Federal Court of Appeal  Cour d'appel fédérale

Date: 20150109

Docket: A-92-14

Citation: 2015 FCA 3

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

BETWEEN:

BRISTOL-MYERS SQUIBB &
GILEAD SCIENCES, LLC AND
MERCK SHARP & DOHME CORP.

Appellants

and

TEVA CANADA LIMITED AND THE
MINISTER OF HEALTH

Respondents

Heard at Toronto, Ontario, on November 25, 2014.

Judgment delivered at Ottawa, Ontario, on January 9, 2015.

REASONS FOR JUDGMENT BY: NEAR J.A.

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

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REASONS FOR JUDGMENT

NEAR J.A.

I. Introduction

[1] Bristol-Myers Squibb & Gilead Sciences, LLC and Merck Sharp & Dohme Corp. (collectively, the appellants) appeal from the January 13, 2014 judgment of the Federal Court (2014 FC 30) dismissing their application made under s. 6 of the *Patented Medicines (Notice of*

Compliance) Regulations, SOR/93-133 (PMNOC Regulations). In the application, the appellants sought an order prohibiting the Minister of Health from issuing a Notice of Compliance to Teva Canada Limited for a generic version of the appellants' combination anti-retroviral medicine marketed under the brand name Atripla.

[2] The appellants' application was made in response to a Notice of Allegation (NOA) dated December 22, 2011, in which Teva asserted that its proposed product would not infringe Canadian Letters Patent 2,279,198, which is owned by Merck and licensed to the other appellants. Teva also alleged that the Patent is invalid.

II. Federal Court Decision

[3] The Federal Court found that the appellants had failed to prove on the balance of probabilities that the Teva tablets will infringe the Patent. Based on its assessment of the expert evidence, the Federal Court was not satisfied that the Teva tablets contain Form I efavirenz, the compound claimed in the Patent.

[4] In particular, the Federal Court found that the appellants had failed to prove that the tests which they had conducted were a reliable proxy for the process Teva used to manufacture its tablets. Among other things, the Federal Court had concerns about: the lack of correspondence between the grinding force applied in the appellants' tests and the force exerted by Teva's process; the lack of particulars on the grinding force applied in the tests; the failure of the appellants' expert to observe the tests; the addition of unnecessary heating steps into the tests;

and the failure to include excipients into the testing material. In finding these facts, the Federal Court generally preferred the evidence of Teva's expert over that of the appellants.

III. Issues

[5] Before this Court, the appellants raise two issues. First, they submit that the Federal Court failed to apply the proper evidentiary standard. Second, they submit that the Federal Court failed to draw an adverse inference against Teva for refusing to produce its tablets to the appellants for testing.

IV. Standard of Review

[6] Contrary to the appellants' submission, this appeal does not raise extricable questions of law but, rather, questions of mixed fact and law suffused by fact, and questions of fact. Therefore, the appellants must demonstrate palpable and overriding error (*Teva Canada Limited v. Novartis Pharmaceuticals Canada Inc.*, 2013 FCA 244 at paras. 10-12, 451 N.R. 246, *Housen v. Nikolaisen*, 2002 SCC 33, at paras. 10, 36, [2002] 2 S.C.R. 235).

V. Analysis

[7] In my view, the Federal Court committed no palpable and overriding error in concluding that the appellants' testing methods were not a reliable proxy for Teva's manufacturing process, and that as such, the appellants had not proven that the Teva tablets infringe.

[8] As well, contrary to the appellants' submission, the Federal Court judge applied throughout the correct burden of proof, the balance of probabilities (at para. 20). The Judge's approach did not impose on the appellants a burden that was impossible to meet.

[9] At the hearing of this appeal, counsel for the appellants placed significant emphasis on one alleged error of the Federal Court in its application of the burden of proof. In particular, counsel stressed that in applications brought under s. 6 of the PMNOC Regulations, the second person (Teva) has an initial burden to put its allegations "into play" by presenting evidence sufficient to give them an air of reality. Counsel argued that it is only after this burden is met that the first person (the appellants) must prove, on the balance of probabilities, that the allegations are not justified (at paras. 31-32, appellants' Memorandum of Fact and Law).

[10] In support of this argument, the appellants cited *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 26 at paragraphs 9, 12, [2007] F.C.J. No. 36 (QL), aff'd 2007 FCA 195, 367 N.R. 98. However, in that case, the Federal Court's finding that the second person must present evidence putting their allegations "into play" relates solely to allegations of invalidity. It was necessary for the Federal Court to make such a finding given the presumption of validity established by s. 43(2) of the *Patent Act*, R.S.C. 1985, c. P-4 – without any evidence from the second person, the legal position is that the patent is valid. However, in the case at bar, the allegation is non-infringement, not invalidity. There is no presumption in play and, thus, no initial onus on the second person to put forward evidence.

[11] Accordingly, I agree with Teva's submission that once it alleged in its NOA that "[t]he Teva Product will not contain Form I nor is Form I used in the manufacture of the Teva Products" (Appeal Book, p. 53), there was no further evidentiary burden on it; its allegation of non-infringement was "in play."

[12] I also reject the appellants' submission that the Federal Court should have drawn an adverse inference against Teva for failing to produce its tablets.

[13] In declining to draw an adverse inference, the Federal Court relied upon a number of facts before it. Among other things, it found that the appellants were "better equipped than most" to make the compound for testing purposes and could have done so (footnote to para. 24). Also, Teva undertook not to assert that the material obtained and tested by the appellants was different in character or composition from Form Teva.

[14] The decision of the Federal Court judge not to draw an adverse inference is bolstered by the fact that production is not required under s. 6(7) of the PMNOC Regulations.

[15] In my view, the appellants have failed to demonstrate any palpable and overriding error on the part of the Federal Court judge on this point.

Conclusion

[16] Therefore, for the foregoing reasons, I would dismiss the appeal, with costs.

"David G. Near"
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

APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE BARNES DATED JANUARY 13, 2014, NO. T-278-12

DOCKET:	A-92-14
STYLE OF CAUSE:	BRISTOL-MYERS SQUIBB & GILEAD SCIENCES, LLC AND MERCK SHARP & DOHME CORP. v. TEVA CANADA LIMITED AND THE MINISTER OF HEALTH
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	NOVEMBER 25, 2014
REASONS FOR JUDGMENT BY:	NEAR J.A.
CONCURRED IN BY:	DAWSON J.A. STRATAS J.A.
DATED:	JANUARY 9 2015

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