Apotex Inc. v. Sanofi-Synthelabo Canada Inc.
[2008] 3 S.C.R. 265, 2008 SCC 61

The judgment of the Court was delivered by

ROTHSTEIN J. —

I. Introduction

[1] This appeal raises questions relating to the validity of what are known as selection patents. In the context of chemical compounds, in general terms, a selection patent is one whose subject matter (compounds) is a fraction of a larger known class of compounds which was the subject matter of a prior patent.

[2] The appellant ("Apotex") challenges the validity of the selection patent in this case on the grounds of anticipation, obviousness and double patenting. I would dismiss the appeal.

II. Facts

[3] The parties have accepted that the Sanofi respondents ("Sanofi") are the relevant holders of patent 1,194,875 ('875 patent). This patent disclosed a genus or class of compounds useful in inhibiting platelet aggregation activity in the blood which is important in treating coronary artery, peripheral vascular and cerebral vascular diseases. This genus patent discloses over 250,000 possible different compounds useful for this purpose. One of the compounds is a racemate described as methyl alpha-5 (4,5,6,7-tetrahydro (3, 2-c)-thieno pyridyl) (2-chlorophenyl)-acetate (the "racemate").

[4] A racemate is a substance containing equal amounts of two structurally different compounds, called enantiomers or optical isomers. The two isomers, the dextro-rotatory isomer and the levo-rotatory isomer, are mirror images of each other and rotate plane-polarized light in opposite directions.

[5] The parties have accepted that Sanofi is also the relevant holder of subsequent Canadian patent 1,336,777 ('777 patent), the patent in suit. It discloses and claims clopidogrel bisulfate, which is marketed by Sanofi under the trade name of Plavix as an anti-coagulant that inhibits platelet aggregation activity in the blood.

[6] Clopidogrel bisulfate is encompassed within the scope of the claims in the '875 patent. Clopidogrel is the dextro-rotatory isomer of the racemate, having beneficial properties over both the racemate and the levo-rotatory isomer. The dextro-rotatory isomer exhibits a platelet aggregation inhibiting activity and is less toxic and better tolerated than the levo-rotatory isomer and racemate. The salts of the dextro-rotatory isomer, such as clopidogrel bisulfate, have a better therapeutic index than the salts of the racemic mixture and in fact, the levo-rotatory isomer exhibits almost no platelet aggregation inhibiting activity, and its toxicity is markedly higher than that of the dextro-rotatory isomer.

[7] On March 10, 2003, Apotex served a notice of allegation under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("*NOC Regulations*"), on Sanofi for the purpose of obtaining a notice of compliance pursuant to s. C.08.004 of the *Food and Drug Regulations*, C.R.C. 1978, c. 870, from the Minister of Health for a generic version of Plavix. The basis of Apotex's notice of allegation was that it would not infringe Sanofi's '777 patent for Plavix because the '777 patent was invalid on account of anticipation, obviousness and double patenting. On April 28, 2003, Sanofi initiated proceedings under s. 6(1) of the *NOC Regulations* in the Federal Court seeking an order prohibiting the Minister of Health from issuing a notice of compliance to Apotex on the grounds that its generic version of Plavix would infringe the '777 patent. The Federal Court granted the order of prohibition ((2005), 271 F.T.R. 159, 2005 FC 390). The Federal Court of Appeal dismissed Apotex's appeal ((2006), 282 D.L.R. (4th) 179, 2006 FCA 421).

III. Selection Patents

[8] This appeal requires the Court to determine whether selection patents are invalid in principle or on the facts of this case on the grounds of anticipation, obviousness and double patenting.

[9] The *locus classicus* describing selection patents is the decision of Maugham J. in *In re I. G. Farbenindustrie A. G.'s Patents* (1930), 47 R.P.C. 289 (Ch. D.). At p. 321, he explained that in the field of chemical patents (which would of course include pharmaceutical compounds), there are often two "sharply divided classes". The first class of patents, which he called originating patents, are based on an originating invention, namely, the discovery of a new reaction or a new compound. The second class comprises patents based on a selection of compounds from those described in general terms and claimed in the originating patent. Maugham J. cautioned that the selected compounds cannot have been made before, or the selection patent "would fail for want of novelty". But if the selected compound is "novel" and "possess[es] a special property of an unexpected character", the required "inventive" step would be satisfied (p. 321). At p. 322, Maugham J. stated that a selection patent "does not in its nature differ from any other patent".

