Federal Court of Appeal | Cour d'appel fédérale

Date: 20150916

Docket: A-284-14

Citation: 2015 FCA 191

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

BETWEEN:

ALCON CANADA INC. and ALCON PHARMACEUTICALS, LTD.

Appellants

and

ACTAVIS PHARMA COMPANY and THE MINISTER OF HEALTH

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 rendered on May 14, 2014 by a Federal Court judge (the Judge) who found that Canadian Patent 2,342,211 (the '211 Patent) was invalid for reasons of obviousness (2014 FC 462). On the basis of this finding, the Judge dismissed the application of

Alcon Canada Inc., Alcon Pharmaceuticals, Ltd., and Bayer Intellectual Property GmbH (the appellants), who had applied 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 respondent) for its generic version of the appellants' drug product Vigamox®.

[2] As per the Notice of Appeal filed on June 13, 2014, Bayer Intellectual Property GmbH is no longer a party in this matter.

[3] The Judge's decision of May 14, 2014 also addresses Canadian Patents 1,340,114 (the '114 Patent) and 2,192,418 (the '418 Patent). While the '418 Patent was not appealed before this Court, the appeal of the '114 Patent is dealt with under a separate set of reasons (2015 FCA 192).

[4] Vigamox® is an antibacterial eye drop commonly used during cataract surgery. Its active ingredient is the antibacterial agent moxifloxacin hydrochloride (moxifloxacin) which belongs to the fluoroquinolone class of antibacterial agents. Moxifloxacin is claimed and disclosed as the most preferred compound in the '211 Patent which covers the use of moxifloxacin in a formulation for treatments of bacterial infections and medicaments to prevent such infections, including ophthalmic infections.

[5] The '211 Patent is entitled, "Antibiotic Compositions for Treatments of the Eye, Ear and Nose" and claims a priority date of September 30, 1998 from US Patent Applications 60/102,506

and 60/102,504. As the Canadian application was filed on September 19, 1999, the '211 Patent will expire September 29, 2019 (Notice of Allegation, Appeal Book, Volume 2, Tab 8-A at page 537).

[6] The only claims made by the '211 Patent which are at issue in this appeal are the independent claims 1, 35, and 61 and their dependents. The essential elements of these independent claims are as follows: the use of moxifloxacin or its pharmaceutically useful salts or hydrates at a concentration of 0.1 to 1.0 wt% for topically treating or preventing ophthalmic infection (Claim 1); the use with a pharmaceutically acceptable vehicle in a composition for the above purpose (Claim 35); and the pharmaceutical composition itself (Claim 61) (Judge's reasons at paragraphs 149-153).

[7] In the decision under appeal, the Judge determined that the '211 Patent was invalid for reasons of obviousness. More specifically, he concluded that the '211 Patent relates to the known compound moxifloxacin being used for a known use (treating and preventing ophthalmic infection) at a concentration known to be effective (0.1 to 1.0 wt%). It would therefore have been obvious or obvious to try to treat or prevent ophthalmic infections with moxifloxacin in a pharmaceutical composition at the specified concentration. In so concluding, the Judge found that there was no difference between the state of the art at the relevant time and the inventive concept of the '211 Patent (Judge's reasons at paragraph 139).

II. Issue

[8] In this appeal, there is only one issue before the Court: did the Judge err in concluding that the '211 Patent was obvious or obvious to try?

[9] For the reasons that follow, I conclude that the Judge did not err in reaching his conclusion. I would accordingly dismiss the appeal.

III. Standard of Review

[10] Following *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 186, [2015] 2 F.C.R. 644 at paragraph 33, the construction of the promise of the patent is a question of law and must therefore be reviewed under the standard of review of correctness (citing *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 at paragraph 76; also *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at paragraph 51; *Mylan Pharmaceuticals ULC v. AstraZeneca Canada Inc.*, 2012 FCA 109, 432 N.R. 292 at paragraph 20). A judge must therefore interpret the patent as it would be understood by a person skilled in the art to which it pertains, taking into account the evidence as to how persons skilled in the art would understand certain words and phrases used in the patent and determine what the patent discloses and claims (*Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504 at page 523).

[11] As per *Pharmascience Inc. v. Canada (Health)*, 2014 FCA 133, 460 N.R. 343 at paragraph 31, the standard of review for factual determinations of the Judge with respect to utility and obviousness in the patent context is palpable and overriding error. Provided a judge

does not misidentify or misapply the legal test, that deferential standard applies. Moreover, provided that a judge's reasons are alive to the issues, the judge is assumed to have considered all evidence before the court and does not make a palpable and overriding error by failing to refer to a particular piece of evidence (*Teva Canada Limited v. Novartis Pharmaceuticals Canada inc.*, 2013 FCA 244, 451 N.R. 246 at paragraphs 10-12, citing *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235 at paragraph 46).

