Date: 20090320

Docket: A-622-08

Citation: 2009 FCA 94

CORAM: **RICHARD C.J.**
PELLETIER J.A.
LAYDEN-STEVENSON J.A.

BETWEEN:

ABBOTT LABORATORIES and ABBOTT LABORATORIES LIMITED

Appellants

and

THE MINISTER OF HEALTH and SANDOZ CANADA INC.

Respondents

Heard at Ottawa, Ontario, on March 11, 2009.

Judgment delivered at Ottawa, Ontario, on March 20, 2009.

REASONS FOR JUDGMENT BY: RICHARD C.J.

CONCURRED IN BY: PELLETIER J.A.
LAYDEN-STEVENSON J.A.

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REASONS FOR JUDGMENT

RICHARD C.J.

[1] This is an appeal and cross-appeal from the decision of Justice Hughes of the Federal Court dated December 11, 2008, in which he dismissed the appellants' application, made pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133, to prohibit the Minister of Health from issuing a Notice of Compliance to the respondent Sandoz Canada Inc. until after the expiry of Canadian Patent No. 2,386,527.

[2] Specifically, the appellants (respondents on cross-appeal) Abbott Laboratories and Abbott Laboratories Ltd. (collectively, Abbott) appeal the applications judge's finding that Sandoz'

allegation of invalidity, with respect to claim 5 of Canadian Patent No. 2,386,527, is justified. The respondent (appellant on cross-appeal) Sandoz Canada Inc. (Sandoz) cross-appeals the applications judge's finding that, if claim 5 is valid, Sandoz' allegation of non-infringement is unjustified. Counsel for Sandoz recognizes that, if this Court agrees that the allegation of invalidity is justified, there is no need to deal with the issue of non-infringement raised on the cross-appeal.

[3] For the following reasons, I would dismiss the appeal.

BACKGROUND

[4] Abbott is the manufacturer of the antibiotic clarithromycin, which is available in different formulations, including an extended-release tablet sold in Canada under the brand name BIAXIN XL.

[5] In order to obtain regulatory approval for its 500 mg extended-release clarithromycin tablets, Sandoz filed an Abbreviated New Drug Submission (ANDS) with the Minister of Health (the Minister), in which it compares its product with Abbott's BIAXIN XL.

[6] Pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations* (the Regulations), Abbott filed a Notice of Application in the Federal Court on January 22, 2007, in which it requested an Order prohibiting the Minister from issuing the regulatory approval sought by Sandoz until after the expiry of several Abbott patents. The only patent claim at issue before the applications judge was claim 5 of Canadian Patent No. 2,386,527 (the '527 patent).

The ’527 Patent

[7] The ’527 patent was filed on July 25, 1997 and is therefore governed by the post-October 1, 1996 version of the *Patent Act*, R.S.C. 1985, c. P-4. It claims priority from U.S. Patent Application No. 08/681,723, which was filed on July 29, 1996.

[8] The ’527 patent discloses that clarithromycin can exist in at least two crystalline forms, which Abbott has named Form I and Form II. There was also evidence before the applications judge that clarithromycin can exist in a third crystal form, known as Form 0. The patent specification describes Form I as having “an intrinsic rate of dissolution about three times that of Form II crystals”, which is asserted to “increas[e] bioavailability of the antibiotic and provid[e] significant formulation advantages” (at page 2 of the ’527 patent). In claim 5, the inventors claim:

> The use of 6-*O*-methylerythromycin A Form I according to claim 1 or 2 in the treatment of bacterial infections in a host mammal.

[9] The only issues before the applications judge were Sandoz’ allegations that claim 5 was invalid for anticipation and obviousness, and its allegation that it would not infringe claim 5.

PERSON SKILLED IN THE ART

[10] The applications judge’s description of the person skilled in the art of the ’527 patent was not challenged on appeal. At paragraph 56 of his Public Reasons for Order and Judgment (2008 FC 1359), he stated:

> The parties are in substantial agreement that, when it is necessary to consider who is a person skilled in the art (POSITA) to whom the ’527 patent is addressed, that person is a chemist or chemical engineer having at least a bachelor level degree and at least three to five years experience in the pharmaceutical industry including substantial experience with crystallization processes.