[10] While not exhaustively defining a selection patent, he set out (at pp. 322-23) three conditions that must be satisfied for a selection patent to be valid.

1. There must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members.

2. The whole of the selected members (subject to "a few exceptions here and there") possess the advantage in question.

3. The selection must be in respect of a quality of a special character peculiar to the selected group. If further research revealed a small number of unselected compounds possessing the same advantage, that would not invalidate the selection patent. However, if research showed that a larger number of unselected compounds possessed the same advantage, the quality of the compound claimed in the selection patent would not be of

a special character.

[11] Although much has been written about selection patents since *I. G. Farbenindustrie*, Maugham J.'s analysis is consistently referred to and is well accepted. I find it is a useful starting point for the analysis to be conducted in this case.

V. Anticipation

(a) *Relevant Legislation*

[12] For purposes of anticipation, it is necessary to have regard to s. 27 of the Act which sets forth the basic conditions necessary for obtaining a patent. [The patent in this case was issued under the old Patent Act. While there are now important differences in grace period, etc. the standard for anticipation itself, which is at issue in this case, is not different.]

. . .

[13] It is with s. 27 in mind that the law of anticipation must be considered. Apotex's arguments based on anticipation are not that the applications judge erred in his analysis of the law of anticipation or its application to the facts of this case. Rather, Apotex implies that the current understanding of the law sets the bar for proving anticipation too high and that the acceptance of a system of genus and selection patents necessarily, or at least on the facts of this case, involves anticipation and therefore invalidity. I would reject the broader objection. A system of genus and selection patents is acceptable in principle, on the line of authority stemming from *I. G. Farbenindustrie*. The real question is whether, on the facts of this case, the particular selection patent has been anticipated.

(b) *Reasons of the Applications Judge*

. . .

(c) *Recent United Kingdom Jurisprudence*

[14] For the reasons that follow, and in light of recent jurisprudence, I am of the respectful opinion that the applications judge overstated the stringency of the test for anticipation that the "exact invention" has already been made and publicly disclosed.

[15] In the 2005 decision of the House of Lords in *Synthon*, Lord Hoffmann has brought some further clarity to the law of anticipation as understood since *General Tire*. His reference at para. 20 to the "unquestionable authority" of Lord Westbury in *Hills v. Evans* (1862), 31 L.J. Ch. (N.S.) 457, at p. 463, makes it plain that his analysis does not depend on any change on English law flowing from the enactment of the *Patents Act 1977* (U.K.), 1977, c. 37, or the U.K.'s adoption of the *Convention on the Grant of European Patents*, 1065 U.N.T.S. 199 (entered into force October 7, 1977). He distinguishes between two requirements for anticipation that were not theretofore expressly considered separately, prior disclosure and enablement.

[16] He explains that the requirement of prior disclosure means that the prior patent must disclose subject matter which, if performed, would necessarily result in infringement of that patent, and states, at para. 22:

> If I may summarise the effect of these two well-known statements [from *General Tire* and *Hills v. Evans*], the 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.

When considering the role of the person skilled in the art in respect of disclosure, the skilled person is "taken to be trying to understand what the author of the description [in the prior patent] meant" (para. 32). At this stage, there is no room for trial and error or experimentation by the skilled person. He is simply reading the prior patent for the purposes of understanding it.

[17] If the disclosure requirement is satisfied, the second requirement to prove anticipation is "enablement" which means that the person skilled in the art would have been able to perform the invention (para. 26). Lord Hoffmann held that the test for enablement for purposes of anticipation was the same as the test for sufficiency under the relevant United Kingdom legislation. (Enablement for the purposes of sufficiency of the patent specification under the Canadian *Patent Act*, s. 34(1)(*b*) of the pre-October 1, 1989 Act, now s. 27(3)(*b*), is not an issue to be decided in this case and my analysis of enablement is solely related to the test for anticipation. The question of whether enablement for purposes of sufficiency is identical in Canada is better left to another day.)

[18] Once the subject matter of the invention is disclosed by the prior patent, the person skilled in the art is assumed to be willing to make trial and error experiments to get it to work. While trial and error experimentation is permitted at the enablement stage, it is not at the disclosure stage. For purposes of enablement, the question is no longer what the skilled person would think the disclosure of the prior patent meant, but whether he or she would be able to work the invention.

