

Federal Court of Appeal



Cour d'appel fédérale

Date: 20150916

Docket: A-286-14

Citation: 2015 FCA 192

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

BETWEEN:

ACTAVIS PHARMA COMPANY

Appellant

and

**ALCON CANADA INC., ALCON
PHARMACEUTICALS, LTD. and BAYER
INTELLECTUAL PROPERTY GmbH**

Respondents

Heard at Toronto, Ontario, on May 27, 2015.

Judgment delivered at Ottawa, Ontario, on September 16, 2015.

REASONS FOR JUDGMENT BY:

BOIVIN J.A.

CONCURRED IN BY:

**DAWSON J.A.
WEBB J.A.**

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REASONS FOR JUDGMENT

BOIVIN J.A.

I. Background

[1] This appeal concerns a decision of a Federal Court judge (the Judge) rendered on May 14, 2014 (2014 FC 462). The Judge granted the application of Alcon Canada Inc., Alcon Pharmaceuticals, Ltd., and Bayer Intellectual Property GmbH (the respondents) under subsection

6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 for an order prohibiting the Minister of Health from issuing a Notice of Compliance (NOC) to Actavis Pharma Company – formally known as Cobalt Pharmaceuticals Company – (the appellant) for its generic version of the product Vigamox®, covered by the Canadian Patent 1,340,114 (the ‘114 Patent).

[2] As per the Notice of Appeal filed on June 13, 2014, the Minister of Health is no longer a party in this matter. Actavis Pharma Company asks our Court to set aside the Judge’s prohibition Order.

[3] The Judge’s decision of May 14, 2014 also addresses Canadian Patent 2,342,211 (the ‘211 Patent), and 2,192,418 (the ‘418 Patent). While the ‘418 Patent was not appealed before this Court, the appeal of the ‘211 Patent is dealt with under a separate set of reasons (2015 FCA 191).

[4] Vigamox® is an antibacterial eye drop commonly used during cataract surgery. It is covered by the ‘114 Patent which was filed on July 13, 1989, issued on November 3, 1998, and will expire on November 3, 2015. The ‘114 Patent claims a class of quinolone compounds, including moxifloxacin hydrochloride (moxifloxacin), the active ingredient in Vigamox®. The compounds of this class are characterized by a fused pyrrolidine bicycle structure at the C-7 position on the core ring of the quinolone compound. At issue in this proceeding are Claims 8 and 13, which claim moxifloxacin and its stereoisomers and mixtures thereof (Judge’s reasons at paragraph 21).

[5] Before the Judge, the appellant argued that the '114 Patent is invalid, essentially on the basis of lack of sound prediction and utility. All of the appellant's contentions regarding the alleged invalidity of the '114 Patent were rejected by the Judge. Specifically, the Judge construed the promise of the '114 Patent and found that utility was soundly predicted. As for the appellant's allegation of obviousness which was largely abandoned in oral argument, the Judge nonetheless held, based on the parties' written representations, that the invention claimed by the portions of the '114 Patent at issue, was neither obvious nor obvious to try.

[6] On appeal, the appellant challenges each of the Judge's holdings regarding the '114 Patent. For the reasons outlined below, I propose to dismiss the appeal. I am unconvinced that the Judge made any reversible error in rejecting the appellant's allegations of invalidity of the '114 Patent.

II. Issues

[7] In this appeal, the issues are as follows:

1. Did the Judge err in construing the promise of the '114 Patent?
2. Did the Judge err in finding that the '114 Patent's utility was soundly predicted?
3. Did the Judge err in determining that the '114 Patent was neither obvious nor obvious to try?

III. Standard of review

[8] Appeals from prohibition applications such as the one at issue are subject to the appellate standards set forth in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235 [*Housen*],

Pharmascience Inc. v. Canada (Health), 2014 FCA 133, 460 N.R. 343 [*Pharmascience*] at paragraph 31. The construction of the patent itself is a matter of law that must be reviewed under the correctness standard (*Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 at paragraph 76 [*Whirlpool*]; *Mylan Pharmaceuticals ULC v. AstraZeneca Canada Inc.*, 2012 FCA 109, 432 N.R. 292 at paragraph 20 [*Mylan*]).