[12] Significantly, a judge's function necessarily involves weighing the evidence and choosing which evidence to rely upon in the face of conflicting expert opinions (*Zero Spill Systems (Int'l) Inc. v. Heide*, 2015 FCA 115, [2015] F.C.J. No. 554 (QL) at paragraphs 47-49 [*Zero Spill*]). Demonstrating a palpable and overriding error is a high threshold: as our Court recently held in *Zero Spill* at paragraph 49, interfering in a judge's weighing of evidence in a patent case requires demonstrating a clear (palpable) and fundamental (overriding) error going to "the very core of the outcome of the case".

IV. Analysis

[13] From the outset, I note that in challenging the Judge's conclusion to the effect that the '211 Patent is invalid, the appellants do not question the Judge's construction of the inventive concept which was identified as "a pharmological (sic) composition for topically treating or preventing an ophthalmic infection, which comprises 0.1 to 1.0 wt% moxifloxacin" (Judge's reasons at paragraph 172). However, the appellants strongly disagree with the evidentiary basis relied upon by the Judge in assessing obviousness from the perspective of a skilled person in the art. Specifically, the appellants argue that the Judge failed to understand the requirements and

implications of what the inventive concept at issue means to a skilled person in the art. This, the appellants maintain, led the Judge to misapply the test for obviousness (*Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 [*Sanofi*]).

[14] In support of their contention, the appellants assert that the Judge erred in both preferring Dr. Lightman's evidence and relying on it. In particular, the appellants contend that the Judge erred in adopting Dr. Lightman's characterization of what can be understood as the "three knowns": the known compound (moxifloxacin); the known use (treating and preventing ophthalmic infections), and the known concentration (to be effective 0.1 to 1.0 wt%) (Judge's reasons at paragraph 139).

[15] According to the appellants, this reliance on Dr. Lightman's affidavit evidence coupled with the failure to consider certain admissions she made on cross-examination led the Judge to adopt an inappropriate "hindsight approach" in assessing obviousness. At this juncture, I find it useful to set out the Judge's reasoning in this regard, at paragraphs 178 and 180-182 of his reasons:

> [178] In reaching a conclusion on this issue, the Court was particularly influenced by the evidence of Dr. Lightman. It was clear, cogent, objective and consistent with the objective evidence of the State of the Art.
>
> …
>
> [180] Dr. Lightman's conclusion was that the 211 Patent was "in one sense" a mere collection of publicly available information on moxifloxacin. There was no difference between the state of the art as of September 30, 1998 and the inventive concept of the 211 Patent claims.
>
> [181] In light of the circumstances and state of the art, it was obvious to try to treat ophthalmic infections with moxifloxacin. The claims of the 211 Patent were directed to a known compound being used for a known use in a concentration known to be effective.

> [182] There was obviously contrary evidence by accepted experts. In placing greater weight on Dr. Lightman's evidence, the Court is not suggesting that these other experts were not honest in their work and opinions nor that they may have had long associations with their client which disqualified their independence. However, Dr. Lightman's evidence, where it conflicted with Alcon's experts, was more persuasive against the backdrop of the state of the art.

[16] The difficulty with the appellants' challenge with regard to the "three knowns" is that it imports concepts related to anticipation into the obviousness analysis. Indeed, the question is not whether the invention had been previously performed in the sense that the said features (compound, use and concentration - the "three knowns") were collectively known.

[17] Rather, one must consider, as the Judge logically did, each of the knowns separately in light of the state of the art with a view to determining whether or not moxifloxacin was obvious or obvious to try at the relevant date. In reaching his conclusion, the Judge carefully set out the prior art evidencing what a skilled person would have knowledge of, *i.e.* what would make moxifloxacin obvious to try given its activity against bacteria, the known concentration range for efficacy of ophthalmic formulations and the efficacy of similar quinolones compounds like ciprofloxican (Judge's reasons at paragraphs 164-166). In this regard, the Judge relied on the Dalhoff poster (1996), the Fass article (1997) and Woodcock article (1997) as support for identifying moxifloxacin as a candidate to replace the compounds of ciprofloxacin and oflaxacin, pointing to its efficacy and potential in a wide range of infections (References respectively: Meetings Highlights, Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Appeal Book, Volume 8, Tab 13 at page 2877; Appeal Book, Volume 8, Tab 10 at pages 2805-2811; Appeal Book, Volume 8, Tab 19 at pages 2980 and 2982). Moreover, the Judge noted that an ophthalmic formulation containing the quinolone compound ciprofloxacin

(Ciloxan®) was already being sold commercially for ophthalmic treatments and that another one containing the quinolone oflaxacin (Ocuflox®) was also used against bacteria in the eye (Judge's reasons at paragraph 166).

[18] The evidence also demonstrates that the '211 Patent disclosed and enabled the essential elements of moxifloxacin claimed in more than one patent addressing the treatment of eye infections (US Patent 4,990,517 (February 5, 1991), Appeal Book, Volume 8, Tab 2 at pages 2624-2682 (US Patent 517); US Patent 5,607,942 (March 4, 1997), Appeal Book, Volume 8, Tab 3 at pages 2683-2734 (US Patent 942)). In addition, the Judge found that other pieces of prior art, *inter alia*, a 1990 European patent, likewise pointed the way to moxifloxacin (Judge's reasons at paragraph 166, European patent WO 90/01933 (March 8, 1990), Appeal Book, Volume 8, Tab 1 at pages 2613-2623).