[19] The *Beloit* decision by which the applications judge rightly felt bound dealt with only one aspect of anticipation, that is, whether or not the invention in a patent had been disclosed in a single prior publication or patent. In that decision, Hugessen J.A. held that it had not. He had no need to consider the further point whether or not, had there been such a clear disclosure, the working of the invention was also enabled by that disclosure. That point was not in issue in *Beloit*. Explicitly separating disclosure and enablement is a refinement of the approach set out in *Beloit*. It explains the process a person skilled in the art would follow if the original patent anticipated the invention of the subsequent patent. I would adopt this approach.

[20] Subject to any limitations expressed in the *Patent Act*, I see no reason why the discussion of anticipation should not apply to other prior art than merely genus patents. Again, subject to limitations in the *Patent Act*, the discussion of anticipation and obviousness would seem applicable to patents generally.

[21] Two questions now must be answered: (1) what constitutes disclosure at the first stage of the test for anticipation, and (2) how much trial and error or experimentation is permitted at the

enablement stage?

i. Disclosure

[22] Section 27(1) of the Act requires as a condition for obtaining a patent that the invention was not "known or used" and was not "described" in any patent or any publication more than two years before the patent application was filed. In the context of genus and selection patents, in *E. I. Du Pont de Nemours & Co. (Witsiepe's) Application*, [1982] F.S.R. 303 (H.L.), Lord Wilberforce stated, at p. 311:

> It is the absence of the discovery of the special advantages, as well as the fact of non-making, that makes it possible for such persons to make an invention related to a member of the class.

The compound made for the selection patent was only soundly predicted at the time of the genus patent. It was not made and its special advantages were not known. It is for those reasons that a patent should not be denied to the inventor who made and discovered the special advantages of the selection compound for the first time.

[23] In the context of disclosure as explained in *Synthon*, "the absence of the discovery of the special advantages" to which Lord Wilberforce was referring in *Witsiepe's* means that the genus patent does not disclose the special advantages of the invention covered by the selection patent. Where there is no such disclosure, there is no discovery of the special advantages of the selection patent as compared to the genus patent, and the disclosure requirement to prove anticipation fails. At this stage, the person skilled in the art is reading the prior patent to understand whether it discloses the special advantages of the second invention. No trial and error is permitted. If in reading the genus patent the special advantages of the invention of the selection patent are not disclosed, the genus patent does not anticipate the selection patent.

ii. Enablement

[24] What amount of trial and error or experimentation is permitted before a prior disclosure will not constitute enabling disclosure? Certainly, if the applications judge finds that an inventive step was required to get to the invention of the second patent, the specification of the first patent will not have provided enabling disclosure. But even if no inventive step is required, the skilled person must still be able to perform or make the invention of the second patent without undue burden.

[25] Two recent United Kingdom decisions are of assistance. In *Halliburton Energy Services Inc. v. Smith International (North Sea) Ltd.*, [2006] EWCA Civ 1715 (BAILII), Jacob L.J., a highly experienced patent judge, states at para. 18:

> Patents are meant to teach people how to do things. If what is "taught" involves just too much [work] to be reasonable allowing for all the circumstances including the nature of the art, then the patent cannot be regarded as an "enabling disclosure." . . . The setting of a gigantic project, even if merely routine, will not do.

[26] Jacob L.J. characterizes the problem at para. 20 as: "[H]ow is one to say when the work involved to perform the invention is too much?" The determination of how much work is too much is inevitably a line-drawing exercise. His answer to the problem is at para. 21:

> The answer is that the line is one to be drawn by an exercise of judgment, taking into account all of the relevant factors, one of which is of course the nature of the invention itself and its field of technology. But there are other factors too — for instance, the width of the patent claim or whether it has functional limitations which require too much work to explore.

[27] A more extensive review of the law of enablement as defined in *Synthon* is contained in a decision of Kitchin J. in *Wobben v. Vestas-Celtic Wind Technology Ltd.*, [2007] EWHC 2636 (Pat.) (BAILII), at paras. 196-97. Although *Wobben* was a case in which the alleged infringer raised as one of its defences insufficiency under the United Kingdom legislation, I think guidance is provided as to what will or will not constitute enablement for purposes of anticipation.

[28] Drawing from this jurisprudence, I am of the opinion that the following factors should normally be considered. The list is not exhaustive. The factors will apply in accordance with the evidence in each case.

