Date: 20071218

Docket: A-75-06

Citation: 2007 FCA 407

PRESENT: LÉTOURNEAU J.A.

BETWEEN:

PFIZER CANADA INC. and PFIZER LIMITED

Appellants

and

THE MINISTER OF HEALTH and RATIOPHARM INC.

Respondents

Dealt with in writing without appearance of parties.

Order delivered at Ottawa, Ontario, on December 18, 2007.

REASONS FOR ORDER BY: LÉTOURNEAU J.A.

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REASONS FOR ORDER

LÉTOURNEAU J.A.

[1] Ratiopharm Inc. ("Ratiopharm") brings an application to set aside a judgement of this Court rendered June 9, 2006 which allowed the appeal brought by Pfizer Canada Inc. and Pfizer Limited ("Pfizer") and prohibited the Minister of Health (the "Minister") from issuing a Notice of Compliance ("NOC") with respect to its proposed amlodipine besylate ("Besylate tablets"). In support of this application, the appellants invoke Rule 399(2)(*a*) of the *Federal Court Rules* SOR/98-106 (the "Rules") and the inherent jurisdiction of the Court.

[2] The application is based on Ratiopharm's submission that events which have occurred since the decision was rendered, including in particular the de-listing of a patent found to have been improperly listed by Pfizer on the patent register make it clear that the prohibition order would not have been issued if these events had unfolded in the manner that it proposes. Accordingly, Ratiopharm asks that the earlier decision of this Court be set aside.

RELEVANT FACTS

[3] On January 23, 2004, Ratiopharm filed a submission with the Minister of Health for a NOC in respect of Ratiopharm's Besylate tablets. In order to establish bioequivalence, Ratiopharm's application made reference to Pfizer's NORVASC Besylate tablets ("NORVASC"), (covered by two patents that Pfizer Canada Inc. had caused to be listed on the patent register (Canada Patent No. 1,253,865 ('865 patent) and Canadian Patent No.1, 321, 393 ('393 patent)). Concurrently with the filing of the abbreviated new drug submission ("ANDS") for its Besylate tablets, Ratiopharm served on Pfizer, a notice of allegation ("NOA") pursuant to subsection 5(3) of the *Patented Medicines (Notice of Compliance) Regulations* ("NOC Regulations"), accepting that the NOC for its Besylate tablets would not issue until the '865 patent expired on May 9, 2006, but alleging that the '393 patent was invalid.

[4] On July 19, 2004, Pfizer filed a notice of application by which it sought to prohibit the Minister from issuing a NOC in respect of the Besylate tablets until after the expiry of the '393 patent, pursuant to subsection 6(1) of the NOC Regulations.

[5] On October 21, 2004, the Minister informed Ratiopharm that its ANDS met the safety and efficacy requirements with the result that, from the point on the Minister was in a position to issue a NOC to Ratiopharm for its Besylate tablets once the requirements of the NOC Regulations had been met – that is, once the ‘865 patent had expired and Ratiopharm had addressed Pfizer’s ‘393 patent.

[6] On January 20, 2006, at the request of Pfizer, the Minister listed a third patent, the ‘493 patent, on the patent register in respect of NORVASC Besylate tablets based on two NOCs, one issued May 2, 2005 and the other issued June 14, 2005.

[7] On February 10, 2006, Ratiopharm served on Pfizer a NOA in respect of the ‘493 patent alleging that the patent was not eligible for inclusion on the patent register in respect of NORVASC. On the same date, Ratiopharm also requested that the Minister exercise his discretion under subsection 3(1) of the NOC Regulations to delete the ‘493 patent from the patent register on the grounds that it did not meet the requirements for listing.

[8] On February 17, 2006, von Finckenstein J. of the Federal Court dismissed Pfizer’s application on the ground that Pfizer had failed to disprove Ratiopharm’s allegation that the ’393 patent was invalid. On February 23, 2006, Pfizer brought an appeal against this decision before the Federal Court of Appeal.

[9] On March 31, 2006, Pfizer commenced an application for a prohibition under subsection 6(1) of the NOC Regulations with respect to the ‘493 patent (‘493 prohibition application) and

consequently, obtained the automatic statutory 24 month stay preventing the Minister from issuing an NOC pursuant to subsection 7(1) of the NOC Regulations.

[10] On April 5, 2006 Ratiopharm brought an application for an order dismissing the ‘493 application pursuant to paragraph 6(5)(*a*) of the NOC Regulations on the ground that the ‘493 patent was not eligible for inclusion on the patent register. Ratiopharm was subsequently advised that the Minister would only resume consideration of Ratiopharm’s request to delete the ‘493 patent from the patent register if Ratiopharm withdrew the ‘493 dismissal application, which Ratiopharm did.

[11] On May 9, 2006, the ‘865 patent expired, however, a NOC did not issue because of the automatic stay which resulted from the filing of the ‘493 prohibition application (see para. 8, above).

[12] On June 2, 2006, the Minister confirmed that the ‘493 patent was appropriately listed on the register.

