Federal Court of Appeal  Cour d'appel fédérale

Date: 20160119

Docket: A-312-15

Citation: 2016 FCA 13

CORAM: **STRATAS J.A.**
DE MONTIGNY J.A.
GLEASON J.A.

BETWEEN:

BAYER INC. and BAYER INTELLECTUAL PROPERTY GmbH

Appellants

and

FRESENIUS KABI CANADA LTD. and THE MINISTER OF HEALTH

Respondents

Heard at Ottawa, Ontario, on January 19, 2016.
Judgment delivered from the Bench at Ottawa, Ontario, on January 19, 2016.

REASONS FOR JUDGMENT OF THE COURT BY: STRATAS J.A.

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REASONS FOR JUDGMENT OF THE COURT
(Delivered from the Bench at Ottawa, Ontario, on January 19, 2016).

STRATAS J.A.

[1] Bayer Inc. and Bayer Intellectual Property GmbH appeal from the order dated June 26, 2015 of the Federal Court (*per* Justice Strickland): 2015 FC 797.

[2] In the Federal Court, Bayer applied for an order under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 prohibiting the Minister of Health from issuing a notice of compliance to Fresenius Kabi Canada Ltd. (formerly Pharmaceutical Partners of Canada Inc.) for its proposed moxifloxacin hydrochloride product for injection until three of Bayer's patents, including Canadian Patent No. 2,378,424, expired. Among other things, Bayer contended that Fresenius was infringing or was inducing the infringement of its '424 Patent.

[3] Prothonotary Lafrenière struck all portions of the application as it concerned the '424 Patent: 2015 FC 388. On the facts, he found that it was plain and obvious that Fresenius was neither infringing nor inducing the infringement of Bayer's '424 Patent. Bayer appealed under Rule 51 to the Federal Court, submitting that Fresenius' product monograph for its proposed moxifloxacin hydrochloride product induced the infringement of its '424 Patent. The Federal Court, following (at paragraph 41) the standard of review set out in *Canada v. Aqua-Gem Investments Ltd.*, [1993] 2 F.C.R. 425, 149 N.R. 273, engaged in *de novo* review. In that *de novo* review, the Federal Court reached the same result as the Prothonotary for substantially the same reasons.

[4] Bayer now appeals to this Court.

[5] This Court is sitting on appeal from the order of the Federal Court made under its appellate jurisdiction from Prothonotaries under Rule 51. The parties both submit that the standard of review is palpable and overriding error. They cite the Supreme Court's decision in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235.

[6] *Housen* would be the controlling authority but for the fact that this is an appeal from a Rule 51 appeal. In appeals from a Rule 51 appeal, the standard of review is different. We may interfere with the Federal Court's decision where the Federal Court had no grounds to interfere with the Prothonotary's decision or, in the event such grounds existed, if the decision of the Federal Court was arrived at on a wrong basis or was plainly wrong: *Z.I. Pompey Industrie v. ECU-Line N.V.*, 2003 SCC 27, [2003] 1 S.C.R. 450 at paragraph 18, citing this Court's decision in *Jian Sheng Co. v. Great Tempo S.A.*, [1998] 3 F.C. 418 (C.A.), *per* Décary J.A., at pp. 427-28. In this case, when the Federal Court sat in appeal under Rule 51 from the Prothonotary, it employed the standard of review in *Aqua-Gem*, not the normal appellate standard of review in *Housen*.

[7] I have previously suggested that these different standards of review have outlived their usefulness and that the general standard of review for civil appeals set out in *Housen*, above, should apply: *Apotex Inc. v. Bristol-Myers Squibb Company*, 2011 FCA 34, 91 C.P.R. (4th) 307 at paragraphs 6-9. In addition to the reasons I offered in that case, I note that *Housen* postdates *Aqua-Gem* and, on its terms, was intended to state the standard of review for all civil appeals: see *Imperial Manufacturing Group Inc. v. Decor Grates Incorporated*, 2015 FCA 100 at paragraph 22. As for the Supreme Court's later articulation of the standard of review in *Pompey*, above, the more recent Supreme Court case of *Hryniak v. Mauldin*, 2014 SCC 7, [2014] 1 S.C.R. 87 may have overtaken it. There, the Supreme Court encouraged courts to take steps to make procedures simpler and more accessible. We have applied this philosophy elsewhere in our standard of review jurisprudence with a view to simplifying and unifying as much as possible the standard of review for civil appeals: *Turmel v. Canada*, 2016 SCC 9; *Imperial Manufacturing*, above.