1. Enablement is to be assessed having regard to the prior patent as a whole including the specification and the claims. There is no reason to limit what the skilled person may consider in the prior patent in order to discover how to perform or make the invention of the subsequent patent. The entire prior patent constitutes prior art.

2. The skilled person may use his or her common general knowledge to supplement information contained in the prior patent. Common general knowledge means knowledge generally known by persons skilled in the relevant art at the relevant time.

3. The prior patent must provide enough information to allow the subsequently claimed invention to be performed without undue burden. When considering whether there is undue burden, the nature of the invention must be taken into account. For example, if the invention takes place in a field of technology in which trials and experiments are generally carried out, the threshold for undue burden will tend to be higher than in circumstances in which less effort is normal. If inventive steps are required, the prior art will not be considered as enabling. However, routine trials are acceptable and would not be considered undue burden. But experiments or trials and errors are not to be prolonged even in fields of technology in which trials and experiments are generally carried out. No time limits on exercises of energy can be laid down; however, prolonged or arduous trial and error would not be considered routine.

4. Obvious errors or omissions in the prior patent will not prevent enablement if reasonable skill and knowledge in the art could readily correct the error or find what was omitted.

[On the facts, the Court held that the disclosure branch had not been satisfied because "the '875

patent did not disclose the special advantages of the dextro-rotatory isomer and of its bisulfate salt, as compared to the levo-rotatory isomer or the racemate and their salts, or the other compounds made and tested or otherwise referred to in the '875 patent, the invention of the '777 patent cannot be said to have been disclosed and therefore it cannot be said to have been anticipated."]

(e) *Conclusion on Anticipation*

[29] As indicated above, in the context of anticipation, the two-step approach, disclosure and enablement, is a refinement of the approach set out in *Beloit* and should be adopted.

[30] In the case at bar, the invention of the '777 patent was not disclosed by the '875 patent and was therefore not anticipated. The allegation of anticipation has not been justified.

VI. Obviousness

(a) *Relevant Legislation*

[31] The definition of invention in s. 2 of the Act is relevant because at the time the pre-October 1, 1989 version of the Act was in force, there was no statutory provision expressly providing that obvious inventions were unpatentable. As explained by Professor D. Vaver in *Intellectual Property Law: Copyright, Patents, Trade-marks* (1997), at p. 136:

> Until very recently, the *Patent Act* did not expressly say that obvious inventions were unpatentable. Courts implied this criterion from the notion of "invention". Inventions implied inventive ingenuity, without which an advance was obvious; and patents are not granted for the obvious.

The definition of invention in s. 2 of the Act provided:

> "invention" means any new and useful . . . composition of matter, or any new and useful improvement in any . . . composition of matter;

(b) *Reasons of the Applications Judge*

[32] Shore J. first correctly observed that at the relevant time obviousness was not mentioned expressly in the Act. He then cited the well-known test for obviousness in *Beloit* (at p. 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. [Emphasis added by the applications judge; para. 75.]

In the view of Shore J., the *Beloit* test would not accommodate a "worth a try" test by the skilled person.

[33] The applications judge accepted that there were five well-known separation techniques in order to obtain the dextro-rotatory isomer of the racemate. At para. 80, he stated:

> . . . what the experts are really saying from a legal perspective is that separating the racemate was worth a try. Having to try different methods, though they be well-known, in order to discover which one will yield the desired result cannot mean that the desired result, in this case, the compounds in claims 1 and 3 and their pharmaceutical compositions, was obvious.

[34] He further held that the dextro-rotatory isomer and its salts had to be tested for their beneficial properties to be discovered and that the isomer and its beneficial properties were therefore not known before the racemate was separated into its isomers. He stated, at para. 81:

> Here again, having to try different separation techniques with uncertainty as to whether each or some specific techniques would actually result in a successful separation and then having to perform tests to discover what the properties of the dextro-rotatory isomer of the racemate were, cannot mean that this compound and its beneficial properties were obvious.

(c) *United Kingdom and United States Approach to Obviousness*

[35] Apotex says that the *Beloit* approach is excessively rigid and is out of step with the tests for obviousness in the United Kingdom and the United States, where "worth a try" has been accepted.