VALIDITY

Anticipation

[11] The applications judge reviewed the law of anticipation in Canada, including the Supreme Court of Canada's recent decision in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, [2008] 3 S.C.R. 265, 2008 SCC 61 (*Sanofi*). The applications judge noted that *Sanofi* identified two requirements for a finding of anticipation: prior disclosure and enablement. He stated:

> [67] Prior disclosure means that the prior patent (publication, use or other disclosure) must disclose subject matter which, if performed, would necessarily result in infringement of the patent (claim at issue). The person skilled in the art looking at the disclosure must be taken to be trying to understand what the prior patent (or other disclosure) meant. There is no room for trial and error, the prior art is simply to be read for the purposes of understanding.
>
> [68] The second requirement is that of enablement which means that the person skilled in the art would have been able to perform what had been disclosed. At this stage the person skilled in the art is assumed to be willing to make trial and error experiments to get it to work.

[12] The applications judge also looked to the following passage from the House of Lords decision in *Synthon BV v. SmithKline Beechman plc*, [2006] 1 All E.R. 685, [2005] UKHL 59, at paragraph 22, which was also cited by Rothstein J. in *Sanofi*:

> [T]he matter relied upon as prior art must disclose subject matter which, if performed, would necessarily result in an infringement of the patent ... It follows that, whether or not it would be apparent to anyone at the time, whenever subject matter described in the prior disclosure is capable of being performed and is such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied.
>
> Reasons for Order and Judgment, at paragraph 74; Sanofi, at paragraph 25.

[13] While he noted that other examples of prior art cited by Sandoz could anticipate claim 5 of the ’527 patent, the applications judge limited his analysis to whether U.S. Patent No. 4,990,602 (the ’602 patent) anticipated claim 5. In examining the ’602 patent, he noted the following:

> [79] The ’602 patent is a prior disclosure which was issued February 5, 1991, that is, over five years prior to the claim date of July 29, 1996. Hence it is timely in terms of prior art.
>
> [80] The ’602 patent begins by stating at the beginning of column I what the parties acknowledge was already previously known, that is that clarithromycin (6-O-methylerythromycin A) was already known as was its use as an antibacterial agent and that there were several known methods for preparing it:
>
> *BACKGROUND OF THE INVENTION*
>
> *1. Field of the Invention*
>
> *The present invention relates to erythromycin A derivatives and a method of the preparation of the same.*
>
> *2. Description of the Prior Art*
>
> *6-O-Alkylerythromycins are useful as anti-bacterial agents or intermediates for synthesis of the antibacterial agents. For examples, 6-O-methylerythromycin A is not only stable under acidic conditions but also has a strong antibacterial activity when compared with erythromycin A. Especially, this compound shows an excellent effect in treatment of infections by oral administration, and therefore it is a useful antibacterial agent.*
>
> *There are known in the past several methods for preparing 6-O-methylerythromycin A, for example…*
>
> [81] An example for the preparation of clarithromycin is provided at column 22 and called Referential Example 1. I will reproduce only the last part:
>
> *(2) To a solution of 2 g of the compound, obtained above, and 1.1 g of sodium hydrogen sulfite in 20ml of ethanol/water (1/1) was added 0.25 ml of 99% formic acid, and the mixture was refluxed for 100 minutes. To the reaction solution was added 30 ml of water, 5 ml of 2N aqueous sodium hydroxide solution was added dropwise, and then the mixture was stirred under ice-cooling for 2 hours. The precipitate which formed was collected by filtration and recrystallized from ethanol to give 1.51 g of 6-O-methylerythromycin A. m.p. 223^{o}-225^{o}C.*

[14] The applications judge examined the affidavit evidence of both the Abbott and Sandoz expert witnesses to find that the ’602 patent disclosed Form I clarithromycin. He stated:

> [90] The evidence also shows that the experts for both Abbott and Sandoz agree that at least some of the crystalline forms produced using the ’602 as well as other prior art references would be Form I. Abbott’s experts Byrn (paragraphs 124 and 134 of his Affidavit) and Atwood (paragraphs 225 of his Affidavit) opine that under the probable drying conditions used, a mixture of Form 0 and Form I crystals would result. The fact that it is not entirely Form I does not matter since the parties have agreed that a proper construction of claim 5 contemplates a mixture of crystalline forms of clarithromycin which includes Form I. Sandoz’s experts were more certain that Form I would be the resultant crystal (Rohani Affidavit paragraph 604, Lee-Ruff Affidavit paragraphs 136 to 138, Eckhardt Affidavit paragraphs 195 and 196). It does not matter whether the crystals were entirely Form I or a mixture of Form I and something else, the agreed upon construction of claim 5 has been met.

