Federal Court of Appeal | Cour d'appel fédérale

Date: 20160915

Docket: A-404-15

Citation: 2016 FCA 230

CORAM: **DAWSON J.A.**
GAUTHIER J.A.
NEAR J.A.

BETWEEN:

TEVA CANADA LIMITED

Appellant

and

NOVARTIS PHARMACEUTICALS CANADA INC., NOVARTIS AG and THE MINISTER OF HEALTH

Respondents

Heard at Ottawa, Ontario, on September 7, 2016.

Judgment delivered at Ottawa, Ontario, on September 15, 2016.

REASONS FOR JUDGMENT BY: DAWSON J.A.

CONCURRED IN BY: GAUTHIER J.A.
NEAR J.A.

Federal Court of Appeal  Cour d'appel fédérale

Date: 20160915

Docket: A-404-15

Citation: 2016 FCA 230

CORAM: **DAWSON J.A.**
GAUTHIER J.A.
NEAR J.A.

BETWEEN:

TEVA CANADA LIMITED

Appellant

and

NOVARTIS PHARMACEUTICALS CANADA INC., NOVARTIS AG and THE MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT

DAWSON J.A.

[1] For reasons cited as 2015 FC 770 the Federal Court issued a judgment prohibiting the Minister of Health from issuing a Notice of Compliance to Teva Canada Limited in respect of a generic version of Novartis Pharmaceuticals Canada Inc.'s patented product EXJADE. The Federal Court concluded that Teva's allegations of inutility, obviousness and insufficiency were

not justified. On this appeal from the judgment of the Federal Court, Teva only places in issue the conclusion of the Federal Court that Teva's allegation of inutility was not justified.

[2] In my view, and Teva agrees, this appeal turns on a single issue: did the Federal Court err in law in its construction of the promise of the relevant patent?

[3] At paragraph 34 of its reasons, the Federal Court set out the principles of law relevant to the utility requirement:

> I believe this approach to construction is supported by well-accepted principles of patent law. Generally speaking, the utility requirement represents a fairly low threshold. The exception is where the inventors explicitly promise a specific result, particularly if the stated utility is set out in the claims as opposed to the disclosure. An explicit promise set out in the disclosure can apply to all claims but, at the same time, it may be appropriate to distinguish between the promise of the compound claims, on the one hand, and the promise of the use claims, on the other (*Apotex Inc v Pfizer Canada Inc*, 2014 FCA 250 at paras 64, 65, 71, 77, 87, 88).

[4] Teva acknowledges that the Federal Court made no error in this statement of relevant principles. Rather, Teva argues that the Federal Court erred in its application of these principles to the evidence before it.

[5] The key passage in the patent disclosure is that:

> It has now been found that certain substituted 3,5-diphenyl-1,2,4-triazoles have valuable pharmacological properties when used in the treatment of disorders which cause an excess of metal in the human or animal body or are caused by it, primarily a marked binding of trivalent metal ions, in particular those of iron.

[6] Teva contends that:

i. this passage makes an explicit promise that the patented compounds had been tested in humans and had been found to be both non-toxic and valuable in the therapeutic treatment of iron-excess disorders in humans by virtue of the compounds' capacity to bind markedly to iron; and,

ii. this promise applies to all of the patent's claims, including the claims made for novel compounds, particularly including claims 5 and 32 which claim the compound that is the active ingredient in EXJADE.

[7] The Federal Court rejected these contentions. It found that the patent "would be read by the skilled person as describing the desirable properties possessed by the compounds of the invention, namely, their distinct ability to bind to iron, their solubility, and their capacity to induce excretion" (reasons, at paragraph 22). This was the promise of the patent as construed by the Federal Court.

[8] At paragraph 24 of its reasons, the Federal Court explained the key passage as follows:

> The reference to "valuable pharmaceutical properties" at the beginning of the sentence is completed by the identification at the end of the sentence of what those properties are: primarily a marked binding to trivalent metals, particularly iron. So, the compounds have valuable properties, most importantly, a striking affinity to iron. The middle of the sentence explains why those properties are valuable: "they are valuable when used in the treatment of iron excess disorders". It is those properties that are said to be valuable when used in the treatment of iron excess disorders; the patent does not say that the compounds have been used for that purpose.