[9] Matters of mixed fact and law require the governing legal principles to be correctly articulated and applied (*Housen* at paragraphs 26 and 27). As a judge's function necessarily involves weighing the evidence put forward by the parties and particularly in the face of conflicting expert opinions, the facts and evidentiary foundation on the basis of which the judge reaches his decision will stand absent a palpable and overriding error (*Cobalt Pharmaceuticals Company v. Bayer Inc.*, 2015 FCA 116, [2015] F.C.J. No. 555 (QL) at paragraph 15 [*Cobalt*]; *Pharmascience* at paragraph 31; *Mylan* at paragraph 20). Demonstrating a palpable and overriding error in connection with this evidentiary exercise is subject to a high threshold (*Zero Spill Systems (Int'l) Inc. v. Heide*, 2015 FCA 115, [2015] F.C.J. No. 554 (QL) at paragraph 49).

[10] Sound prediction and obviousness are matters of mixed fact and law (*Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at paragraph 42 [*AZT*]; *Cobalt* at paragraph 48; *Apotex Inc. v. Allergan Inc.*, 2015 FCA 137, [2015] F.C.J. No. 953 (QL) at paragraph 7). It follows that absent a palpable and overriding error, a judge's finding in this regard will not be disturbed.

IV. Analysis

The Promise of the '114 Patent

[11] In challenging the Judge's decision regarding the '114 Patent, the appellant frames its main argument around the question of the promise of the '114 Patent and argues that the Judge erred in making multiple, inconsistent, and ultimately incorrect holdings, which amounted to errors of law on the construction of the promise of the '114 Patent.

[12] Specifically, the appellant alleges that the Judge erred in law by choosing Dr. Domagala's evidence on the basis of his patent experience and conferring upon him the status of legal expert on patents. In support of this allegation, the appellant points to instances where the Judge prefers Dr. Domagala's evidence over the evidence of the appellant's expert witness, Dr. Hoban, on the basis of the latter's relative inexperience (Judge's reasons at paragraphs 61 and 66).

[13] This allegation is without merit. Indeed, a judge is entitled to prefer one expert's evidence over another on a number of grounds. Here, a full reading of the Judge's reasons demonstrates that his stated preference for Dr. Domagala's evidence was also based on Dr. Domagala's experience with quinolones (Judge's reasons at paragraphs 48 and 66). Moreover, the Judge explained that he preferred the respondents' expert evidence regarding the '114 Patent as being "both individually and read as whole, [...] more consistent internally and externally" (Judge's reasons at paragraph 31). In the circumstance, the Judge's preference for one expert over another accordingly does not amount to a reviewable error.

[14] The appellant also alleges that paragraph 71 of the Judge's reasons demonstrates that he not only erred in construing the promise of the patent but that he also misunderstood the law by stating as follows:

[71] Much of Cobalt's submissions on the issue of utility are premised on an erroneous construction of the promise. As discussed above, I reject Cobalt's construction of the promise. To the extent the patent promises anything, it is limited to a promise that the class as a whole will have *in vitro* activity against a broad spectrum of bacteria. Accordingly, based on *Plavix* [*Apotex v. Sanofi-Aventis*, 2013 FCA 186, 230 ACWS (3d) 851] the question becomes whether there is a scintilla of utility. [Emphasis added].

[15] Again, the appellant's allegation fails. A fair reading of the Judge's reasons as a whole demonstrates that his above-reproduced statement regarding the requirement of a mere scintilla of utility, is not reflective of what he found as the promised utility or what he looked for in terms of being soundly predicted.

[16] Before the Judge, both parties argued that the claims at issue had promised a certain utility, but disputed the content of that promise. The Judge ultimately accepted the respondents' expert evidence regarding the promised utility of Claims 8 and 13 as tendered by Dr. Domagala to the effect that the skilled person would interpret the '114 Patent to promise only that "the new quinolone compounds have potent antibacterial activity *in vitro* against a broad spectrum of bacterial organisms, and in particular against Gram-positive bacteria" (Judge's reasons at paragraph 66). The Judge then construed the promise through the lens of this expert evidence, which he was entitled to prefer, and specifically rejected the appellant's analysis of the promised utility (Judge's reasons at paragraphs 69 and 71). This illustrates that the Judge properly applied the law regarding utility.