[15] In the preceding paragraph, the applications judge also found that the ’602 patent satisfied the requirement of enablement. He explained:

> [89] The ’602 patent is enabling. It describes clarithromycin, its use and how to make it in a crystalline form that is Form I. To practice what is taught by the ‘602 patent would be to infringe claim 5 of the ‘527 patent.

[16] The applications judge concluded that Sandoz’ “allegation that claim 5 of the ’527 patent is invalid for anticipation is therefore justified” (at paragraph 92).

[17] In its memorandum of fact and law, Abbott asserts that the applications judge erred in finding that the ’602 patent anticipated claim 5 of the ’527 patent, since the ’602 patent failed to disclose the “special advantages” of Form I clarithromycin over Form II clarithromycin. As noted previously in these reasons, these purported advantages are described in the patent specification as

the improved bioavailability and significant formulation advantages of Form I due to its increased solubility as compared to Form II.

[18] The applications judge construed claim 5 as follows (at paragraph 55):

> *"5. The use of clarithromycin, at least some of which is Form I, for the treatment of bacterial infections in a host mammal"*.

[19] Based on the applications judge's construction of claim 5 and his analysis of anticipation, it appears that he did not consider the special advantages to be an essential element of claim 5.

[20] Whether a particular element of a claim is "essential" is a matter of claims construction, which is a question of law (*Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067, 2000 SCC 67, at paragraph 61 (*Whirlpool*)). Therefore, the applications judge's construction of claim 5 is reviewable on a standard of correctness, as per *Housen v. Nikolaisen*, [2002] 2 S.C.R. 235, 2002 SCC 33, at paragraph 8.

[21] The Supreme Court in *Whirlpool* set out the approach to be followed when construing a patent claim. Claims are to be construed purposively so as to identify, with the assistance of a person skilled in the art of the patent, "the particular words or phrases in the claims that describe what the inventor considered to be the 'essential' elements of his invention" (*Whirlpool*, at paragraph 45).

[22] As noted by the applications judge at paragraph 50 of his Public Reasons for Order and Judgment, it is not contested by either party that claim 5 includes the use of Form I clarithromycin

to treat bacterial infection even where Form I is mixed with other forms of clarithromycin, such as Forms 0 and II. Given that claim 5 covers the use of clarithromycin where very little of that substance is in Form I, I do not see how the increased solubility of Form I over Form II is an essential element of the claim.

[23] Accordingly, I find that the applications judge did not err in failing to consider whether the '602 patent disclosed the special advantages of Form I over Form II in his anticipation analysis.

[24] With respect to his analysis of whether the allegation of anticipation was justified, the standard of review to be applied by this court is that of palpable and overriding error (*Pfizer Canada Inc. v. Canada (Minister of Health)*, [2007] 2 F.C. 137, 2006 FCA 214, at paragraph 35; leave to appeal ref'd [2006] S.C.C.A. No. 335 (QL)). In *Elders Grain Co. v. M/V Ralph Misener (The)*, [2005] 3 F.C. 367, 2005 FCA 139, I described a palpable and overriding error as "an obvious deficiency in the trial judge's findings of fact that affects the outcome of the trial" (at paragraph 10).

[25] While I agree with Abbott that the applications judge erred in his factual finding regarding the melting point of Form I (at paragraphs 81-83 of his Public Reasons for Order and Judgment), nothing turns on that error with respect to his conclusion that the allegation of anticipation was justified. As described above, the applications judge found that the expert witnesses for both Sandoz and Abbott agreed that the skilled person would make at least some Form I when following the teachings of the '602 patent. In my view, this finding is sufficient for the applications judge to have concluded that the '602 patent disclosed Form I.

[26] Abbott does not contest the applications judge's finding that the use of clarithromycin in the treatment of bacterial infections was disclosed in the '602 patent. Consequently, I do not find that the applications judge erred in finding that Sandoz' allegation of anticipation was justified.

[27] Although it was unnecessary for him to do so in light of his finding that the allegation of anticipation was justified, the applications judge went on to consider the allegations of obviousness and non-infringement. I find that it is unnecessary for this Court to consider these issues in order to dispose of this appeal.

[28] Accordingly, the appeal will be dismissed with costs to the respondent Sandoz.

"J. Richard"
Chief Justice

"I agree
J.D. Denis Pelletier J.A."

"I agree
Carolyn Layden-Stevenson J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-622-08
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CONCURRED IN BY:	Pelletier J.A. and Layden-Stevenson J.A.
DATED:	March 20, 2009

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