Federal Court of Appeal | Cour d'appel fédérale

Date: 20120411

Docket: A-344-11

Citation: 2012 FCA 109

CORAM: **EVANS J.A.**
SHARLOW J.A.
DAWSON J.A.

BETWEEN:

MYLAN PHARMACEUTICALS ULC

Appellants
(Respondent)

and

ASTRAZENECA CANADA, INC.
ASTRAZENECA UK LIMITED and
THE MINISTER OF HEALTH

Respondents
(Applicants, Respondent)

Heard at Toronto, Ontario, on March 27, 2012.

Judgment delivered at Ottawa, Ontario, on April 11, 2012.

REASONS FOR JUDGMENT BY: EVANS J.A.

CONCURRED IN BY: SHARLOW J.A.
DAWSON J.A.

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REASONS FOR JUDGMENT

EVANS J.A.

Introduction

[1] This is an appeal by Mylan Pharmaceuticals ULC (Mylan) from a decision of the Federal Court, reported at 2011 FC 1023. In that decision, Justice Rennie (Judge) granted an application by AstraZeneca Canada Inc. and AstraZeneca UK Limited (collectively, AstraZeneca) under section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, for an order of prohibition.

[2] The Judge's order prohibits the Minister of Health from issuing a Notice of Compliance to Mylan to sell its version of the medicine anastrozole in Canada until after the expiry of Canadian Patent No. 1,337,420 (420 patent) on October 24, 2012. The 420 patent relates to the compound anastrozole.

[3] In its Notice of Allegation Mylan alleged that its sale of a generic version of anastrozole would not infringe the 420 patent because the patent was invalid for lack of utility and obviousness. Mylan no longer challenges the patent on the ground that the invention is obvious. The Judge held that AstraZeneca had established that Mylan's Notice of Allegation was not justified.

[4] This appeal turns principally on the construction of one sentence in the specification of the 420 patent. At the outset, however, it is helpful to identify two of the claims set out in the patent. Claim 14 claims a pharmaceutical composition comprising an effective amount of anastrozole, and claim 15 relates to the use of anastrozole as an inhibitor of the enzyme aromatase. Neither claim is in dispute in this appeal

[5] An aromatase inhibitor blocks the conversion of androgens to estrogens, which reduces the availability of circulating estrogens in the body. The reduction of estrogens has particular significance for the treatment of forms of breast cancer that depend on estrogen for their growth.

[6] It is agreed that anastrozole is a new and useful compound, and is patentable under section 2 of the *Patent Act*, R.S.C. 1985, c. P-4. It is also agreed that the 420 patent demonstrated that, by

June 15, 1988, the Canadian filing date, anastrozole inhibited the enzyme aromatase, as claim 14 of the patent states, and that the invention was therefore useful.

[7] The law sets the bar low for utility when the specification does not promise that the invention will produce a specific result. Inventors are not required to make such a promise. However, when they do, an invention that does not do what the specification promises lacks utility for the purpose of section 2: *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Limited*, [1981] 1 S.C.R. 504 at 525 (*Consolboard*); *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197, 85 C.P.R. (4th) 413 at para. 76 (*Eli Lilly*).

[8] The question in dispute in this appeal concerns the construction of the underlined sentence in the following paragraph from the patent specification.

> A variety of compounds possessing aromatase inhibitory activity is known, of which the most important clinically is aminogluthethimide [AG]. [AG], however, has the drawback that it affects other aspects of steroid metabolism, with the consequence that its use is often associated with undesirable side-effects. <u>It is a particular object of the present invention to provide aromatase inhibitory compounds with fewer undesirable side effects than [AG]</u>.

[9] Although not relevant to the disposition of this appeal, I should add by way of completeness that anastrozole has proved to be a highly effective clinical treatment for estrogen-dependent breast cancer and a great commercial success for AstraZeneca. It is both a potent inhibitor of aromatase and, because it is highly selective in its inhibitory effects, it has much less toxicity than earlier generations of aromatase inhibitors, including AG.

Mylan's position

[10] Mylan says that the underlined sentence in the extract quoted above constitutes a promise that anastrozole has fewer undesirable side effects than AG, the first aromatase inhibitor to be used in the treatment of breast cancer. This first generation drug effectively inhibited aromatase. However, because it was not selective, AG inhibited other enzymes necessary for a healthy functioning body. A focus of pharmaceutical research in the 1980s was to discover an aromatase inhibitor that was both potent and selective in the enzymes that it inhibited.