[36] Generally, in the United States, it appears that at the Court of Appeals level, the "obvious to try" test had not been accepted. In *Application of Tomlinson*, 363 F.2d 928 (C.C.P.A. 1966), Rich J. wrote, at p. 931:

> Slight reflection suggests, we think, that there is usually an element of "obviousness to try" in any research endeavor, that is not undertaken with complete blindness but rather with some semblance of a chance of success, and that patentability determinations based on that as the test would not only be contrary to statute but result in a marked deterioration of the entire patent system as an incentive to invest in those efforts and attempts which go by the name of "research".

See also *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988), at p. 903.

[37] However, in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), Kennedy

J., for a unanimous court, rejected the restrictive approach that the Court of Appeals had taken in that case. He stated, at p. 1739:

> Throughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM [Teaching-Suggestion-Motivation] test here. To be sure, *Graham* recognized the need for "uniformity and definiteness." Yet the principles laid down in *Graham* reaffirmed the "functional approach" of *Hotchkiss*. To this end, *Graham* set forth a broad inquiry and invited courts, where appropriate, to look at any secondary considerations that would prove instructive.

[38] At p. 1742, he was clear that "obvious to try" could be a relevant test in an obviousness inquiry:

> The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." . . . When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.

[39] In the United Kingdom the "obvious to try" test has been accepted since at least 1967: see *Johns-Manville Corporation's Patent*, [1967] R.P.C. 479 (C.A.). The current state of the law in the United Kingdom was summarized in *H. Lundbeck A/S v. Generics (UK) Ltd.*, [2008] R.P.C. 19 (p. 437), [2008] EWCA Civ 311. Lord Hoffmann stated the following, at paras. 24-25, in response to the argument that the trial judge in that case, Kitchin J., had refused to consider the "obvious to try" test:

> [The trial judge] cited from *Angiotech Pharmaceuticals Inc. v. Conor Medsystems Inc.* [2007] R.P.C. 20, which represents this [Court of Appeal's] last word on the extent to which the notion of some step being obvious to try is helpful in deciding whether an invention is obvious. The judge then summed up (at para. 72) the current state of the law:
>
> > "The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success."
> >
> > No criticism has been made of this statement of principle . . . .

See also *Angiotech Pharmaceuticals Inc. v. Conor Medsystems Inc.*, [2007] R.P.C. 20 (p. 487), [2007] EWCA Civ 5, at para. 45 (rev'd [2008] R.P.C. 28 (p. 716), [2008] UKHL 49). The passage at para. 45 in the decision of the Court of Appeal remains relevant and uncontested.

[40] There is a similarity between the current state of the law in the United Kingdom and the United States in respect of "obvious to try". It is now clear that both jurisdictions accept that an "obvious to try" test can be relevant in an obviousness inquiry. The United States Supreme Court has now stated so explicitly in *KSR*. The convergence of the United Kingdom and the United States law on this issue suggests that the restrictiveness with which the *Beloit* test has been interpreted in Canada should be re-examined.

(d) *Approach to Obviousness in Canada*

[41] I take as a starting point the words of Diplock L.J. in *Johns-Manville*, at pp. 493-94:

> Patent law can too easily be bedevilled by linguistics, and the citation of a plethora of cases about other inventions of different kinds. The correctness of a decision upon an issue of obviousness does not depend upon whether or not the decider has paraphrased the words of the Act in some particular verbal formula. I doubt whether there is any verbal formula which is appropriate to all classes of claims.

Although we are not here dealing with obviousness provided by an express statutory test, but rather by necessary implication based on the requirement for invention in the *Patent Act*, the words of Diplock L.J. are nonetheless apt because the courts have often tended to treat the word formulation of *Beloit* as if it were a statutory prescription that limits the obviousness inquiry.

[42] I do not think that Hugessen J.A. in *Beloit* intended that the rather colourful description of obviousness that he coined be applied in an acontextual manner applicable to all classes of claims. I note particularly that "obvious to try" is not a mandatory test in the United Kingdom or in the United States. It is one factor of a number that should be considered, having regard to the context and the nature of the invention.

[43] In *KSR*, Kennedy J. warns against an overly rigid rule that limits the obviousness inquiry. Rather, an expansive and flexible approach that would include "any secondary considerations that [will] prove instructive" will be useful (p. 1739). I read *KSR* as teaching that as in most matters in which a judge or a jury is called upon to make a factual determination, rigid rules are inappropriate unless mandated by statute.

