Date: 20061222

Docket: A-168-05

Citation: 2006 FCA 421

CORAM: **RICHARD C.J.**
NOËL J.A.
EVANS J.A.

BETWEEN:

APOTEX INC.

Appellant
(Respondent)

and

SANOFI-SYNTHELABO CANADA INC.
and SANOFI-SYNTHELABO

Respondents
(Applicants)

and

THE MINISTER OF HEALTH

Respondent
(Respondent)

Heard at Toronto, Ontario, on December 12 and 13, 2006.

Judgment delivered at Ottawa, Ontario, on December 22, 2006.

REASONS FOR JUDGMENT BY: NOËL J.A.

CONCURRED IN BY: RICHARD C.J.
EVANS J.A.

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REASONS FOR JUDGMENT

NOËL J.A.

[1] This is an appeal from the judgment of Shore J. of the Federal Court (2005 FC 390) prohibiting the Respondent Minister of Health from issuing a Notice of Compliance ("NOC") to Apotex Inc. ("Apotex" or "the appellant"), pursuant to the *Patented Medicines*

(Notice of Compliance) Regulations, SOR/93-133 ("NOC Regulations"), with respect to its 75 mg clopidogrel bisulfate tablets until the expiry of Canadian Letters Patent No. 1,336,777 ("the '777 Patent").

[2] The appellant alleges that the patent in issue is invalid on the grounds of anticipation, obviousness and double patenting and that accordingly there was no basis for the issuance of an order of prohibition.

RELEVANT FACTS

[3] By Notice of Application dated April 28, 2003, Sanofi-Synthelabo Canada Inc. and Sanofi-Synthelabo (collectively "the respondent" or "Sanofi") initiated a proceeding before the Federal Court seeking an order, in accordance with subsection 6(1) of the NOC Regulations, prohibiting the Minister from issuing a NOC to Apotex in connection with its 75 mg clopidogrel bisulfate tablets until the expiry of Sanofi's '777 Patent in 2012.

[4] The '777 Patent relates to the invention of clopidogrel, a process for its preparation and pharmaceutical compositions containing it. Clopidogrel is one half of a larger chemical compound: Methyl alpha-5- (4, 5, 6, 7 tetrahydro (3,2-c) thieno pyridyl) (2-chlorophenyl)-acetate. The compound in question is a racemate: a substance containing equal amounts of two optical isomers, known as the dextro-rotatory isomer (also known as the *d* enantiomer, and represented by [+]) and the levo-rotatory isomer (also known as the *l* enantiomer, and

represented by [-]). Clopidogrel is the common name for the dextro-rotatory isomer of the compound.

[5] The dextro-rotatory isomer has beneficial properties over both the racemate and the levo-rotatory isomer. Specifically, the advantages of the dextro-rotatory isomer are that it contains all of the platelet aggregation inhibiting activity and is less toxic and better tolerated (Reasons, paras. 22 and 81):

> In an unexpected manner only the dextro-rotatory enantiomer I_d exhibits a platelet aggregation inhibiting activity, the levo-rotatory enantiomer I_1 being inactive. Moreover, the inactive levo-rotatory enantiomer I_1 is the less well tolerated of the two enantiomers ('777 Patent A.B. Vol. 1 p. 71).

[6] The '777 Patent also relates to the invention of the bisulfate salt of the dextro-rotatory isomer. The dextro-rotatory isomer in a free base form (i.e. not as a salt) exists as an oil. Oily products are difficult to purify and products which can be purified by crystallization (e.g. salts) are better suited for the preparation of pharmaceutical compositions. It was observed by the inventors that many of the salts of the dextro-rotatory isomer precipitated in an amorphous form and/or were hygroscopic, a property which makes them difficult to handle on an industrial scale. Therefore, many of the salts classically used in pharmacy proved to be difficult to purify. The '777 Patent states that the claimed bisulfate salts crystallized easily, were not hygroscopic and were sufficiently water soluble to make their use particularly advantageous in pharmaceutical compositions (Reasons, para. 23).