[13] On June 9, 2006, this Court allowed Pfizer’s appeal from von Finckenstein J.’s decision. The judgment upholds the validity of the ‘393 patent and prohibits the Minister from issuing a NOC to Ratiopharm in respect of its Besylate tablets until the expiry of the ‘393 patent (due to expire on August 17, 2010). A motion to have this decision reconsidered was later dismissed, and leave to appeal the decision to the Supreme Court was also dismissed.

[14] On June 23, 2006, Ratiopharm brought a second motion for an order dismissing the ‘493 application pursuant to paragraph 6(5)(*a*) of the NOC Regulations on the basis that it was not eligible for inclusion on the patent register. On April 26, 2007, Barnes J. of the Federal Court held that the ‘493 patent was not eligible for listing on the patent register in respect of NORVASC and thereby dismissed the ’493 prohibition application.

[15] Ratiopharm has since commenced an action in the Federal Court, seeking a declaration that the ‘393 patent is invalid.

POSITIONS OF THE PARTIES

[16] Ratiopharm submits that the order that this Court issued on appeal from the decision of von Finckenstein J., prohibiting the Minister from issuing a NOC, upon the validity of the ‘393 patent being upheld, should be set aside on the basis that had the ‘493 patent not been improperly listed on the patent registry, the NOC would have issued on the date that the ‘865 patent expired given that the Federal Court had determined that the ‘393 patent was invalid and the Federal Court of Appeal had not yet heard the appeal. If the NOC had issued as contended, the Federal Court of Appeal, based on the consistent jurisprudence of this Court, would not have considered the appeal regarding the ‘393 patent, given that the issue would have been moot.

[17] In support of the Court’s jurisdiction to set aside this order, Ratiopharm relies on Rule 399(2)(*a*) of the Rules as well as the inherent jurisdiction of the court to set aside a court order and

the change in law (following the Federal Court of Appeal decision regarding the ‘393 patent) as a result of Hughes J.’s decision in *Ferring Inc. v. Canada*, (2007) 55 C.P.R. (4th) 271 (FC) aff’d 2007 FCA 276, whereby it was held that patents listed on the registry after the submission of an ANDS do not need to be addressed by the company filing the ANDS unless it made use of changes to the comparator drug approved by the Minister through such a NOC for the purpose of bioequivalence. Consequently, Ratiopharm should not have had to consider the ‘493 patent as it was listed on the register after Ratiopharm’s ANDS application was filed.

[18] Pfizer submits that Ratiopharm’s argument is purely hypothetical as there is no evidence that the appeal regarding the ‘393 patent would have been moot but for the improperly listed ‘493 patent. Further, Pfizer argues that the fact that the ‘493 patent was subsequently found to be improperly listed does not qualify as “new matter” according to Rule 399(2)(*a*) of the Rules and that the finality of decisions militates against setting aside the judgement particularly in light of the fact that the motion does not put into question the correctness of the Court’s decision.

ANALYSIS & DECISION

[19] This application cannot succeed. The judgment which the applicant seeks to set aside was based on the following conclusion (Reasons, para. 37):

> I would allow the appeal with costs and set aside the order of the Applications Judge dated Fevruary 17, 2006. Proceeding to render judgment that he should have rendered, I would allow the appellants’ application with costs and issue an order prohibiting the Minister from providing an NOC to Ratiopharm in respect of its proposed amlodipine besylate products, until the expiry of the ‘393 Patent.
>
> [My emphasis]

[20] This conclusion is consistent with paragraph 52 (*c*)(i) of the *Federal Courts Act* which empowers the Court on an appeal from a decision of the Federal Court to "give the decision which should have been given" (in French "rendre la décision qui aurait dû être rendue"). It follows that had von Finkelstein J. given the decision which he should have given, the validity of the '393 patent would have been upheld and, contrary to the scenario painted by Ratiopharm, the NOC with respect to its Besylate tablets would not have issued. This Court's judgment in effect precludes the scenario on which the application is based.

[21] Beyond this, the course of events proposed by Ratiopharm is too speculative to give rise to a new "matter" within the meaning of Rule 399(2)(*a*) or to justify the invocation of this Court's inherent jurisdiction in order to set aside this Court's prior decision. Ratiopharm assumes, amongst other things, that if the '493 patent had not been improperly listed, the Minister would have issued a NOC with respect to its Besylate tablets prior to the time when Pfizer's appeal before this Court was to be heard and in any event, before the Court rendered its decision with the result that the Court would have exercised its discretion against disposing of the appeal and a prohibition would not have been issued.

[22] There are an infinite number of intervening events which could have altered the scenario painted by Ratiopharm. It is simply impossible to assume that the events would have unfolded as Ratiopharm suggests or to give this scenario the certainty that would be required in order to justify the setting aside of the earlier decision of this Court.

[23] On the issue of costs, Pfizer submits that this application should never have been brought and requests solicitor-client costs or costs established at the high end of Column V of Tariff B of the *Federal Court Rules*. Although I recognize that the application brought by Ratiopharm is novel, I see no reason for making a special award of costs.

[24] I would therefore dismiss the application with costs, assessed in the usual manner.

"Gilles Létourneau"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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MOTION DEALT WITH IN WRITING WITHOUT APPEARANCE OF PARTIES

REASONS FOR ORDER BY:	LÉTOURNEAU J.A.
DATED:	December 18, 2007

APPEARANCES:

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