[44] While I do not think the list is exhaustive, the factors set forth by Kitchin J. and adopted by Lord Hoffmann in *Lundbeck*, referred to at para. 59 of these reasons, are useful guides in deciding whether a particular step was "obvious to try". However, the "obvious to try" test must be approached cautiously. It is only one factor to assist in the obviousness inquiry. It is not a panacea for alleged infringers. The patent system is intended to provide an economic encouragement for research and development. It is well known that this is particularly important in the field of pharmaceuticals and biotechnology.

[45] In *Saint-Gobain PAM SA v. Fusion Provida Ltd.*, [2005] EWCA Civ 177 (BAILII), Jacob L.J. stated, at para. 35:

> Mere possible inclusion of something within a research programme on the basis you will find out more and something might turn up is not enough. If it were otherwise there would be few inventions that were patentable. The only research which would be worthwhile (because of the prospect of protection) would be into areas totally devoid of prospect. The "obvious to try" test really only works where it is more-or-less self-evident that what is being tested ought to work.

In *General Tire*, Sachs L.J. said, at p. 497:

> "Obvious" is, after all, a much-used word and it does not seem to us that there is any need to go beyond the primary dictionary meaning of "very plain".

In *Intellectual Property Law*, at p. 136, Professor Vaver also equates "obvious" to "very plain". I am of the opinion that the "obvious to try" test will work only where it is very plain or, to use the words of Jacob L.J., more or less self-evident that what is being tested ought to work.

[46] For a finding that an invention was "obvious to try", there must be evidence to convince a judge on a balance of probabilities that it was more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough.

[47] It will be useful in an obviousness inquiry to follow the four-step approach first outlined by Oliver L.J. in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*, [1985] R.P.C. 59 (C.A.). This approach should bring better structure to the obviousness inquiry and more objectivity and clarity to the analysis. The *Windsurfing* approach was recently updated by Jacob L.J. in *Pozzoli SPA v. BDMO SA*, [2007] F.S.R. 37 (p. 872), [2007] EWCA Civ 588, at para. 23:

> In the result I would restate the *Windsurfing* questions thus:
>
> (1) (a) Identify the notional "person skilled in the art";
>
> (b) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
>
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the

> person skilled in the art or do they require any degree of invention? [Emphasis added.]

It will be at the fourth step of the *Windsurfing/Pozzoli* approach to obviousness that the issue of "obvious to try" will arise.

i. When Is the "Obvious to Try" Test Appropriate?

[48] In areas of endeavour where advances are often won by experimentation, an "obvious to try" test might be appropriate. In such areas, there may be numerous interrelated variables with which to experiment. For example, some inventions in the pharmaceutical industry might warrant an "obvious to try" test since there may be many chemically similar structures that can elicit different biological responses and offer the potential for significant therapeutic advances.

ii. "Obvious to Try" Considerations

[49] If an "obvious to try" test is warranted, the following factors should be taken into consideration at the fourth step of the obviousness inquiry. As with anticipation, this list is not exhaustive. The factors will apply in accordance with the evidence in each case.

1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?

2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?

3. Is there a motive provided in the prior art to find the solution the patent addresses?

[50] Another important factor may arise from considering the actual course of conduct which culminated in the making of the invention. It is true that obviousness is largely concerned with how a skilled worker would have acted in the light of the prior art. But this is no reason to exclude evidence of the history of the invention, particularly where the knowledge of those involved in finding the invention is no lower than what would be expected of the skilled person.

[51] For example, if the inventor and his or her team reached the invention quickly, easily, directly and relatively inexpensively, in light of the prior art and common general knowledge, that may be evidence supporting a finding of obviousness, unless the level at which they worked and their knowledge base was above what should be attributed to the skilled person. Their course of conduct would suggest that a skilled person, using his/her common general knowledge and the prior art, would have acted similarly and come up with the same result. On the other hand, if time, money and effort was expended in research looking for the result the invention ultimately provided before the inventor turned or was instructed to turn to search for the invention, including what turned out to be fruitless "wild goose chases", that evidence may support a finding of non-obviousness. It would suggest that the skilled person, using his/her common general knowledge and the prior art, would

have done no better. Indeed, where those involved including the inventor and his or her team were highly skilled in the particular technology involved, the evidence may suggest that the skilled person would have done a lot worse and would not likely have managed to find the invention. It would not have been obvious to him/her to try the course that led to the invention.