[7] On March 10, 2003, Apotex served a Notice of Allegation ("NOA") on Sanofi in an attempt to obtain a NOC for a generic version of Sanofi's 75 mg clopidogrel bisulfate tablets, which are commercially known to as PLAVIX. In the NOA, Apotex alleges that claims 1, 3, 10, and 11 of the '777 Patent are invalid because they are anticipated by Canadian Letters Patent No. 1,194,875 ("the '875 Patent"), published on its issue date of October 8, 1985. Alternatively, Apotex alleges that all of the said claims are invalid on the basis of obviousness or double patenting.

[8] The construction of these claims is not in dispute.

[9] The '875 Patent, as well as its American and French counterparts, discloses and claims a large class of compounds useful in providing platelet aggregation inhibiting activity, and a process for the preparation of such compounds. While the '875 Patent discloses over 250,000 possible different compounds, only 21 individual compounds are specifically identified (referred to as derivatives 1-21). All of these derivatives are racemates. Example 1 at page 3 of the '875 Patent deals with derivative No. 1 which is the racemate from which the separated isomers were obtained in the '777 Patent ('875 Patent, page 3, A.B., Vol. VII at p. 2372).

[10] The Applications Judge notes that the compounds identified in the '875 Patent can exist as racemates or isomers, and quotes in his reasons the passages of the '875 Patent which state the existence of isomers directly or by reference to other claims (Reasons, para.

29). However, there is no teaching on how to separate the racemates into their isomers, and no mention or suggestion that there are any pharmaceutical or toxicological differences between the isomers of the disclosed racemates with respect to activity or tolerability (Reasons, para. 30).

DECISION UNDER APPEAL

[11] In the decision under appeal Shore J. held that the '777 Patent was valid and rejected Apotex' allegations of anticipation, obviousness and double patenting. In particular, the Applications Judge concluded, that claim 1 of the '777 Patent was not anticipated by the prior art, since an ordinary person skilled in the art who followed the teachings of the '875 Patent would only be able to replicate the racemate and not the dextro-rotatory isomer (Reasons, para. 88).

[12] He further held that claim 1 was not obvious, since a chemist would not be able to determine which isomer possessed the beneficial properties without first separating the optical isomer and testing them (Reasons, para. 89).

[13] The Applications Judge further found that claim 3 was neither anticipated, nor obvious, since the '875 Patent does not explain how to obtain a separated dextro-rotatory isomer of the racemate, and there is sufficient inventive ingenuity in the selection of the bisulfate salt that it could not have been obtained following the prior art (Reasons, paras. 90 and 91).

[14] Finally, given these findings, the Applications Judge held that claims 10 and 11 with respect to pharmaceutical compositions of the dextro-rotatory isomer of the racemate are neither anticipated, nor obvious (Reasons, para. 92).

ISSUES

[15] The issues, as defined by the appellant, are restricted to the following three questions of law:

a. Did the Applications Judge err in failing to adopt the perspective of the notional technician skilled in the art for the purpose of construing the '777 Patent and the prior patents, and for the purpose of assessing the questions of anticipation, obviousness and double patenting?
b. Did the Applications Judge err in stripping the notional person skilled in the art of the ability to perform workshop activity when assessing the questions of anticipation, obviousness and double patenting, and by finding that the application of known techniques to ascertain the inherent properties of known compounds was inventive?
c. Did the Applications Judge err in failing to follow this Court's decision in *SmithKline Beecham Pharma Inc. v. Apotex Inc*. on the question of anticipation?

ANALYSIS

Preliminary Comment

[16] As background to its arguments on appeal, the appellant claims that Shore J. erred in treating the patent in issue as a valid selection patent. Although Shore J. did not actually use the expression "selection patent", he did conduct his analysis on the basis that the '777 Patent came within that description. Simply put, a valid selection patent is one which claims

an advantage for a compound within a previously disclosed class of compounds which has not been disclosed in the prior patent.