[8] We have not received full argument on this point. Accordingly, for the purposes of this case we shall apply the standard set out in *Jian Sheng*, above. As will be evident from the reasons that follow, we would reach the same result if we were to consider this appeal on the basis of the standard of review in *Housen*.

[9] In our view, Bayer's appeal must fail. Bayer has not persuaded us that the Federal Court had grounds to interfere with the Prothonotary's decision. Bayer has not demonstrated that the decision of the Federal Court was arrived at on a wrong basis or was plainly wrong.

[10] At paragraphs 43-51 of its reasons, the Federal Court set out the applicable principles of law on inducement. As it noted (at paragraph 43), the parties did not dispute these principles. In this Court, the parties do not dispute them. Thus, the decision of the Federal Court was not arrived at on a wrong basis.

[11] At paragraphs 53 of its reasons and following, the Federal Court applied these principles to the facts before it. In our view, in doing so, it was not plainly wrong. It found as a factual matter that the product monograph in question does not instruct or direct that Fresenius' product is to be co-administered or co-administered with 0.9% sodium chloride (at paragraphs 59-61). It also found that a general reference to sodium chloride in the product monograph was obligatory and fell short of inducement (at paragraphs 64-65). That was a factually-suffused finding in circumstances where the Federal Court had instructed itself properly on the principles relating to inducement.

[12] Finally, the Federal Court found that the product monograph in this case spoke for itself, the expert evidence tendered by Bayer commenting on the product monograph was irrelevant, unhelpful, and speculative (at paragraphs 58-64), and so (at paragraph 70) it distinguished cases such as *AB Hassle v. Genpharm*, 2004 FCA 413, aff'g 2003 FC 1443 and *Abbott Laboratories Limited v. Canada (Ministry of National Health and Welfare)*, 2007 FCA 251, aff'g 2006 FC 1411. In our view, the Federal Court did not err in principle in making these findings and was not clearly wrong in making them on the facts of this case.

[13] Bayer submitted that the Federal Court applied too low a test for striking out the application under paragraph 6(5)(*b*) of the Regulations insofar as it concerned the '424 Patent. In our view, the Federal Court was entitled to assess whether the evidence offered in support of the application was relevant or could conceivably support the application: see, *e.g.*, *Pfizer Canada Inc. v. Novopharm Limited*, 2008 FCA 263 at paragraph 3. The Federal Court found that it was neither relevant nor could it conceivably support the application and, accordingly, dismissed the application insofar as it concerned the '424 Patent. Again, we see no error in principle on the part of the Federal Court in making these findings and it was not clearly wrong in making them on the facts of this case.

[14] Therefore, despite the able submissions of Mr. Davis, we shall dismiss the appeal with costs. Counsel agreed that costs shall be fixed in the amount of $2,500, all inclusive.

"David Stratas"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-312-15
APPEAL FROM AN ORDER OF THE HONOURABLE MADAM JUSTICE STRICKLAND DATED JUNE 26, 2016	
STYLE OF CAUSE:	BAYER INC. AND BAYER INTELLECTUAL PROPERTY GMBH v. FRESENIUS KABI CANADA LTD. AND THE MINISTER OF HEALTH
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	JANUARY 19, 2016
REASONS FOR JUDGMENT OF THE COURT BY:	STRATAS J.A. DE MONTIGNY J.A. GLEASON J.A.
DELIVERED FROM THE BENCH BY:	STRATAS J.A.

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