Date: 20090325

Docket: A-84-08

Citation: 2009 FCA 97

CORAM: **DESJARDINS J.A.**
NOËL J.A.
TRUDEL J.A.

BETWEEN:

ELI LILLY CANADA INC.

Appellant
(Applicant)

and

APOTEX INC.,
THE MINISTER OF HEALTH

Respondents
(Respondents)

and

ELI LILLY AND COMPANY LIMITED

Respondent / Patentee
(Respondent / Patentee)

Heard at Toronto, Ontario, on March 24, 2009.

Judgment delivered at Toronto, Ontario, on March 25, 2009.

REASONS FOR JUDGMENT BY: NOËL J.A.

CONCURRED IN BY: DESJARDINS J.A.
TRUDEL J.A.

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REASONS FOR JUDGMENT

NOËL J.A.

[1] This is an appeal from the decision of Justice Hughes (the Federal Court Judge) (2008 FC 142) dismissing the application brought by Eli Lilly Canada Inc. (the appellant or Eli Lilly) to

prohibit the Minister of Health (the Minister) from issuing a Notice of Compliance (NOC) to Apotex Inc. (the respondent or Apotex) pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 in respect of the respondent's drug containing the active ingredient known as raloxifene for use in the treatment and prevention of osteoporosis, particularly in post-menopausal women, until after the expiration of the appellant's Canadian Patent No. 2,101,356 (the '356 Patent).

[2] We were reminded during the hearing of the appeal that time is of the essence insofar as the disposition of this appeal is concerned given that the Minister could potentially grant the NOC to Apotex in respect of its drug product raloxifene as soon as a related decision, presently pending before the Federal Court, is released. At the conclusion of the hearing, the Court undertook to deliver its decision as quickly as possible. Hence, the short reasons which follow.

[3] The Federal Court Judge dismissed Eli Lilly's application on the basis that Apotex's allegation in respect of lack of sound prediction was justified because the '356 Patent lacks adequate disclosure. He further found that Apotex's allegation that the claims are broader than the invention disclosed was justified in respect of Claims 1, 3, and 15, but not in respect of Claim 17 (Reasons, para. 182).

[4] In support of its appeal, the appellant contends that the Federal Court Judge committed legal and factual errors in holding that the '356 Patent lacks adequate disclosure. It adds that the Federal Court Judge breached the duty of procedural fairness in disposing of the application on this ground

as it was not alleged by the respondent. At the hearing of the appeal, the appellant further argued, for the first time, that the ‘356 Patent was not based on a prediction since the utility of the invention had been conclusively established by the Canadian filing date. According to the appellant, the Federal Court Judge erred in conducting his analysis on the basis that the patented invention was based on a prediction.

[5] Dealing first with this last argument, the finding by the Federal Court Judge that the invention claimed in the ‘356 Patent was based on a prediction is one of fact.

[6] In this respect, he first determined that the claimed monopoly in the ‘356 Patent, as construed, is that a group of benzothiophenes, specifically raloxifene and raloxifene hydrochloride, are useful in treating or preventing osteoporosis of any kind (Claim 1) or bone loss of any kind (Claim 3), particularly in a post-menopausal female (Claim 15), or particularly without eliciting significant estrogenic responses in primary sex tissues (Claim 17). (Reasons, para. 76)

[7] Having construed the claims, the Federal Court Judge held that the question to be asked, with respect to what the patent discloses, is whether the disclosure in the patent was adequate to tell a person skilled in the art how to practice the invention or whether it discloses enough information so that a person skilled in the art could soundly predict that it would work (Reasons, para. 96).

[8] The Federal Court Judge then reviewed the disclosure made in the ‘356 Patent and found that what the patentee discloses to the public for the purpose of securing the claimed monopoly is:

i. Raloxifene is a known compound having certain known medical uses in estrogen treatment, and it is known how to make it (Reasons, para. 81).

ii. Studies on seventy-five day old female Sprague Dawley rats which are fed raloxifene show that bone loss is prevented in a dose dependent manner with minimal increases in uterine weight (Reasons, para. 81).

iii. Studies on post-menopausal female humans are contemplated which are expected to show an inhibition of the markers associated with bone resorption in estrogen deficient individuals as an indication that raloxifene is effective in inhibiting bone loss (Reasons, para. 81).

[9] In assessing the evidence, the Federal Court Judge noted that the parallels between the prior art, specifically Dr. Jordan's paper entitled "*Effects of Anti-Estrogens on Bone in Castrated and Intact Female Rats*", and the disclosure of the '356 Patent are readily apparent. He held that both studies show that raloxifene used in Sprague Dawley ovariectomized rats demonstrates positive effects in respect of bone loss and uterine weight. He noted that the Jordan paper concluded that a long term study on post-menopausal women was warranted. The disclosure in the '356 Patent suggests that such a study on women was underway and that certain results were expected with a long term study to follow (the results of the study are not part of the disclosure of the '356 Patent). The Federal Court Judge therefore, held that the Jordan paper and the '356 Patent disclosure were at the same point, the rat studies were positive, and human studies were warranted. He noted that the '356 Patent simply claimed that raloxifene is an appropriate medicine for humans without any further supporting disclosure (Reasons, paras 105 and 106).

[10] Based on the foregoing, it is clear that the invention was based on a prediction. Although the rat studies were positive, only a prediction could allow for the proposition that raloxifene had the same effect on women, let alone estrogen deficient post-menopausal women who suffered from bone loss. In other words, the claimed utility required for patentability was not demonstrated but predicted based on the information provided in the ‘356 Patent.

