Federal Court of Appeal  Cour d'appel fédérale

Date: 20150706

Docket: A-420-14

Citation: 2015 FCA 158

CORAM: **DAWSON J.A.**
RYER J.A.
WEBB J.A.

BETWEEN:

ASTRAZENECA CANADA INC.
ASTRAZENECA AKTIEBOLAG and
ASTRAZENECA UK LIMITED

Appellants

and

APOTEX INC. and
APOTEX PHARMACHEM INC.

Respondents

Heard at Toronto, Ontario, on June 17, 2015.
Judgment delivered in Ottawa, Ontario, on July 6, 2015.

REASONS FOR JUDGMENT BY: DAWSON J.A.

CONCURRED IN BY: RYER J.A.
WEBB J.A.

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REASONS FOR JUDGMENT

DAWSON J.A.

[1] For reasons cited as 2014 FC 638, a judge of the Federal Court declared Canadian patent 2,139,635 to be invalid because of inutility. The Federal Court found that, while the patent promised that its compounds provide improved pharmacokinetic and metabolic properties which will give an improved therapeutic profile, such as a lower degree of interindividual variation, this promise was neither demonstrated nor soundly predicted at the time the patent was filed. For

completeness, the Federal Court also dismissed Apotex' assertions that the patent was both obvious and anticipated.

[2] On this appeal from the judgment of the Federal Court, AstraZeneca asserts that the Federal Court erred in law by misconstruing the promise of the relevant claims. More specifically, it argues that the Federal Court erred by failing to consider utility, and any promise of utility, on a claim by claim basis, erred by construing the utility of the claims in issue in a manner that was inconsistent with their inventive concept and further erred by failing to apply a purposive construction to the promise of utility.

[3] I disagree that the Federal Court erred for the following reasons.

[4] I begin by observing that, as AstraZeneca argues, it is well settled law that inutility must be assessed on a claim by claim basis (*Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 (Sildenafil), at paragraphs 42 and 80; and, *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 (AZT), at paragraphs 53 to 59).

[5] It is also now settled law that some promises can be construed to impose utility requirements across each of a patent's claims, while other promises may touch only a subset of the claims. In every case it is a question of proper construction of the relevant claims (*Pfizer Canada Inc. v. Apotex Inc.*; *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, 2014 FCA 250, 465 N.R. 306 (Celecoxib), at paragraphs 86 to 89).

[6] I further agree that, when construing any promise made in the patent, the Federal Court did not explicitly consider any single claim or subset of claims. However, in light of the evidence and submissions before the Court, this failure was neither an error of law nor a palpable and overriding error of fact or mixed fact and law. I reach this conclusion on the following basis.

[7] It is important to understand that at trial AstraZeneca did not ask the Federal Court to construe the promise of the patent on a claim by claim basis. The patent contains 29 claims, of which only claims 1, 2, 4, 5, 7, 8, and 25 to 27 were in issue. Claims 1 to 8 are compound claims; claims 25 to 27 are use claims. AstraZeneca's expert on the issue of utility, Dr. Tracy, asserted that the claimed compounds promised that optically pure salts of (-)-omeprazole were useful as proton pump inhibitors, would resist racemization and had improved pharmacokinetic and metabolic properties over the racemate.

[8] The Federal Court received expert evidence from Apotex' expert, Dr. Meyer, as to why a skilled reader would understand the patent to promise not just what was asserted by AstraZeneca, but to additionally promise that the claimed compounds promised an improved therapeutic profile and lower degree of interindividual variation over the racemate. In this circumstance, the analysis of the Federal Court cannot be faulted. The Federal Court was entitled to rely upon the *lis* as framed by the parties. The Court explained why it found Dr. Meyer's evidence to be preferable to that of Dr. Tracy. AstraZeneca has not shown any error that warrants our intervention.

[9] Before leaving this issue I wish to address AstraZeneca's submission that in paragraph 125 of its reasons the Federal Court demonstrated that it rejected the notion that utility should be construed on a claim by claim basis. I disagree. On a fair reading, paragraph 125 was directed to the weight to be given to Dr. Tracy's evidence; the Federal Court was not rejecting a claim by claim construction.

[10] I now turn to AstraZeneca's argument that the Federal Court erred by construing the utility of the claims in issue in a manner inconsistent with their inventive concept. AstraZeneca argues that because it is a fundamental rule of claim construction that a claim receives one interpretation for all purposes, there must be a unitary, harmonious understanding of the essential elements of the claim, inventive concept and utility. At trial, AstraZeneca argued that the inventive concept of the compound claims (and inherent in the inventive concept of the use claims) was an optically pure salt of (-)-omeprazole, together with improved pharmacokinetic and metabolic properties over omeprazole and high stability to racemization. As this inventive concept did not include an improved therapeutic profile, the Federal Court is said to have erred by construing the claims to promise an improved therapeutic profile.

[11] Again, I disagree that the Federal Court erred. The Court's reasons show that the Federal Court directed itself to the correct legal tests applicable to claims construction, inventive concept and utility. In oral argument, AstraZeneca was unable to show that its submission was supported by the jurisprudence. While it pointed to an admittedly *obiter* passage in *Canada (Attorney General) v. Amazon.com, Inc.*, 2011 FCA 328 , [2012] 2 F.C. 49, at paragraphs 37 to 41, the *obiter* comments found there do not support AstraZeneca's submission that a promise of utility

must be construed to be virtually coterminous with the inventive concept of the relevant claim or claims.

[12] AstraZeneca also argues that the Federal Court gave the disclosure elevated emphasis when construing the promise. As noted by Apotex, at trial AstraZeneca conceded that resort to the disclosure was warranted in order to construe its truncated promise of utility that the compound claims promised improved pharmacokinetic and metabolic properties. In my view, the Federal Court did not err by construing the promise within the context of the patent as a whole (*Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197, 405 N.R. 1 (Olanzapine), at paragraph 93). Similarly, on the evidence it accepted, the Federal Court did not err by giving effect to all, not just a portion, of the sentence in the disclosure relied upon by AstraZeneca to establish the promise of pharmacokinetic and metabolic properties.

[13] I now turn to AstraZeneca's argument that the Federal Court failed to apply a purposive construction to the promise of utility and instead applied a non-contextual construction of the promise by embracing an overly narrow definition of the word "will". The Federal Court acknowledged the difference between goals and promises, and at paragraphs 118 to 120 of its reasons explained why it rejected the submission that the use of the word "will" was indicative of a goal or expectation. The Federal Court's construction of the promise was reached reading the patent as a whole through the eyes of the skilled reader. In light of the statement in the disclosure, relied upon by the Federal Court, that described as "desirable" compounds "with improved pharmacokinetic and metabolic properties which will give an improved therapeutic

profile" and the further statement that "[t]he present invention provides such compounds", the Federal Court did not err in law by applying too low a threshold in order to establish a promise.

[14] To conclude, AstraZeneca has not demonstrated any legal error in the Federal Court's construction of the promise of the relevant claims of the patent. Nor has it demonstrated any palpable and overriding error in the Federal Court's appreciation of the evidence.

[15] For these reasons, I would dismiss the appeal with costs. It follows that it is unnecessary to consider the assertions advanced by Apotex that the Federal Court erred in failing to find the patent to be both obvious and anticipated.

"Eleanor R. Dawson"

J.A.

"I agree.
C. Michael Ryer J.A."

"I agree.
Wyman W. Webb J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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