[9] On this appeal Teva argues that the Federal Court erred in its construction of the promise of the patent by:

i. relying on the patent's abstract to construe the promise;

ii. distinguishing between the promise made in respect of the patented formula I and formula II compounds; and,

iii. applying the doctrine of claim differentiation.

[10] I agree that the Federal Court ought not to have considered the abstract when construing the promise of the patent (*Apotex Inc. v. ADIR*, 2009 FCA 222, 392 N.R. 96, at paragraphs 104-105). However, in my view this error was not material to the decision of the Federal Court. Prior to this reference to the patent's abstract the Court had, at paragraph 24 of its reasons, construed the key passage textually and contextually. The Federal Court also supported its construction by reference to a later portion of the paragraph containing the key passage that dealt with tests on rats and monkeys, not humans (reasons, at paragraph 28). Also of relevance is that this paragraph contains a reference to prior art which described iron binding observed *in vitro* (a study which did not consider toxicity).

[11] I also reject the argument that the Federal Court erred by drawing a distinction between the compounds of formula I and the compounds of formula II when determining the promise of the patent.

[12] The patent expressly differentiates between the two classes of compounds in both the claims and the disclosure. Thus, the formula I compounds are described from the bottom of page 2 of the patent to the middle of page 10 of the patent. The formula II compounds are described

on page 10 and following of the patent. The formula II compounds are a subset of the formula I compounds.

[13] Contrary to Teva's assertion, the Federal Court was well aware that the formula II compounds were a subset of the formula I compounds (reasons, at paragraphs 13 and 14).

[14] The compounds of formula II are said to be novel. The patent states that one of the inventions of the patent relates to these novel compounds, which are described in the examples set out on pages 18-31 of the patent.

[15] Conversely, the formula I compounds contain some compounds that had previously been made. The novelty of these compounds is their use, not the compounds themselves. At pages 3 and 6 the patent states in reference to these compounds that the invention relates to the use of the compounds of formula I:

> … in the treatment of diseases which cause an excess of metal in the human or animal body or are caused by it; preferably in the form of pharmaceutically acceptable preparations, in particular in a method for the therapeutic treatment of the human body, and to a treatment method of this type.

[16] The patent contains 43 claims. All of these claims relate to the substituted 3,5-diphenyl-1,2,4-triazoles described in formulas I or II. Some of the claims relate to the use of these compounds (or their salts or pharmaceutical preparations containing them) in the treatment of a disease which causes (or is caused by) an excess of metal in a human or animal body (see, for example, claim 1). Other claims relate to the use of these compounds (or their salts) for the

treatment of an excess of iron in a human or animal body (see, for example, claim 41). Claim 43 relates to a process to make compounds of formula II.

[17] Claims such as claims 5 and 32 are compound claims (as opposed to use claims). Claim 5 claims all of the compounds of formula II and their salts. Claim 32 claims the compound at issue in the prohibition proceeding.

[18] It can be seen from a reading of the patent that all of the statements of use found in the disclosure from the bottom of page 2 through to page 10 relate only to the formula I compounds. The disclosure contains no statements of use of the formula II compounds, other than the key passage quoted above at paragraph 5.

[19] Dr. Baillie's evidence was that the patent differentiates between the two formulas "for reasons of convenience in that the formula II compounds were all novel structures" whereas some of the formula I compounds were previously known (cross-examination of Dr. Baillie, Appeal Book volume 12, tab 104, page 2304). Dr. Baillie is a medicinal chemist called on behalf of Novartis.

[20] The Federal Court was also alert and attentive to the fact that the expressions formula I and formula II were used as a convenient means to point to support in the disclosure for particular claims. When the patentee wanted to refer to all the compounds covered by both expressions, he described them as certain substituted 3,5-diphenyl-1,2,4-triazoles (as in the key passage at page 2 of the disclosure). Thus, the Federal Court was correct to find that the other

passages relied upon by Teva (found at pages 6-9 of the disclosure) were not particularly useful when construing the promise in respect of the compounds of formula II claimed in claims 5 and 32.