[17] The law with respect to selection patents was recently applied by this Court in *Pfizer Canada Inc. v. (Minister of Health)*, 2006 FCA 214 (*Pfizer v. Canada*). Malone J.A. writing for the Court explained the rationale for the treatment given to selection patents:

> [3] There are two general classes of chemical patents. The first is the 'originating patent' where there is an originating invention involving the discovery of a new reaction or a new compound. The second is the 'selection patent', which is based on a selection from related compounds derived from the original compound and which have been described in general terms and claimed in the originating patent (see *In the Matter of I.G. Farbenindustrie A.G.'s Patents*, (1930) 47 R.P.C. 283 at page 321 per Maugham J.).
>
> [4] While there is little Canadian jurisprudence on the subject of selection patents, its elements are well defined in *I.G. Farbenindustrie*. Lord Diplock cited this decision with approval in the House of Lords where he stated that the 'inventive step in a selection patent lies in the discovery that one or more members of a previously known class of products possess some special advantage for a particular purpose which could not be predicted before the discovery was made' (see *Beecham Group Ltd. v. Bristol Laboratories International S.A.* [1978] R.P.C. 521 at page 579). All claimed members of the known class must have the advantage and the advantage must not be one that those skilled in the art would expect to find in a large number of the previously disclosed class (i.e. a quality of special character) (see *I.G. Farbenindustrie* at page 323).
>
> [5] Selection patents exist to encourage researchers to further use their inventive skills so as to discover new advantages for compounds within the known class. A selection patent can be claimed for a selection from a class of thousands or for a selection of one out of two (see for example *I.G. Farbenindustrie* at page 323 and *E.I. Dupont de Nemours & Co (Witsiepse's) Application*,[1982] F.S.R. 303 (H.L) at page 310).

[18] In *E.I. Dupont de Nemours & Co.*, Lord Wilberforce provided the following guidance in determining when a prior publication will preclude the patenting of a related development (pp. 310-311):

> …, disclosing a prior invention does not amount to prior publication of a later invention if the former merely points the way which might lead to the latter. A much quoted and useful passage is that from the judgment of the Court of Appeal in *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co.* [1972] R.P.C. 456 at 486. There Sachs L.J. said:

> "A signpost, however, clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee."

Attractive metaphors may be dangerous for those in search of precision, but the passage illustrates the necessity that the alleged prior disclosure must clearly indicate that use of the relevant material (i.e. that ultimately selected) does result in a product having the advantages predicted for the class. The point is well put by the New Zealand Court of Appeal. Dealing with semi-synthetic penicillin, the court (per Cooke J.) said:

> "If such a compound has not been made before, its properties often cannot be predicted with any confidence; and where that is the case we do not consider that the invention claimed can fairly or accurately be described as 'published', even if a skilled chemist would realize that to make the compound by routine means would be practicable. A making of the compound and a discovery of its properties is necessary before the 'invention' has occurred and can be published." (My emphasis)

This is in line with, but adds a useful precision to what was said by Maugham J.:

> "It must be remembered, of course, that the selected compounds have not been made before, or the patent would fail for want of novelty." (I.G. Farbenindustrie A.G.'s Patents, 1.c. p. 321.)

[19] The '875 Patent and the '777 Patent lend themselves to the analysis predicated for selection patents. The '875 Patent discloses a general class of compounds useful in providing platelet aggregation inhibiting activity and a process for the preparation of such compounds. The '777 Patent on the other hand identifies the dextro-rotatory isomer of a particular racemate disclosed in the '875 Patent which has never been separated and which, once separated, produces an isomer found to have special properties.

[20] It follows that both patents must be examined to see whether the '875 Patent directs the way to this isomer (clopidogrel) and its special properties with sufficient clarity to bring it within the ambit of the '875 Patent. This is how the Applications Judge conducted his

analysis and this is the background against which the appellant's allegations of invalidity are to be assessed in this appeal.

Invalidity Based on Anticipation

[21] The appellant argues that the Applications judge erred in failing to apply the legal test for anticipation as formulated in *SmithKline Beecham Pharma Inc. v. Apotex Inc.*, 2002 FCA 216 (*SmithKline*). The *SmithKline* case, the appellant argues, is precisely analogous to the case at bar and should have been followed by Shore J. The appellant further argues that Shore J. erred in not permitting the person skilled in the art to exercise mechanical skill by employing trial and error experiments to arrive at the invention. Finally, the appellant submits that Shore J. erred by mistaking the inventor for the notional skilled person.