[11] Mylan argues that by June 15, 1988, the inventors of anastrozole had not demonstrated that it produced fewer side effects than AG. In any event, any utility with respect to side effects was not sufficiently disclosed in the patent. Because this promise of the patent was not demonstrated, the invention lacked utility and the allegation that the patent was invalid was therefore justified.

[12] Mylan argued in the Federal Court that the patent also promised that anastrozole had therapeutic utility in the treatment of breast cancer. Consequently, since it had not been demonstrated that anastrozole produced fewer side effects than AG, there was no basis for this promise and Mylan's allegation of invalidity was therefore justified.

[13] The Judge found that no such promise was made and dismissed the argument. Mylan stated in its memorandum of fact and law (paragraph 30), and in oral argument, that it is content to rest its utility argument solely on the unfulfilled promise that anastrozole will produce fewer side effects

than AG. Accordingly, counsel said, the Court need not address whether the patent also promises therapeutic utility.

AstraZeneca's position

[14] AstraZeneca's position on the construction of the disputed sentence in the specification is that the "object of the invention" refers to the forward-looking or aspirational aim of the invention. It is not a promise that anastrozole had achieved this goal by the date of filing, but merely looks to its future attainment. Hence, Mylan's allegation was not justified in so far as it alleged that the patent was invalid for lack of utility because it did not demonstrate by June 15, 1988 that anastrozole had fewer side effects than AG.

[15] In any event, AstraZeneca argues, even if Mylan is correct to say that, properly construed, the patent does promise fewer side effects than AG, it had been demonstrated by the filing date of the 420 patent that anastrozole was a selective enzyme inhibitor and thus produced fewer undesirable side effects than AG. The invention therefore had utility because it did what it promised.

Federal Court's decision

[16] The Judge agreed with the construction of the specification advanced by AstraZeneca and therefore concluded that Mylan's allegation that the 420 patent was invalid for lack of utility was not justified. He approached the construction of the promise on the basis of the following interpretative principles.

[17] First, both the disclosure of the patent as a whole and its specific language must be examined (para. 88). Second, the promise of the invention must be construed from the perspective of persons of skill in the art relevant to the invention (POSITA). These include those with a medical degree or Ph.D. in a relevant field, and two to three years' experience in pharmaceutical research and drug development. Third, the patent must also be construed in the light of the state of scientific knowledge at the time of filing (para. 89). Fourth, patents should be read neither too generously nor too strictly, but should be construed with an eye to ensuring that an inventor is not deprived of any protection for a useful invention (at para. 88): *Consolboard* at 520-21.

[18] In the alternative, the Judge held that if Mylan's construction of the specification is correct, it was not demonstrated in the patent that by June 15, 1988 anastrozole had fewer side effects than AG. Accordingly, on this construction of the patent, the allegation of lack of utility was justified.

[19] I am not persuaded that the Judge erred in law in his construction of the patent's promise. Hence, I need not comment on his conclusion that, if the patent promises fewer side effects than AG, it is invalid for lack of utility because it refers to no study that demonstrates this. I would leave this interesting question for another day.

Analysis

[20] **Standard of review** Since the construction of a patent, including its specification, is a question of law, correctness is the applicable standard of review: *Eli Lilly* at para. 80. However, any assessment of the evidence (concerning the state of scientific knowledge at the relevant time, or

how a reasonable POSITA would understand the patent, for example) made by the Judge in the course of reaching his conclusion on the construction of the patent is reviewable for palpable and overriding error.

[21] **Did the Judge make an error of law?** Mylan does not disagree with the interpretative framework adopted by the Judge for construing the promise of the 420 patent, but says that he erred in law by giving more weight to some factors and not enough to others. I shall deal with the errors that Mylan says are apparent in the Judge's reasoning.

[22] For convenience, I set out again the one sentence in the 55-page patent on which Mylan relies in order to show that anastrozole not only inhibits aromatase, but also produces fewer side effects than AG.

> It is a particular object of the present invention to provide aromatase inhibitory compounds with fewer undesirable side effects than [AG].

[23] It will be recalled that the question is whether the words "object of the present invention" mean that anastrozole produces fewer effects than AG, as Mylan argues, or whether, as AstraZeneca says, it means that this is what the invention aims to do, without promising that it has succeeded.

(i) *undue reliance on dictionary definition*

[24] The Judge stated (at para. 132) that the plain meaning of the word "object" suggests that it means an aim to be fulfilled, and referred to the following part of the definition of "object" given in the *The Oxford English Dictionary*. 3rd ed., on line version:

> A goal, purpose, or aim; the end to which effort is directed; the thing sought, aimed at, or striven for.