[17] Along the same lines, the appellant points to various statements made by the Judge regarding the promise of the '114 Patent in an attempt to argue that he erred by making multiple conflicting constructions of the utility of the claims at issue. Specifically, the appellant directed the Court's attention to varying phrasing adopted by the Judge in this regard (Judge's reasons at paragraphs 66, 71 and 87). Read as a whole, these slight differences in wording can be understood in a coherent manner and are therefore inconsequential.

Utility and Sound Prediction

[18] The Judge found that Claims 8 and 13 of the '114 Patent contained a limited promise of utility. This finding then underpinned the Judge's analysis of whether that utility had been soundly predicted. Given that it was conceded that utility had not been demonstrated, the Judge correctly turned to the soundness of the prediction to pursue his analysis (Judge's reasons at paragraphs 73 and 74).

[19] There is no allegation that the Judge misstated the law. Indeed, he based his analysis on the *AZT* requirements that there be a factual basis for a sound line of reasoning as to the utility of the invention, supported by proper disclosure (Judge's reasons at paragraph 74). The Judge summarized the result of his analysis as follows:

[102] Given the three components governing the principle of sound prediction, I conclude that the requirements of factual basis, line of reasoning and level of disclosure seen through the eyes of a Skilled Person have been met.

[103] The factual basis consisted of:

- MIC data for nine representative samples and ciprofloxacin data as a comparator;

- the method of using MIC data was well accepted method for determining antibacterial activity;
- Example 15 was the most potent compound (better than ciprofloxacin against certain Gram-positive bacteria). The fact that it was ultimately proven toxic does not undermine its usefulness in the line of reasoning;
- the use of comparative data gives reliability and predictability of activity without requiring that utility be measured as being superior to ciprofloxacin;
- based on Example 15 (the closest example to Claims 8 and 13), there was a valid basis to predict that the compounds in Claims 8 and 13, including moxifloxacin, would have high antibacterial activity against a broad spectrum of bacteria;
- the excellent activity exhibited by Example 15 would lead a Skilled Person to predict that this activity would be retained when the methoxy group was substituted in the 8 position and that single enantiomer including moxifloxacin and its hydrochloride salt would have high antibacterial activity especially against Gram-positive bacteria; and
- the common general knowledge on the methoxy group at the 8 position provided a sound basis to predict substituting methoxy for the fluorine found in Example 15 at the 8 position would lead to this high antibacterial activity.

[104] As the expert opinion established, generally good activity in vitro more likely than not leads to good activity in vivo. There was extensive history of the antibacterial effectiveness of quinolones (so much so that Cobalt relies on it to say the patent was obvious). There was a basis for a reasonable inference of utility.

[105] The fact that there was good in vitro activity is sufficient. There was no claim to in vivo activity but that does not mean there is inutility. In vivo activity at a minimum points to topical use or use as a preservative.

[106] In summary, I conclude that;

- there was a factual basis for the prediction;
- as of the date of the patent application there was an articulate and sound line of reasoning from which the desired result could be inferred from the factual basis. The fact that further testing was required confirms that there is an air of uncertainty. If that were not the case, it would not be prediction but certainty and possibly obvious; and
- there was proper disclosure in the detailed description of the fused pyrrolidine bicycle, its synthesis and how to attach it to the quinolone molecule.

[20] Given the above, rather than questioning the Judge's legal analysis, the appellant attacked the evidentiary basis for sound prediction. The appellant points to its expert evidence, which included a table that claimed to show what testing data was not reported in the patent and submitted that all omitted data was where the compounds performed poorly (Hoban Affidavit, Appeal Book, Volume 2, Tab 6 at page 441; Appellant's compendium, Tab 15). Essentially, the appellant contends that the exclusion of this testing data from the patent meant that soundly predicting the utility of Example 15 – and hence moxifloxacin – was impossible, and that the Judge made a palpable and overriding error in holding otherwise.

