de la période :
(*a*) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court concludes that (i) the certified date was, by the operation of *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, chapter 23 of the Statutes of Canada, 2004, earlier than it would otherwise have been and therefore a date later than the certified date is more appropriate, or (ii) a date other than the certified date is more appropriate; and	*a*) débutant à la date, attestée par le ministre, à laquelle un avis de conformité aurait été délivré en l'absence du présent règlement, sauf si le tribunal conclut : (i) soit que la date attestée est devancée en raison de l'application de la *Loi modifiant la Loi sur les brevets et la Loi sur les aliments et drogues (engagement de Jean Chrétien envers l'Afrique)*, chapitre 23 des Lois du Canada (2004), et qu'en conséquence une date postérieure à celle-ci est plus appropriée, (ii) soit qu'une date autre que la date attestée est plus appropriée;
(*b*) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.	*b*) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance.
(2) A second person may, by action against a first person, apply to the court for an order requiring the first person to compensate the second person for the loss referred to in subsection (1).	(2) La seconde personne peut, par voie d'action contre la première personne, demander au tribunal de rendre une ordonnance enjoignant à cette dernière de lui verser une indemnité pour la

	perte visée au paragraphe (1).
(3) The court may make an order under this section without regard to whether the first person has commenced an action for the infringement of a patent that is the subject matter of the application.	(3) Le tribunal peut rendre une ordonnance aux termes du présent article sans tenir compte du fait que la première personne a institué ou non une action en contrefaçon du brevet visé par la demande.
(4) If a court orders a first person to compensate a second person under subsection (1), the court may, in respect of any loss referred to in that subsection, make any order for relief by way of damages that the circumstances require.	(4) Lorsque le tribunal enjoint à la première personne de verser à la seconde personne une indemnité pour la perte visée au paragraphe (1), il peut rendre l'ordonnance qu'il juge indiquée pour accorder réparation par recouvrement de dommages-intérêts à l'égard de cette perte.
(5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).	(5) Pour déterminer le montant de l'indemnité à accorder, le tribunal tient compte des facteurs qu'il juge pertinents à cette fin, y compris, le cas échéant, la conduite de la première personne ou de la seconde personne qui a contribué à retarder le règlement de la demande visée au paragraphe 6(1).
(6) The Minister is not liable for damages under this section.	(6) Le ministre ne peut être tenu pour responsable des dommages-intérêts au titre du présent article.

[9] I should say that the issue before us is not about determining whether Ratiopharm would or would not have a lawful recourse against Pfizer Limited pursuant to section 8. As previously mentioned, the debate turns on the applicability of Rule 399 to the 2006 order. However, section 8 is an important component of the NOC Regulations and is central to the determination of the interplay between NOC and impeachment proceedings.

Analysis of the parties' contentions

a) Whether the issues raised on this motion to set aside are now moot

[10] Counsel for Pfizer Limited argues that the 2006 order having now expired, a NOC been issued and Ratiopharm being on the market with its own product, the matter is now moot: see *Eli Lilly Canada Inc. v. Novopharm Limited and the Minister of Health*, 2007 FCA 359, at paragraph 14. Therefore, Ratiopharm's motion should be dismissed.

[11] Mootness means that a court is not required to embark upon a hearing to decide matters which no longer have a practicability, for which there is no remaining controversy between the parties and no public interest in proceeding to an adjudication.

[12] This is not, however, the case where fraud on the court is alleged as a ground for setting aside an order that the court issued. Inasmuch for itself as for the public, the court has an interest in ensuring that its process is not being abused and that the guilty party does not reap the benefits of its blameworthy behaviour. I have no hesitation in concluding that the matter is not moot with respect to the challenge under Rule 399(2)(*b*). The principle of finality which normally attaches to a judgment must give way when the judgment is obtained by fraud. *Fraus omnia corrumpit*: fraud negates everything.

[13] I agree with counsel for Pfizer Limited that the issue is moot insofar as a determination is sought under Rule 399(2)(*a*). However, Ratiopharm's challenge and the recurring litigation surrounding the interpretation and application of section 8 show that there still seems to be some ambiguity concerning the interplay between NOC and impeachment proceedings. I think it would be in the public interest and in the interest of would-be litigants to provide what we hope will be clear guidance.

b) Whether the decision of Hughes J. in the impeachment proceedings is a new matter under Rule 399(2)(*a*)

[14] I begin my analysis with two settled principles. First, NOC proceedings and impeachment proceedings are different in scope, purpose and procedure. Consequently, different legal consequences ensue. Second, NOC proceedings are not preemptive of an impeachment proceeding under the Act to have a patent declared invalid. They are not a final determination of a patentee's rights.