The Test

[22] The test for anticipation was set out by Hugessen J.A. in *Beloit Canada Ltd. v. Valmet Oy* (1986), 8 C.P.R. (3d) 289 (F.C.A.) at p. 297, and later adopted by the Supreme Court in *Free World Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024 (*Free World*), at paragraph 26:

> One must, in effect, be able to look at a prior single publication and find in it all the information which, for practical purposes, is needed to produce the claimed invention without the exercise of any inventive skill. The prior publication must contain so clear a direction that a skilled person reading and following it would in every case and without the possibility of error be led to the claimed invention. [emphasis added]

[23] Thus, the prior art must provide clear and sufficient direction which, if followed, would be within the claim. If further ingenuity is required to put the prior art into practice, it is not anticipation. In *Free World*, at paragraph 25, the Supreme Court of Canada noted the difficulty of establishing anticipation:

> Anticipation by publication is a difficult defence to establish because courts recognize that it is all too easy after an invention has been disclosed to find

> its antecedents in bits and pieces of earlier learning. It takes little ingenuity to assemble a dossier of prior art with the benefit of 20-20 hindsight.

[24] In *SmithKline*, the test for anticipation was explained by Linden J.A. He held, at paragraph 19:

> The cases referred to by SmithKline [*Pfizer Canada Inc. v. Apotex Inc.* (1997), 77 C.P.R. (3d) 547; *Farbwerke Hoechst v. Halocarbon (Ontario) Ltd.*, [1979] 2 S.C.R. 929, at page 942; and *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co.*, [1972] R.P.C. 457 (C.A.)] are distinguishable from the situation before this Court. In each of the cases cited by SmithKline, the instructions of the prior art set out a general class of compounds or reactions from which one could arrive at the later invention. The later inventions were not anticipated in those cases because the particular compounds in the claimed invention were not identified in the prior art and, therefore, the identification of the particular compounds used in the claimed invention was novel and inventive. In those cases, the prior art did not "enable a person of ordinary skill and knowledge in the field to understand . . . `the nature of the invention and carry it into practical use without the aid of inventive genius but purely by mechanical skill'" (*Free World Trust, supra*, at paragraph 26). Since the prior art in those cases did not clearly and simply describe the latter alleged invention, a further inventive step was required.

Linden J.A. added that where an "inventive step or skill" was required, there could be no anticipation.

[25] In the present case, the Applications Judge found that the impugned claims of the '777 Patent were not anticipated. His conclusion was based on the finding that, although the '875 Patent generally discloses the existence of optical isomers as part of a large class of compounds, it does not specially disclose the optical isomers of the compound in question or their properties. Shore J. also noted that if one were to follow the teachings of the prior art, one would obtain a racemate, and never an optical isomer (Reasons, para. 60).

[26] In holding that anticipation had not been demonstrated, Shore J. relied on the decision of the Federal Court, Trial Division in *Pfizer Canada Inc. v. Apotex Inc.* (1997), 77

C.P.R. (3d) 547 (*Pfizer v. Apotex*). In that case, a prior art patent was found not to be an anticipation of a specific compound because one could follow the prior art and not be able to make the compound. While Apotex argued before Shore J. that *Pfizer v. Apotex* was implicitly overuled by *SmithKline*, he found that the latter decision merely distinguished *Pfizer v. Apotex* on its facts. It did not, as Apotex suggested, preclude a finding that a prior art patent that does not identify a specific compound of a broad generic class of compounds is not anticipated (Reasons, para. 59 *infine*).

[27] There is no doubt about the correctness of that conclusion, given the recent pronouncement by this Court in *Pfizer v. Canada*, *supra* in which the Court upheld the validity of a patent as a selection patent despite the fact that the claimed substance came within the general class of compounds claimed in a prior patent.