[21] The reality, however, is that the "omitted data" issue was also argued before the Judge and dealt with by the Judge (Judge's reasons at paragraphs 88, 90, 92-99). More particularly, in distinguishing this case from *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625, the Judge concluded that there was no evidence that any testing data had been excluded for an improper purpose (Judge's reasons at paragraph 92). The Judge therefore

declined to draw an inference that any discrepancies in data were made in bad faith, and further held that the inclusion of this data would not have had any impact on how the skilled person would have read the '114 Patent (Judge's reasons at paragraph 100). These holdings are supported by evidence (Zanel cross-examination, Appeal Book, Volume 13, Tab 15 at page 3213, Qs 232-235; Zanel Validity Affidavit at paragraphs 150-152, Appeal Book Volume 11, Tab 14; Respondents' compendium, Tab 129). I also note that the Judge's analysis conforms to our Court's recent decision in *Bell Helicopter Textron Canada Ltée v. Eurocopter*, 2013 FCA 219, 449 N.R. 111 at paragraphs 149-155, with regard to the adequacy of disclosure.

[22] Hence, the Judge's conclusion that the utility of the '114 Patent had been soundly predicted was based on expert evidence that he was entitled to accept. Importantly, he found that the necessary factual basis for sound prediction of the utility of the compounds claimed in Claims 8 and 13 could be based on Example 15 identified in the '114 Patent, which, while not identical to the compounds of those claims, is "structurally very similar" (Judge's reasons at paragraph 78). This was supported by the Domagala Affidavit (Respondents' compendium, Tab 133 at paragraphs 45-47). The Judge further held that moxifloxacin fulfills its utility as promised in Claims 8 and 13 as long as its activity can be described as "high" (Judge's reasons at paragraph 87; Zanel Validity Affidavit at paragraphs 150-152, Respondents' compendium, Tab 129). As the respondent noted, and I agree, the definition of "high activity" was on the record (Zanel Validity Affidavit at paragraphs 145, 148-149, Respondents' compendium, Tab 129).

[23] In sum, I find that the appellant has essentially attempted to re-argue its case by pleading evidence that it would have liked the Judge to prefer, in the hopes of having our Court overturn

the factual determinations made by the Judge. This amounts to asking our Court to re-weigh evidence. This is not our role and the appellant's challenge in this regard must also fail.

Obvious or obvious to try

[24] Although the Judge observed that the appellant had “largely abandoned” the allegations of obviousness in oral argument (Judge's reasons at paragraph 108), the Judge nonetheless proceeded to address these allegations based on the parties' written submissions. The governing law in respect of obviousness is found in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 [*Sanofi*]. The Judge sets this out at paragraphs 110-113 of his reasons.

[25] As noted at the outset, obviousness is a conclusion of mixed fact and law. In cursory submissions before our Court, the appellant neither contests the Judge's statement of the law, nor disputes that the choice of a fused pyrrolidine bicycle at the C-7 position of the quinolone ring was inventive. Instead, the appellant now affirms that the Judge made inconsistent holdings on the inventive concept of the claims, and points to paragraphs 108 and 124 to advance that “high” antibacterial activity must have been part of that inventive concept.

[26] As with the evidentiary elements of the sound prediction analysis, this Court's intervention on obviousness would require a palpable and overriding error, which the appellant has again failed to demonstrate.

[27] Significantly, the appellant failed to lead evidence in this regard before the Judge. The Judge ultimately preferred the respondents' expert evidence overall (Judge's reasons at paragraph 31) and, on this particular point, the implication of this holding is that he accepted the evidence of Dr. Domagala that the inventive concept was neither obvious nor obvious to try in light of any of the prior art (Confidential Domagala Validity Affidavit, Volume 1, Appeal Book, Volume 7, Tab 11 at paragraphs 59 and 1497). It was open to the Judge to make this holding and I find no palpable and overriding error that would otherwise warrant the intervention of this Court.

V. Conclusion

[28] For the above reasons, I would dismiss the appeal with costs.

“Richard Boivin”

J.A.

“I agree
Eleanor R. Dawson J.A.”

“I agree
Wyman W. Webb J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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