[15] The nature, purpose and scope of the NOC proceedings and their relationship with impeachment proceedings have been conveniently summarized by Layden-Stevenson J. (as she then was) in *Fournier Pharma Inc. v. Canada (Minister of Health)* (2004), 38 C.P.R. (4th) 297, 2004 FC 1718. At paragraphs 6, 8 and 9, she writes:

> [6] As noted, this proceeding is brought under the Regulations. The history and scheme of the Regulations have been delineated in various decisions of the Federal Court of Appeal and need not be repeated here. See: *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1994), 55

> C.P.R. (3d) 302 (F.C.A.);…). Basically, issues of non-infringement and validity between the patent holder (first person) and the person seeking a NOC from the Minister (second person) originate with a NOA, served on the first person by the second person, setting out the second person's allegations, including the legal and factual basis in support. The first person may disagree and apply to the court for an order prohibiting the Minister from issuing a NOC to the second person until after expiration of the patent.
>
> …
>
> [8] Section 6 proceedings are not to be likened to actions for determining validity or infringement. They are proceedings in judicial review, to be held expeditiously, whose aim is to determine whether the Minister is free to issue the requested NOC. Their scope is confined to administrative purposes: *Apotex Inc. v. Canada (Minister of National Health and Welfare)* (1997), 76 C.P.R. (3d) 1 (F.C.A.). The determination must turn on whether there are allegations by the second person sufficiently substantiated to support a conclusion for administrative purposes (the issuance of a NOC) that an applicant's patent would not be infringed if the second person's product is put on the market: *Pharmacia Inc. v. Canada (Minister of National Health and Welfare)* (1994), 58 C.P.R. (3d) 209 (F.C.A.).
>
> [9] By merely commencing the proceeding, the applicant obtains what is tantamount to an interlocutory injunction without having satisfied any of the criteria a court would require before enjoining issuance of a NOC: *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1998), 80 C.P.R. (3d) 368 (S.C.C.);…). The Regulations allow a court to determine summarily, on the basis of the evidence adduced, whether the allegations are justified. Section 6 proceedings are not adjudicative and cannot be treated as res judicata. The patentee is in no way deprived of all the recourses normally available to enable it to enforce its rights. If a full trial of validity or infringement issues is required, this can be obtained in the usual way by commencing an action: *Pfizer Canada Inc. v. Apotex Inc.* (2001), 11 C.P.R. (4th) 245 (F.C.A.);…).
>
> [Emphasis added]

[16] As this Court said in *AB Hassle v. Canada (Minister of National Health and Welfare)* (2000), 7 C.P.R. (4th) 272, at pages 286-287, the first person gains a significant short-term advantage when it obtains a prohibition order. However, it exposes itself to a claim for compensatory damages under section 8 if the application for prohibition is withdrawn, discontinued

or dismissed by the court hearing the application. The remedy of section 8 is also available if the prohibition order granted is reversed on appeal. This balance struck between the rights and obligations of the parties "promotes the use of the PM (NOC) Regulations for the purpose for which they are intended: the prevention of infringement": see *Apotex Inc. v. Merck & Co. Inc.*, [2010] 2 F.C.R. 389, at paragraph 60, 2009 FCA 187.

[17] The section 6 proceedings are instituted by the patentee who seeks 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 a declaration" of invalidity or non-infringement: see the statement of Hugessen J.A. in *Merck Frost Canada Inc. v. Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302 (F.C.A.) at pages 319 and 320, approved by the Supreme Court of Canada in *Eli Lilly & Co. v. Novopharm Ltd.*, [1998] 2 S.C.R. 129, at paragraph 95. "Patent invalidity, like patent infringement, cannot be litigated in this kind of proceeding" notwithstanding that paragraph 7(2)(*b*) of the NOC Regulations seems to envisage such declaration: *ibidem*.

[18] The scope of application of section 8 and its interplay with impeachment proceedings were reviewed by our Court in *Apotex Inc. v. Syntex Pharmaceuticals International Ltd.*, 2010 FCA 155. Writing for a unanimous court, Dawson J.A. held at paragraph 36:

> [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.
>
> [Emphasis added]

[19] Counsel for Ratiopharm argued that this finding of Dawson J.A. was made in respect of an earlier version of section 8 and, therefore, should not be followed. With respect, I think the finding is still good and sound law under the new section 8 and ought to be applied in this case. The invalidity of the '393 Patent found in the impeachment proceedings is a fact discovered after the 2006 order. However, it is not a new matter within the meaning of Rule 399(2)(*a*) which, as a matter of law, would warrant setting aside the 2006 order on the basis that the '393 Patent had "expired" within the meaning of paragraph 7(2)(*a*) and section 8 of the NOC Regulations. The subsequent decision invalidating the '393 Patent does not provide a basis upon which the prohibition order issued by this Court should be set aside.

