Federal Court of Appeal | Cour d'appel fédérale

Date: 20130724

Docket: A-7-12

Citation: 2013 FCA 186

CORAM: **NOËL J.A.**
PELLETIER J.A.
GAUTHIER J.A.

BETWEEN:

SANOFI-AVENTIS

Appellant

and

APOTEX INC.

Respondent

BETWEEN:

SANOFI-AVENTIS and
BRISTOL-MYERS SQUIBB SANOFI
PHARMACEUTICALS HOLDING PARTNERSHIP

Appellants

and

APOTEX INC.
APOTEX PHARMACHEM INC. and
SIGNA SA de CV

Respondents

Heard at Toronto, Ontario, on January 28, 2013.

Judgment delivered at Ottawa, Ontario, on July 24, 2013.

REASONS FOR JUDGMENT BY:	PELLETIER J.A.
CONCURRED IN BY:	NOËL J.A.
CONCURRING REASONS BY:	GAUTHIER J.A.

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REASONS FOR JUDGMENT

PELLETIER J.A.

INTRODUCTION:

[1] Plavix is a very successful anti-coagulant drug which was developed, patented, and marketed by the appellant, Sanofi-Aventis (Sanofi). Apotex Inc. (Apotex), a well known manufacturer and distributor of generic drugs, attempted to create and market its own version of the active ingredient in Plavix, clopidogrel bisulfate (clopidogrel). It applied for a Notice of Compliance from the Minister of Health, alleging that its version of clopidogrel did not infringe Sanofi's patent which, it alleged, was invalid in any event for a number of reasons, including obviousness. Sanofi responded by applying to the Federal Court for an order prohibiting the Minister from issuing the Notice of Compliance to Apotex. That application was successful so that Sanofi continued to enjoy a monopoly with respect to the manufacture and sale of Plavix: *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, 2005 FC 390, [2005] F.C.J. No. 482 (QL). Appeals to the Federal Court of Appeal, *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, 2006 FCA 421, [2006] F.C.J. No. 1945 (QL), and to the Supreme Court of Canada, *Apotex Inc. v. Sanofi-Synthelabo Canada inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 (*Plavix*), were unsuccessful.

[2] Apotex then commenced an action in the Federal Court seeking a declaration that Sanofi's patent, Canadian Patent No. 1,336,777 (the '777 Patent) was invalid. Sanofi replied by commencing its own action, alleging that Apotex had infringed its patent by importing clopidogrel into Canada from Mexico and then exporting it from Canada for sale in other countries including the United States. The two actions were consolidated and were heard by Boivin J. (the Trial Judge or simply, the Judge). Following a 26 day trial, the latter found that the

‘777 Patent was invalid for lack of utility on the basis that the promise of the patent had neither been demonstrated nor soundly predicted. In addition, the Trial Judge found that the invention described in the patent was obvious. Though the Trial Judge also found that Apotex had infringed the ‘777 Patent, that finding was overtaken by his conclusion that the patent was invalid. The Trial Judge’s decision is reported as *Apotex Inc. v. Sanofi-Aventis,* 2011 FC 1486, [2011] F.C.J. No. 1813 (QL), (Reasons).

[3] This is an appeal of that decision. It raises a variety of issues including the promise of the patent, obviousness, and the limitation period applicable to certain acts of patent infringement.

BACKGROUND

[4] The following factual background will provide context for the analysis which will follow.

[5] The ‘777 Patent is a selection patent which means that it claims a subset of compounds which are already within the scope of another patent, Canadian patent 1,194,875 (‘875 Patent). I can do no better, in terms of describing the relationship of the patents and compounds in issue, than to quote paragraphs 3 to 6 of the Supreme Court’s decision in *Plavix*:

> **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.

[6] While there are differences in the evidence which was before the Supreme Court in the Notice of Compliance proceedings (which gave rise to the *Plavix* decision) and the evidence in this action, none of those differences affect the accuracy the Supreme Court's description of the relationship of the compounds in issue and their structure.

The '777 Patent

[7] The issues raised by this appeal require an understanding of the '777 Patent.

[8] The patent begins with a description of its subject matter:

> The present invention relates to the dextro-rotatory enantiomer of methyl alpha-5 (4,5,6,7-tetrahydro (3,2-c) thieno pridyl) (2-chorophenyl)-acetate, a process for its preparation and pharmaceutical compositions containing it.