[25] Mylan makes two points. First, the Judge put undue weight on the dictionary definition of "object", rather than considering its meaning in the context of patent law. Counsel referred us to cases, including *Amfac Foods Inc. v. Irving Pulp & Paper, Ltd.* (1986), 12 C.P.R. (3d) 193 (F.C.A.) at 199, where the Court relied on an "object clause" to define the scope of the invention. On the basis of these authorities, he argued that the "object of an invention" was virtually a legal term of art and formed part of the definition of the invention.

[26] I do not agree. Patents are not required to contain a clause describing the object of the invention. When they do, the meaning of the object clause depends on the specific context, including the wording of the particular clause in question and its relationship to the rest of the patent. Indeed, in oral argument counsel conceded that object clauses should not necessarily always be construed as promises of the invention.

[27] Second, counsel for Mylan said that the Judge referred to only some of the dictionary synonyms for, or definitions of, "object"; in particular, he omitted "purpose", a word that connotes what the invention does. In my view, however, this kind of close semantic parsing of the Judge's reasons in this case is not productive. Reading them in their entirety, I am satisfied that the Judge placed relatively little weight on the dictionary definitions in reaching his conclusion that the patent does not promise that anastrozole has fewer side effects than AG. For example, he said (at para. 139):

> In sum, the plain language of the patent, when read in the context of the patent as a whole, does not support a promise of fewer undesirable side effects. I accept AstraZeneca's argument that not all statements of advantage in a patent rise to the level of a promise. A goal is not necessarily a promise. The third paragraph of the 420 Patent refers to a forward looking goal, a hoped-for advantage of the invention.

[28] A better reading of the reasons, in my view, is that the Judge relied on the dictionary definitions and synonyms to confirm that, in its ordinary usage, the word "object" is capable of bearing the meaning that he had assigned to it on the basis of other considerations: the evidence of Dr Dowsett discussed at paragraphs 40-42 of these reasons, and his examination of the patent as a whole.

(ii) *context of the patent*

[29] In examining the patent in its entirety, the Judge noted that, apart from the "object of the invention" sentence in the specification, nowhere else in the patent is there any indication that anastrozole has fewer side effects than AG. In contrast to the statement of the invention's object, the claims to the compound anastrozole and its inhibitory effects on aromatase are precise and specific. For example, Claim 13 covers "the compound [anastrozole]", and Claim 15 relates to "The use of the compound [anastrozole] as an inhibitor of the enzyme aromatase."

[30] Moreover, it is agreed that the 420 patent would be valid if it only claimed the compound anastrozole and its inhibitory effects on aromatase. It was thus unnecessary for the patent also to promise fewer side effects than AG. Even though tests, which AstraZeneca did not disclose, had been conducted showing that anastrozole was selective, a promise in the patent to this effect would

be entirely gratuitous, and could only provide competitors with another basis for attacking its validity.

[31] Mylan counters these arguments by saying that the word “provide”, which appears in the object clause, is used elsewhere in the patent in connection with the claims of the patent. Thus, by stating that “it is a particular object of the invention to provide aromatase inhibitory compounds with fewer undesirable side effects than [AG]”, the object clause should, counsel argues, be interpreted as a promise.

[32] I do not agree. In my view, this microscopic approach to the construction of the provisions of a patent is misguided. The fact that such an ordinary word as “provide” is used in sentences containing the claims of the patent does not mean that when used in other sentences, it should be construed as connoting a promise of the patent.

[33] I agree with the Judge that an examination of the patent as a whole supports the conclusion that, unlike the express claims of the patent, the object clause contains no more than a forward-looking aim of the invention. In my view, the fact that side effects are not mentioned elsewhere in the patent is telling.

(iii) *state of existing knowledge*

[34] The state of scientific knowledge at the date of the Canadian filing of a patent is an important aspect of the context within which a patent must be construed. Mylan argues that in the

1980s the major problem with the aromatase inhibitors then used to treat estrogen-dependent breast cancer was that they were not selective in their inhibitory effects. In particular, AG, the most widely used drug for this purpose, has the undesirable side effect of inhibiting cortisol synthesis. Cortisol is essential to the body's stress response and a cortisol deficiency is potentially life-threatening.

[35] In 1988, scientists were searching for a compound that would selectively target aromatase and thus not have this side effect. Hence, says Mylan, a reasonable POSITA would interpret the statement in the 420 patent that the "particular object" of anastrozole is to provide aromatase inhibitory compounds with fewer side effects than AG as a promise that AstraZeneca had discovered what the industry was looking for, namely, a compound that would not have the side effects of AG. A compound that produced no fewer side effects than AG would not be commercially and clinically useful.