c) Whether the 2006 order ought to be set aside pursuant to Rule 399(2)(*b*) for fraud

[20] In the case of *Imperial Oil Ltd. et al. v. Lubrizol Corp.* (2000), 6 C.P.R. (4th) 417, Nadon J. (as he then was) ruled at paragraph 53:

> [53] For a party to succeed on a Rule 1733 motion, the following elements must be established to the satisfaction of the court:
>
> 1. that a false representation has in fact been made;
> 2. that the false representation was made either
>
> (i) knowingly, without an honest belief in its truth, or
>
> (ii) recklessly, careless of whether it be true or false.

[21] The learned judge went on to cite with approval, at paragraph 57, the following propositions stated by Osborne J. in the case of *International Corona Resources Ltd. v. LAC Minerals Ltd.* (1988), 66 O.R. (2d) 610 (H.C.J.):

> (1) The fraud alleged must be proved on a reasonable balance of probability. The more serious the fraud alleged, the more cogent the evidence going to establish it will have be to meet the civil onus of proof. The reasonable balance of probability is not an inflexible standard of proof.
>
> (2) The proved fraud must be material, that is, it must go to the foundation of the case.
>
> (3) The evidence of fraud must not have been known at the time of trial to the party seeking to rely upon it on a motion to set aside a trial judgment.
>
> (4) The unsuccessful trial party is exposed to a test of due or reasonable diligence. This is clear from cases such as, *MacDonald v. Pier*, *supra*; *Johnston v. Barkley*, *supra*, and *Industrial Development Bank v. Bertolo*, *supra*. In my view, the onus is on the moving party to establish due diligence. Evidence cannot be stockpiled during the litigation to be taken from inventory after an unsuccessful trial or appeal: see *Becker Milk Co. Ltd. v. Consumers' Gas Co.* (1974), 2 O.R. (2d) 554 at p. 558, 43 D.L.R. (3d) 498 at p. 502 (C.A.).
>
> (5) If the fraud alleged is that of a non-party, and if the successful party at trial is not connected with the fraud alleged, the tests to which I have referred must be more stringent than for the fraud of a party. It is not, however, necessary for me to set out the added burden to be placed upon a moving party seeking a new trial in the face of the fraud of a non-party, as I have concluded that LAC has not established a right to

> success when its case is measured against the standards imposed in cases involving fraud of a party.
>
> (6) The test imposed upon the unsuccessful trial party to obtain relevant evidence – that is, evidence going to establish fraud – with due diligence, is objective. The questions to be asked are: what did the moving party know, and what ought the moving party to have known?
>
> (7) Delay will defeat a motion to set aside a trial judgment under rule 59.06. I refer in this regard to cases where the evidentiary burden has been met and the due diligence test passed, but where there is unreasonable delay in bringing or pursuing the motion to set aside. *Johnston v. Barkley, supra*, is ample authority for the proposition above referred to.
>
> (8) Relief under rule 59.06 is discretionary. The conduct of the moving party is relevant.
>
> (9) At the end of the day, the central question to be answered is as stated in *Wentworth v. Rogers (No. 5), supra*, at p. 539:
>
> > "... it must be shown, by the party asserting that a judgment was procured by fraud, that there has been a new discovery of something material, in the sense that fresh facts have been found which, by themselves or in combination with previously known facts, would provide a reason for setting aside the judgment."

[22] In the impeachment proceedings, Hughes J. found that Pfizer intentionally made three misstatements in its petition in respect of the patent and that in consequence, pursuant to section 53 of the Act, the patent was invalid. At paragraph 196 of his reasons, Justice Hughes described section 53 of the Act to "come close" to being directed to fraud. Chief among the criteria for establishing fraud and setting aside the impugned 2006 order is the requirement that the fraud be material, that is to say that the fraud goes to the foundation of the case. Of course, in order to be material, the fraud on the court must have been committed in the proceeding in which the 2006 order sought to be set aside was rendered.

[23] In the present instance, while Hughes J. was satisfied that the ‘393 Patent obtained from the Registrar was invalid for numerous reasons, including false representations, Ratiopharm must establish that fraud on this Court was committed in the NOC proceedings in the Federal Court and in the appeal of the Federal Court’s decision dismissing the respondents’ application for prohibition. In other words, it must be established that were it not for the fraud, this Court would not have reversed the Federal Court decision and issued the 2006 order. With respect, I think that, for the following reasons, Ratiopharm’s evidence and submissions fall short of establishing the required materiality.