[21] A further example of the differentiation between the two classes of compounds is that claims 1 to 4 of the patent claim the use of the formula I compounds for the treatment of a disease, while claims 40 to 42 claim the formula II compounds, or a pharmaceutically accepted salt thereof, for use in treatment of an excess of iron in an animal or human body.

[22] Notwithstanding the manner in which the patent differentiates between the formula I and formula II compounds, Teva argues that because every formula II compound is a subset of the formula I compounds, there is no basis to exempt the formula II compounds from the utility in humans promised for the formula I compounds.

[23] In my view, this argument ignores the fact that at law different claims can have different utilities for the same compound (see, for example, *Apotex Inc. v. Pfizer Canada Inc.*, 2014 FCA 250, 465 N.R. 306 (Celebrex); *Teva Canada Limited v. Novartis AG*, 2013 FC 141, 109 C.P.R. (4th) 1 (Imatinib)).

[24] Given the manner in which the patent differentiates between the formula I and II compounds (particularly in the disclosure and in claims 1 and 5) the statements of use at the bottom of page 2 through to page 10 of the disclosure can only relate to claims 1 to 4. They cannot relate to the novel compounds (claims 5 to 37).

[25] The Federal Court's construction of the promise of the patent was consistent with differentiation contained in the disclosure and the claims. It is also consistent with the useful advance over the prior art described in the patent. The Federal Court's construction was correct.

[26] Before leaving this issue it is relevant to note that the promise of the patent doctrine will hold an invention to an elevated standard of utility "only where a clear and unambiguous promise has been made." Where a patent's validity is "challenged on the basis of an alleged unfulfilled promise, the patent will be construed in favour of the patentee where it can reasonably be read by the skilled person as excluding this promise" (Celebrex, at paragraph 66).

[27] As the Federal Court found, this patent can be read by a person skilled in the art as excluding Teva's asserted elevated promise of utility.

[28] I also reject the argument that the Federal Court erred by applying "claim differentiation" to construe the promise of the novel formula II compounds claims to be different from the promise of the formula I use claims. For the above reasons, the Federal Court was correct to differentiate between the compounds and use claims.

[29] Finally, in oral argument Teva argued that the Federal Court erred in determining that the skilled person could, but need not be, a physician (reasons, at paragraph 21). This was not an issue raised in Teva's memorandum of fact and law. In any event, I am satisfied the Federal Court's determination of the attributes of the skilled person was supported in the evidence.

[30] Having construed the stated utility of the patent to be the capacity of the compounds to bind markedly to iron and to be sufficiently soluble to induce iron excretion, the Federal Court went on to conclude that the stated utility had been clearly demonstrated or soundly predicted as of the filing date of the patent (reasons, at paragraph 40). It followed that Teva's allegation of inutility was not justified.

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

"Eleanor R. Dawson"
J.A.

"I agree.
Johanne Gauthier J.A."

"I agree.
D. G. Near J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-404-15
STYLE OF CAUSE:	TEVA CANADA LIMITED v. NOVARTIS PHARMACEUTICALS CANADA INC., NOVARTIS AG AND THE MINISTER OF HEALTH
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	SEPTEMBER 7, 2016
REASONS FOR JUDGMENT BY:	DAWSON J.A.
CONCURRED IN BY:	GAUTHIER J.A. NEAR J.A.
DATED:	SEPTEMBER 15, 2016

APPEARANCES:

Jonathan Stainsby Scott Beeser	FOR THE APPELLANT
Anthony G. Creber Alex Gloor	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Aitken Klee LLP Barristers and Solicitors Ottawa, Ontario	FOR THE APPELLANT
Gowling WLG (Canada) LLP Barristers and Solicitors Ottawa, Ontario	FOR THE RESPONDENTS NOVARTIS PHARMACEUTICALS CANADA INC. AND NOVARTIS AG