[36] I do not agree with this argument. In my view, the fact that the pharmaceutical industry was seeking a solution to a particular problem would not lead a POSITA to necessarily think that the "particular object" of anastrozole was that it solved one of the pressing research problems of the day. It is equally plausible to read the object clause as simply stating that its aim is to solve the problem, without promising that it had succeeded.

[37] Further, even if anastrozole would not be commercially or clinically useful if it produced no fewer side effects than AG, it is agreed that it was patentable as a novel and useful compound, and as an aromatase inhibitor. It would be rational to seek patent protection for anastrozole on this basis,

in case it turned out to be selective, as AstraZeneca had good reason to believe at the time of the Canadian filing of the 420 patent that it would, because of male side effect (MSE) tests on rats that had been conducted prior to 1988, but were not disclosed in the 420 patent.

(iv) *expert evidence*

[38] The subjective intention of the inventor counts for relatively little in construing the provisions of a patent. Much more important is how its addressees, the reasonable POSITA, would understand them: *Consolboard* at 521; *Pfizer Canada Inc. v. Canada (Minister of Health),* 2005 FC 1725, 46 C.P.R. (4th) 244 at para. 28. Both parties produced expert witnesses who testified on the issue of utility. Mylan's expert was Dr Coombes, a medical doctor and a professor of oncology who had been involved in the development of aromatase inhibitors. He testified that, in his opinion, a POSITA would read the object clause in the 420 patent as promising fewer side effects than AG.

[39] Dr Hartmann was AstraZeneca's expert on obviousness. He was a professor of pharmaceutical and medicinal chemistry, and had worked on aromatase inhibitors in the treatment of breast cancer. He seems to have been of the view that a POSITA would read the object clause in the 420 patent as saying that anastrozole would result in fewer side effects. The Judge acknowledged this in his reasons (at para. 124).

[40] AstraZeneca's expert on utility was Dr Dowsett, a professor of biochemical endocrinology whose research had focussed almost exclusively on breast cancer. The Judge accepted Dr Dowsett's

evidence that a reasonable POSITA would read the object clause as a mere statement of the inventors' aim, not as a promise that anastrozole achieved it.

[41] Mylan argues that the Judge's conclusion on how a POSITA would understand the promise of the patent was not supported by any of the experts. This is because he failed to notice that Dr Dowsett admitted at one point in his cross-examination that the object clause would cause a POSITA to construe the 420 patent as promising fewer side effects.

[42] I do not agree. The trier of fact's assessment of the evidence of a witness can only be impeached on appeal on the basis of palpable and overriding error: *Halford v. Seed Hawk Inc*., 2006 FCA 275, 54 C.P.R. (4th) 130 at para. 11.

[43] In my view, when Dr Dowsett's alleged concession is read in the context of the entire cross-examination, its meaning is far from clear. In fact, immediately before and immediately after the alleged concession, Dr Dowsett clearly indicates that he understands "object of the invention" to mean its goal.

[44] It was thus reasonably open to the Judge to base his conclusion on Dr Dowsett's explicit testimony that the object clause set out the long-term aim of producing fewer side effects, and his doubt that "the patent is actually stating that this is what they have achieved." Hence, the Judge made no reversible error in assessing the evidence and preferring that of Dr Dowsett (at para. 125).

(v) ***internal incoherence of the Judge's reasons***

[45] Mylan submits that the Judge erred by inferring from the absence in the patent of any description of clinical trials that the patent could not have promised something only demonstrable by clinical trials. Counsel argues that the Judge thereby confused the construction of the patent (the first step in the analysis) with whether that promise was fulfilled. As a related point, Mylan says that the Judge makes contradictory statements about whether clinical trials were necessary to demonstrate that anastrozole produced fewer side effects.

[46] In my view, neither of these arguments warrants the interference of this Court with the Judge's decision. Even if, as Mylan argues, the Judge appears at some points to infer the meaning of the patent from the absence of clinical trials, a reading of his reasons in their entirety shows that this played only a minor role in leading him to conclude that the 420 patent does not promise that anastrozole produces fewer side effects than AG.

[47] Nor was the Judge confused about the need for clinical trials to demonstrate fewer side effects. It is clear from his reasons that he understood that the MSE test was sufficient to show that anastrozole was selective and therefore did not give rise to the main undesirable side effect of AG, namely cortisol deficiency. He was equally alert to the fact that clinical tests were needed to demonstrate that anastrozole produced other side effects, such as rashes.

Conclusion

[48] For all these reasons, I would dismiss the appeal with costs.

"John M. Evans"
J.A.

"I agree
K. Sharlow J.A."

"I agree
Eleanor R. Dawson J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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