[19] Against this background, the Judge was entitled to accept Dr. Lightman's expert opinion without necessarily adopting every single aspect of it. Indeed, upon reading the Judge's reasons, it is clear that he did not merely accept Dr. Lightman's evidence unreservedly. Rather, the Judge considered the entire body of conflicting expert evidence put before him and concluded that Dr. Lightman's evidence was the most consistent with the prior art from the perspective of the skilled reader in the art.

[20] Thus, the contention that the Judge embarked on an "unescorted romp" through the evidence must fail. Relying on carefully considered expert testimony and having properly situated himself as the skilled person in the art, the Judge, equipped with the "goggles" of the

person skilled in the art, drew his own factual conclusions from the evidence on the prior art and the inventiveness steps. It follows that, regardless of any alleged deficiencies in Dr. Lightman's approach to obviousness, I am satisfied that the Judge drew his own conclusions on the evidence adduced as to whether the inventive step of trying moxifloxacin for the claimed application would have been obvious to the skilled person in the art.

[21] The appellants also allege that the Judge erred in assessing obviousness by misapprehending or ignoring evidence that a new compound for the treatment of eye infections could not have been developed unless certain features were known, namely the compound's toxicity, penetration, and activity of moxifloxacin against *P. aeruginosa*. The appellant contends that the existing prior art in this regard taught away from moxifloxacin:

- Moxifloxacin showed limited *in vitro* resistance to *P. aeruginosa*;
- Quinolones were considered to be toxic;
- Drug ocular penetration must be known and until moxifloxacin was formulated it remained unknown.

[22] In making this contention, the appellants are essentially asking the Court to accept that the skilled person in the art would have understood at the relevant time that a compound claimed "for topically treating or preventing an ophthalmic infection" to necessarily also be "safe and effective" in clinical practice. Yet, the inventive concept of the '211 Patent does not require such features. Rather, it covers the treatment of ophthalmic infections. I note that the Judge considered this contention and rejected it (Judge's reasons at paragraphs 163, 173 and 175) finding that:

i. the '211 Patent is focused on the treatment of a range of pathogens and does not emphasize *P. aeruginosa* (Judge's reasons at paragraphs 151, 162-163, and 175);

ii. on penetration, he found that three of the four factors required to determine ocular penetration were disclosed in the Petersen poster (Judge's reasons at paragraph 177, citing "Synthesis and In Vitro Activity of BAY 12-8039, a New 8-Methoxyquinolone," Appeal Book, Volume 1, Tab 6-B, p. 248);

iii. oflaxacin had worse activity than moxifloxacin but was developed into a commercial product (Judge's reasons at paragraphs 168 and 169);

iv. on concentration in the formulation, moxifloxacin was similar to other quinolones ophthalmic solution such as Ciloxan® and Ocuflox®; and

v. there was reason to believe that toxicity would not be a concern for moxifloxacin (Vohr poster (1996) "Meeting Highlights – Anti-infectives: 36th Interscience Conference on Antimicrobial Agents and Chemotherapy", Appeal Book, Volume 8, Tab 13, p. 2877; Staβ Schuhly abstract (1997) "8th European Congress of Microbiology and Infectious Diseases", Appeal Book, Volume 8, Tab 4, p. 2739).

[23] Finally, the appellants insist that the Judge erred in failing to evaluate the *Sanofi* factors in his obvious to try analysis. It is to be recalled that the Judge's reasons concerning the '211 Patent are part of a decision which also addressed two other patents that were at issue in the underlying application: the '114 Patent and the '418 Patent. In paragraph 112 of his reasons, regarding the '114 Patent, the Judge explicitly set out the *Sanofi* factors of the obvious to try test. And significantly, in the context of his analysis of the '211 Patent, the Judge made reference to the obvious to try test on a number of occasions (Judge's reasons at paragraphs 139, 144, 160-170, 174, 175, 181, and 183). I am thus satisfied that the Judge was alive to the obvious to try factors in his '211 Patent reasons which he had in turn carefully considered in his reasons with respect to the '114 Patent.

[24] I am therefore unconvinced that the Judge made a palpable and overriding error in his factual finding or reasoning. In light of the foregoing, there is no need to address the submissions with respect to anticipation.

[25] Before concluding, I have the following observation.

[26] At the hearing before this Court, the appellants referred to a flurry of evidence before the panel which allegedly pointed to the opposite conclusions from those reached by the Judge. Throughout their submissions, the appellants argued that several errors allegedly committed by the Judge constituted errors of law. In reality, the grounds raised by the appellants in this appeal, although dressed as errors of law, directly challenged the Judge's factual findings. In so doing, the appellants actually attempted to re-argue their case on appeal, asking this Court to reweigh the evidence. This is not the role of a Court of Appeal.

[27] For these 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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