[28] In my respectful view, it was open to the Application Judge on the record before him to conclude that the ‘875 Patent did not specifically lead to the claimed invention. The processes disclosed only resulted in a racemate and although Example 1 in the ‘875 Patent refers to the separation of the isomers “if desired” there are no references to techniques for separating the isomers (Reasons, para. 29). Indeed, the evidence shows that it is impossible to predict which method of separating the enantiomers will work.

Trial and Error

[29] Apotex attempted to fill the gap by insisting on the uncontested fact that the methods for separating the enantiomers are well known to persons skilled in the art. According to Apotex such a person could eventually obtain the isomer through what amounts to mere verification.

[30] However, the Applications Judge found that the evidence with respect to the methods of separation including that of the inventor, shows that the identification of clopidogrel and its advantages required extensive investigation over a period of months (Reasons, paras 68 to 70). Shore J. further found that the special properties of the claimed isomer could not have been ascertained before it was produced and tested (Reasons, paras. 81 and 82). These findings are inconsistent with Apotex' argument that only mere verification was involved (i.e., confirming predicted and predictable qualities of known compounds) and indeed exclude the possibility of anticipation (see *Pfizer v. Canada*, *supra*, at paras. 21 to 24).

[31] Shore J. went on to find that the '875 Patent did not disclose the advantages which flow from using only the dextro-rotatory isomer (i.e., in contrast with the levo-rotatory isomer, it is both more active and less toxic). He found that both these beneficial properties were unexpected and could not have been anticipated from the teachings of the '875 Patent.

[32] At the hearing of the appeal, Apotex argued that there was no evidentiary foundation for the finding that the advantages of the dextro-rotatory isomer were unexpected. Counsel for Apotex referred to the evidence of Dr. McClelland, that on the basis of the prior art it was known that these advantages would "often" result. Counsel argued that if this is so, the alleged advantages could not have been unexpected.

[33] However, counsel for the respondent took us to the affidavit evidence and the transcript of Dr. McClelland's cross-examination and demonstrated that while Dr. McClelland did indicate that you "often" get more activity, the answer to the question whether this increased activity was to be found in the levo-rotatory isomer (the *l* enantiomer) or the dextro-rotatory isomer (the *d* enantiomer) was unknown (see the Affidavit of Dr. McClelland, A.B.,Vol. II, p. 369 at para. 42 and the Cross-examination of Dr. McClelland, A.B., Vol. III, at pages 928-930). Moreover, there was no evidence that the person skilled in the art would know that the more active isomer would also be less toxic (Cross-examination of Dr. McClelland, supra, question 322).

Person Skilled in the Art

[34] Apotex further argues that Shore J. erred in confusing the inventor of the compound (Mr. Badorc) with the ordinary person skilled in the art. According to Apotex, this error was compounded when Shore J. concluded that, since Mr. Badorc did not easily arrive at the invention, it could not have been anticipated (Appellant's Memorandum, paras. 31-34).

[35] With respect, I do not believe that to be the case. Shore J. set the parameters of the ordinary person skilled in the art, based on the description proposed by the parties at paragraphs 18 and 19 of his reasons, and concluded at paragraph 69 that Mr. Badorc "possessed the characteristics" of a person skilled in the art. In my view, this shows that Shore J. did not equate Mr. Badorc to the notional construct of the skilled person. Rather, he held that, although the inventor, Mr. Badorc also had the characteristics of the person skilled in the art.

[36] According to Shore J., even though Mr. Badorc possessed these characteristics, he was still unable to separate the isomer "in every event and without the possibility of error". Not only does this show that the prior art was lacking in clarity and direction for the separation of the isomers in question, it also serves to demonstrate that, despite Mr. Badorc's intuitive abilities, he was unable to replicate the experiment without difficulty and without error.

[37] In my respectful view, Apotex has failed to demonstrate that in this case, the prior art would lead the person skilled in the art in every case and without the possibility of error to the claimed invention. The argument that Shore J. erred in concluding that the '777 Patent is invalid based on anticipation must accordingly fail.