(e) *Application to the Facts of This Case*

[52] Applying the four steps of *Windsurfing/Pozzoli*, I accept the applications judge's findings of fact where they are unaffected by his rejection of the "obvious to try" test. Where application of the obvious to try test requires further consideration of the evidence, it will be necessary for this Court to make some findings of fact. In this case, I think it is preferable to remitting the matter to the trial judge for redetermination and subjecting his decision to further possible appeals.

[53] Apotex filed its notice of allegation in 2002. It is now some six years later. If the '777 patent is invalid, and provided all other requirements are met, Apotex should be entitled to a notice of compliance from the Minister without any further delay. Indeed, the *NOC Regulations* are intended to be a summary procedure. I think it is time that this matter finally be resolved. I would conduct the following analysis:

i. Identify the Notional Person Skilled in the Art

[54] Both parties agreed that a trained pharmachemist is that person.

ii. Identify the Relevant Common General Knowledge of That Person

[55] Apotex reiterates its submissions made with respect to anticipation, 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. Shore J. found on the evidence before him that there were five well-known methods to separate this racemate into its isomers. However, he did not find that the relative advantage of the dextro-rotatory isomer would have been known by the skilled person.

iii. Identify the Inventive Concept of the Claim in Question or, if That Cannot Readily Be Done, Construe It

[56] The construction of the claims in the '777 patent is not an issue. It is agreed that they constitute the dextro-rotatory isomer of the racemate and its pharmaceutically acceptable salts and processes for obtaining them.

[57] The inventive concept of the claims is not readily discernable from the claims themselves. A bare chemical formula in a patent claim may not be sufficient to determine its inventiveness. In such cases, I think it must be acceptable to read the specification in the patent to determine the inventive concept of the claims. Of course, it is not permissible to read the specification in order to construe the claims more narrowly or widely than the text will allow.

[58] In the present case, it is apparent that the inventive concept of the claims in the '777 patent is a compound useful in inhibiting platelet aggregation which has greater therapeutic effect and less toxicity than the other compounds of the '875 patent and the methods for obtaining that compound.

iv. Identify What if Any Differences Exist Between the '875 Patent and the '777 Patent

[59] The '875 patent disclosed over 250,000 possible different compounds predicted to inhibit platelet aggregation. Twenty-one compounds were made and tested. Nothing distinguishes the racemate in this case from other compounds disclosed or tested in terms of therapeutic effect or toxicity. As stated above, there is no disclosure in the '875 patent of the specific beneficial properties associated with the dextro-rotatory isomer of this racemate in isolation; nor was there disclosure of any advantages which flow from using the bisulfate salt of the dextro-rotatory isomer. The '875 patent did not differentiate between the properties of the racemate, its dextro-rotatory isomer and levo-rotatory isomer or indeed the other compounds made and tested or predicted to work.

[60] On the other hand, the '777 patent claims that the invention of the dextro-rotatory isomer of the racemate, clopidogrel, and its bisulfate salt discloses their beneficial properties over the levo-rotatory isomer and the racemate and expressly describes how to separate the racemate into its isomers.

v. Viewed Without Any Knowledge of the '777 Patent, Do Those Differences Constitute Steps Which Would Have Been Obvious to the Person Skilled in the Art or Do They Require a Degree of Inventiveness?

[61] At this stage, it must be determined whether the nature of the invention in this case is such as to warrant an "obvious to try" test. The discovery of the dextro-rotary isomer and its bisulfate salt came after experimentation. There were interrelated variables with which Mr. Badorc had to experiment. An "obvious to try" test in this case would recognize the evidence of the expert witnesses as to the discovery of the beneficial properties of the dextro-rotary isomer and its bisulfate salt and the methods for finding them.

[62] The applications judge cannot be faulted for the analysis he conducted as far as it went. However, he erred in not allowing for the application of the "obvious to try" test, which is warranted in this case.

[63] The following factors are therefore relevant at this fourth step of the obviousness inquiry:

(1) *Is It More or Less Self-Evident That What Is Being Tried Ought to Work?*

[64] As I have observed earlier, Shore J. found that the skilled person would not know, before separating this particular racemate into its isomers and then testing the separated isomers, that the properties of the dextro-rotatory isomer would be different from the properties of the racemate or

the levo-rotatory isomer (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 (para. 82).

[65] Just because there are known methods of separating a racemate into its isomers does not mean that a person skilled in the art would necessarily apply them. The fact that there are such known methods of separation will be of no account if the evidence does not prove that it was more or less self-evident to try them. It is true that at the relevant time there was evidence that a skilled person would know that the properties of a racemate and its isomers might be different. However, a possibility of finding the invention is not enough. The invention must be self-evident from the prior art and common general knowledge in order to satisfy the "obvious to try" test. That is not the evidence in this case.