[11] The appellant further argues that the Federal Court Judge erred in holding that the ‘356 Patent lacks adequate disclosure. In this respect, the appellant essentially alleges that there is no requirement that the underlying data supporting a sound prediction be disclosed in the patent. It contends that the Federal Court Judge misconstrued recent judicial pronouncements on the issue of sound prediction.

[12] In making this argument, the appellant at the hearing accepted for purposes of the appeal the conclusion reached by the Federal Court Judge at paragraphs 155 and 156 of his reasons that the Hong Kong study was required in order to turn the prediction on which the ‘356 Patent was predicated into a sound one. According to the Federal Court Judge, the Hong Kong abstract of the study conducted by the appellant on 251 post-menopausal women which concluded that “raloxifene show[ed] promise as a skeletal anti-resorptive” would have been a sufficient factual basis upon which a sound prediction of utility for raloxifene could have been made as of the filing date. However, this study was not disclosed in the ‘356 Patent with the result that the underlying factual basis for the prediction and the sound line of reasoning that grounded the inventors’ prediction were not disclosed.

[13] The importance of the disclosure obligation in applying for a patent has been emphasized by the Supreme Court of Canada on a number of occasions in recent years (*Pioneer Hi Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 at paragraph 23; *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142 at paragraph 46; *Free World Trust v. Électro Santé Inc.* 2000 SCC 66, [2000] 2 S.C.R. 1024 at paragraph 13; *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at paragraph 37 (commonly referred to as *AZT* and hereinafter referred to as such)).

[14] The decision of the Supreme Court in *AZT* is particularly significant to the disposition of this appeal. According to *AZT*, the requirements of sound prediction are three-fold: there must be a factual basis for the prediction; the inventor must have at the date of the patent application an articulable and sound line of reasoning from which the derived result can be inferred from the factual basis; and third, there must be proper disclosure (*AZT*, *supra*, at paragraph 70). As was said in that case (para. 70): “the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly”. In sound prediction cases there is a heightened obligation to disclose the underlying facts and the line of reasoning for inventions that comprise the prediction.

[15] In my respectful view, the Federal Court Judge proceeded on proper principle when he held, relying on *AZT*, that when a patent is based on a sound prediction, the disclosure must include the prediction. As the prediction was made sound by the Hong Kong study, this study had to be disclosed.

[16] Absent a legal error, a decision as to whether or not a prediction is sound gives rise to a question of fact which cannot be overturned in the absence of a palpable and overriding error.

[17] In this respect, the appellant properly accepted that the Hong Kong study was required in order to make the prediction underlying the ‘356 Patent sound. After taking all of the relevant evidence into consideration, it was open to the Federal Court Judge to find that as of the priority date the prior art Jordan article and the disclosure of the ‘356 Patent were at the same point given that both studies demonstrated positive effects in respect of bone loss in rats and both concluded that human studies were warranted. In particular, the ‘356 Patent did not disclose any more than the Jordan article did, and as such, the person skilled in the art was given, by way of disclosure, no more than such a person already had available in the prior art.

[18] The appellant argues that in requiring the complete disclosure of the factual basis underlying the sound prediction (i.e. requiring data to substantiate the invention), the Federal Court Judge has changed the disclosure requirements as set out in subsection 27(3) of the *Patent Act*, R.S.C. 1985, c. P-4. I respectfully disagree. In *AZT*, the Supreme Court, with obvious reference to subsection 34(1) of the *Patent Act* (the predecessor to subsection 27(3)), held that where the claimed invention had not yet actually been reduced to practice, the patent must provide a disclosure such that a person skilled in the art, given that disclosure, could have as the inventors did, soundly predicted that the invention would work once reduced to practice. Significantly, in *AZT*, the Court went on to state that the disclosure requirements had been met given that both the underlying facts

(the test data) and the sound line of reasoning (the chain terminator effect) were in fact disclosed (*AZT*, para. 70).

[19] The appellant further argues that requiring the complete disclosure of the factual basis underlying the sound prediction is inconsistent with the *Patent Cooperation Treaty*, 1970, 28 U.F.T. 7647 (*Treaty*). However, this *Treaty* specifically contemplates the supremacy of national law in setting the rules for substantive conditions of patentability (see article 27(5) of the *Treaty*). We are concerned here with substantive conditions of patentability.

[20] Finally, the appellant contends that the respondent did not allege that there had been a failure to properly disclose the facts underlying the sound prediction within the ‘356 Patent specification and that the Federal Court Judge breached the duty of procedural fairness in disposing of the application on that basis. However, a review of the Notice of Allegation (NOA) shows that the respondent did in fact allege that the ‘356 Patent was invalid on the basis of lack of sound prediction. More specifically, the respondent alleged that the inventors’ rat studies did not provide a factual basis for a sound prediction i.e. it could not be soundly predicted that the results obtained from *in vivo* testing in rats would demonstrate utility in humans. Further, the respondent alleged that by the Canadian filing date, the inventors had not demonstrated that raloxifene hydrochloride could be used as a treatment for the prevention of osteoporosis and/or bone loss in humans. In its NOA, the respondent notes that while the disclosure of the ‘356 Patent indicates that a clinical trial in healthy post-menopausal women was underway to compare the effects of conjugated estrogen and raloxifene, the results of the study were not reported in the patent. When regard is had to the NOA,

the lack of sound prediction, specifically the lack of disclosure of any human data in the ‘356 Patent as a ground of invalidity, was clearly in issue.

[21] I would dismiss the appeal with costs to Apotex.

“Marc Noël”

J.A.

“I concur
Alice Desjardins J.A.”

“I agree
Johanne Trudel J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-84-08
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CONCURRED IN BY:	DESJARDINS J.A. TRUDEL J.A.
DATED:	MARCH 25, 2009

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