[24] Ratiopharm has filed with us no record of the proceedings which were before the original panel of our Court and which could establish that the original panel was the victim of a fraud. Indeed, the Federal Court and our Court were faced with an application for a prohibition pursuant to section 6 of the NOC Regulations.

[25] The only issue in the prohibition proceedings was whether, pursuant to subsection 6(2), the allegation of invalidity by reason of anticipation, obviousness and being an improper selection patent made by Ratiopharm was justified. On the basis of the evidence provided by Ratiopharm in its challenge of the application for prohibition, the original panel found that the Federal Court made an error when it concluded that the investigation conducted by Pfizer Limited concerning the valuable properties of the chemical substance at play amounted to mere verification and not invention.

[26] In addition, the Federal Court had expressed concerns about Pfizer Limited's selection of the threshold factors for determining the solubility, stability, non-hygroscopicity and processability of the nine salts tested. At paragraph 52 of its decision, the Federal Court concluded that all four factors had a totally unexplained minimum threshold. The original panel ruled that the Federal Court had failed to recognize that the scarce evidence on the issue of thresholds was due to the fact that Ratiopharm never objected to them in its Notice of Allegation as it was required to do.

[27] The original panel's rationale for its 2006 order appears at paragraphs 26, 27, 32 and 33 of said order:

> [26] In opposition, Ratiopharm argues that the applications Judge was correct to hold that the '393 patent teaches "mere verification", relying on an old English Court of Appeal decision in *Sharpe & Dohme Inc. v. Boots Pure Drug Company Ld.* (1928), 45 R.P.C. 153 (C.A.). In that case, Sargant L.J. opined that it is verification and not invention to ascertain the valuable properties of a chemical substance obtained through the usual, well-known tests to establish their identity and their respective therapeutic value.
>
> [27] In my view, the learned applications Judge erred when he concluded that the investigation conducted by Pfizer amounted to mere verification. As we have seen, verification deals with compounds already discovered and made, yet as the applications Judge found, and as all five experts admitted, the formulation properties of any salt of amlodipine could never have been expected but must be determined empirically (reasons, at paragraph 39). Had he applied the principles enunciated in *I.G. Farbenindustrie*, *Beecham*, *E.I. Du Pont* and *Dreyfus* to his factual findings, the applications Judge could only conclude that the '393 patent is a valid selection patent because of Pfizer's discovery of besylate's special formulation properties creating a special advantage in dosage stability and processability. In essence, as stated by the Supreme Court of Canada in *Southam*, the applications Judge effectively applied the wrong test, thus leading to a legal error.
>
> …

> [32] The applications Judge was also concerned that the thresholds could be manipulated, and commented that there was no evidence offered by Pfizer to justify them. However, he failed to recognize that there was little evidence on the issue of thresholds because Ratiopharm never objected to them in its NOA. Threshold issues had to be raised in the NOA so that Pfizer could know the case it had to meet (see *Pfizer Canada Inc. v. Novopharm Ltd.*). Deciding a case on a theory not raised by parties may give rise to an argument for procedural unfairness.
>
> […] In summary, the applications Judge's erroneous application of the principle of verification caused him to conclude that besylate had no "special advantage" or "quality of a special character" capable of supporting a selection patent. In my analysis, based on the uncontested facts and the findings of the applications Judge, besylate has, in terms of stability, solubility, non-hygroscopicity and processability, both a special advantage and quality of a special character, thus giving rise to a valid claim for a selection patent.
>
> [Emphasis added]

[28] No perjured evidence and no forged documents were filed in the NOC proceedings. Nothing in these proceedings indicated an intention to mislead and no allegation of fraud was made. The sole evidence of the alleged material fraud on the original panel that Ratiopharm relies on is the '393 Patent filed which contained omissions and inflating qualities of the invention. However, the '393 Patent benefited from a presumption of validity which was not rebutted as Ratiopharm's allegations of invalidity were found to be unjustified. Our Court never adjudicated on the issue of the validity of Pfizer Limited's patent. In the context and for the purpose of the application for a prohibition order, it merely gave effect to the presumption of validity over unjustified allegations of invalidity by Ratiopharm.

[29] I cannot see how it can be said on the basis of the existing record that the impugned 2006 order in the NOC proceedings was induced by and resulted from the misrepresentations later found in the impeachment proceedings to have been made to obtain the Patent.

Conclusion

[30] For these reasons, I would dismiss with costs Ratiopharm's motion to set aside the 2006 order of this Court.

"Gilles Létourneau"
J.A.

"I agree
Eleanor R. Dawson J.A."

"I agree
David Stratas J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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