(2) *What Is the Extent, Nature and Amount of Effort Required to Achieve the Invention?*

[66] As indicated, the applications judge found that there were five well-known techniques for separating this racemate into its isomers. He also found that there was no evidence that at the relevant time, a person skilled in the art would know which one would work with the racemate at issue in this case. The evidence was that a skilled person would eventually find the right technique.

[67] As earlier indicated, Shore J. also found that there was no evidence that at the relevant time a person skilled in the art would know before separating the racemate and testing the isomers what their properties would be, although the specific properties of the isomers could be discovered. There was evidence that, using known techniques, the properties of different pharmaceutically acceptable salts to be used with the dextro-rotatory isomer could be discovered.

[68] However, in considering whether it was "obvious to try" to find the invention, once it was decided to isolate the dextro-rotatory isomer, the methods for doing so were known, the methods for testing the properties of the isomers were known and the method for determining the beneficial properties of the salts to be used with the isomer would also have been known.

[69] According to Mr. Badorc's affidavit, it took from November 1985 to April 1986 to find the '777 invention, and he was already familiar with the '875 invention. Potentially five different methods to separate the racemate would have had to have been tried and tested before determining the properties of the dextro-rotatory isomer. As in the case of anticipation, one might infer that the applications judge, if asked to decide this question, would have held that the investigation here was not routine, but rather was prolonged and arduous. In any event, on the facts of this case, this factor would assume small significance in view of the finding I make with respect to the whole course of conduct discussed at para. 91 below.

(3) *Is There a Motive From the Prior Art to Find the Solution That the '777 Patent Addresses?*

[70] It is well known that the pharmaceutical industry is intensely competitive. Market participants are continuously in search of new and improved medications and want to reach the

market with them as soon as possible. So demand for an effective and non-toxic product to inhibit platelet aggregation might be assumed to exist. However, nothing in the '875 patent or common general knowledge provided a specific motivation for the skilled person to pursue the '777 invention. The prior patent was a genus patent, and selection might be expected. However, the prior patent did not differentiate between the efficacy and the toxicity of any of the compounds it covered. This suggests that what to select or omit was not then self-evident to the person skilled in the art.

(4) *What Is the Course of Conduct Which Was Followed Which Culminated in the Making of the Invention?*

[71] Mr. Badorc's affidavit reveals that for several years prior to November 1985, Sanofi was in the process of developing the racemate in its salified form. In November 1985, the racemate was being tested in preliminary human clinical trials. It was at that time that Mr. Badorc was asked to separate the racemate into its isomers. After he discovered that the dextro-rotatory isomer was active and non-toxic and that the levo-rotatory isomer was non-active and toxic, Sanofi decided to develop the dextro-rotatory isomer and abandon its work on the racemate. However, this was after it had "spent millions of dollars and several years developing [the racemate] up to the point of preliminary human clinical trials" without at least trying to see if the dextro-rotatory isomer had advantageous properties to those of the racemate (Affidavit of Mr. Badorc, at para. 25). This evidence was uncontradicted.

(5) *Was the Invention of the '777 Patent "Obvious to Try"?*

[72] The methods to obtain the invention of the '777 patent were common general knowledge. It can be assumed that there was a motive to find a non-toxic efficacious product to inhibit platelet aggregation in the blood. However, it was not self-evident from the '875 patent or common general knowledge what the properties of the dextro-rotatory isomer of this racemate would be or what the bisulfate salt's beneficial properties would be and therefore that what was being tried ought to work. The course of conduct and the time involved throughout demonstrate that the advantage of the dextro-rotatory isomer was not quickly or easily predictable. Had the dextro-rotatory isomer been "obvious to try", it is difficult to believe that Sanofi would not have opted for it before unnecessary time and investment were spent on the racemate. I conclude that the prior art and common general knowledge of persons skilled in the art at the relevant time were not sufficient for it to be more or less self-evident to try to find the dextro-rotatory isomer.

(f) *Conclusion on Obviousness*

[73] As I have earlier explained, there was a significant difference between the '875 genus patent and the '777 selection patent. The difference was not obvious. Having regard to the foregoing analysis, I conclude that the allegation of obviousness is not justified.