Obviousness

[38] The test for obviousness was set out in *Beloit*, at 294:

> The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be asked is whether this mythical creature (the man in the Clapham omnibus of patent law) would, in the light of the state of the art and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy.

[39] Apotex submits that Shore J. incorrectly applied this test. In its memorandum, it argues that the correct approach to determine the obviousness of a claim for a single enantiomer of a previously-known racemate was described in the recent Federal Court decision refusing the issuance of an order of prohibition in *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2004 FC 1631, per Mosley J (Appellant's Memorandum, para. 46). In that case, it was found that the claims for levofloxacin, its salts and their formulations were obvious, even though the process required the skilled person to separate the enantiomers, compare their utility and prepare suitable formulations. Apotex takes the position in its memorandum that the separation process involved in the present case is indistinguishable. Mosley J's decision was confirmed on appeal, but on grounds which do not address its merits (2005 FCA 2; leave to appeal to the S.C.C. refused, [2005] 1 S.C.R. 776).

[40] However, since that time and after Apotex filed its memorandum, Hughes J. of the Federal Court rendered a further decision in an infringement case involving the same patent and the same parties in which, relying on a more fulsome record, he declined to follow the approach predicated by Mosley J. and indeed came to the opposite conclusion on the issue

with which we are concerned (see *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2006 FC 1234 at paras. 115-116). Apotex, without withdrawing its argument that Mosley J. adopted the proper approach, did not speak to this argument at the hearing of the appeal. Given that the decision of Hughes J. is currently under appeal it is sufficient to say that I can detect no error in Shore J's application of the law to the facts before him.

[41] Beyond this first argument, Apotex repeats and adopts the submissions made with respect to anticipation (as applicable) insisting that, since the methods of separation were well known, the claimed invention and its advantages would have been obvious to the person skilled in the art (Memorandum, paras. 54-57).

[42] However, as alluded to earlier, Shore J. found that although well known, the separation techniques had to be tried with uncertainty as to which would actually result in a successful separation. He further found that the person skilled would not know, before separating the racemate into its isomers and then testing the separated isomers, what the properties of the dextro-rotatory isomer would be (Reasons, para. 81). Similarly, he found that the person skilled in the art would not know before trying the different salts in combination with the dextro-rotatory isomer what the bisulfate salt's beneficial properties would be (Reasons, para. 82). Moreover, it would seem from the evidence of Mr. Badorc that each of the methods of separation presented their own technical difficulties. It was not a matter of mechanically going through questions on a checklist.

[43] These findings of fact as to the difficulty involved in producing the claimed compounds and the impossibility of predicting the claimed advantages before the compounds could be produced and actually tested are amply supported by the record and unchallenged by Apotex (otherwise than by its attempt to recast these findings through its own – and in my respectful view flawed – vision of the person skilled in the art).

[44] In the end, Shore J. held, at paragraph 84 of his reasons, that "a person skilled in the art would not, in light of the prior art, have been led directly and without difficulty to the dextro-rotatory isomer of the racemate, its bisulfate salt and their pharmaceutical compositions." It has not been shown that Shore J. committed any reviewable error in coming to this conclusion.

Double Patenting

[45] Finally, Apotex submits that the claims for the '777 Patent are invalid for double patenting. A claim of a patent is invalid for double patenting if the same invention is the subject of a prior patent. The rule is that no person may obtain two patents for the same invention thereby extending the statutory monopoly for what is claimed in the first patent (*Whirlpool v. Canco*, 2006, 9 C.P.R. (4th) 129 at para. 63 (S.C.C.).

[46] The short answer to this argument is that in this case, the relevant art relied upon for double patenting is the same as that which has been canvassed in the analysis pertaining to

anticipation and obviousness. Since, based on that analysis, the ‘875 Patent and the ‘777 Patent claim different and distinct compounds, there cannot be “double patenting”.

[47] I would dismiss the appeal with costs.

“Marc Noël”

J.A.

“I agree
J. Richard C.J.”

“I agree
John M. Evans J.A.”

FEDERAL COURT OF APPEAL

Names of Counsel and Solicitors of Record

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