[9] Following a description of the formula of the invention, the patent describes its advantages:

> In an unexpected manner only the dextro-rotatory enantiomer I_d exhibits a platelet aggregation inhibiting activity, the levo-rotatory enantiomer I_l being inactive. However, the inactive levo-rotatory enantiomer I_l is the less well tolerated of the two enantiomers.
>
> The invention also relates to the addition salts of the compounds of formula (I_d) with pharmaceutically acceptable mineral or organic acids.

[10] The patent then describes the processes by which the invention can be made, setting out detailed instructions by which the enantiomer can be separated from its racemate and a suitable salt obtained.

[11] The next section of the patent is entitled "Pharmacological Activity". In it, one finds a comparison between the compound of the '777 patent and the racemic mixture from which it was derived with respect to platelet inhibiting activity and toxicity. Platelet aggregation studies in rats showed that the levo-rotatory isomer is inactive and that the dextro-rotatory isomer is at least as active as the racemate. A test of anti-thrombotic activity showed that the levo-rotatory isomer showed no anti-thrombotic activity whereas the racemate and the dextro-rotatory isomer did. Toxicity studies in rats showed that the toxicity of the racemic mixture was similar to that of the levo-rotatory isomer while the dextro-rotatory isomer is markedly less toxic.

[12] This section concludes as follows:

> The pharmacological study just presented has demonstrated the interesting inhibitory properties towards platelet aggregation of the compound I_d and the absence of any activity of its isomer I_l.
>
> The medicine of the invention can be made available for oral administration in form of tablets, sugar-coated tablets, capsules, drops, granules, or a syrup. It can also be made available in the form of suppositories or for parenteral administration in the form of an injectable solution.
>
> …
>
> On account of its interesting inhibitory properties towards platelet aggregation and its interference in the mechanism of formation of arterial and venous thromboses, the medicine of the invention can be usefully administered in the treatment and prevention of platelet disorders due to extracorporeal blood circuits or the consequence of complications in artheroma.

[13] The patent concludes with 11 claims which can be summarized as follows:

> - Claim 1 claims the dextro-rotatory isomer of methyl alpha-5 (4,5,6,7-tetrahydro (3,2-c) thieno pridyl) (2-chorophenyl)-acetate,
>
> - Claims 2 to 5 claim salts of the compound in Claim 1,
>
> - Claims 6 to 9 claim processes for preparation of the compound described in Claim 1,
>
> -Claim 10 claims a pharmaceutical composition comprising an effective amount of the compound in Claim 1 in admixture with a pharmaceutically acceptable carrier, and
>
> -Claim 11 claims a composition according to Claim 10 within a given dosage range.

THE DECISION UNDER APPEAL

[14] After disposing of a number of preliminary questions which are not in issue in this appeal, the Trial Judge addressed the construction of the patent. He first described the "inventive concept" of the patent, quoting the Supreme Court's statement in *Plavix*:

> 78 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.
>
> *Plavix*, at paragraph 78

[15] The Trial Judge then inquired into the relationship between the inventive concept and the invention itself. After a brief analysis relating to selection patents, the Trial Judge described the invention of the '777 Patent as follows:

> …a compound which is useful in inhibiting platelet aggregation, has greater therapeutic effect and less toxicity than the other compounds of the '875 Patent, has the advantages of the salts (crystallize easily, not hygroscopic, and sufficiently water soluble) and the methods for obtaining that compound.
>
> Reasons, at paragraph 140

[16] This led to the analysis of the promise of the patent. The Trial Judge identified the relationship between utility and the promise of the patent:

> It is also worth recalling the role of the promise of the patent with respect to utility. On behalf of the Federal Court of Appeal, Justice Laydon-Stevenson in *Ely Lilly Canada Inc.*, above, (FCA *Olanzapine*), at para 76, stated the following:
>
> > [76] Where the specification does not promise a specific result, no particular level of utility is required; a "mere scintilla" of utility will suffice. However, where the specification sets out an explicit "promise", utility will be measured against that promise: *Consolboard* ; *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2009] 1 F.C.R. 253, 2008 FCA 108 (*Ranbaxy*). The question is whether the invention does what the patent promises it will do.

> Reasons, at paragraph 143 (my emphasis)

[17] After having reviewed the expert evidence, the Trial Judge framed the issue as whether the '777 Patent promises use in humans or merely potential use in humans. The Judge then considered the wording of the '777 Patent, including the references to "the medicine of the invention" and "pharmaceutical compositions", as well as its relationship to the '875 Patent which explicitly referred to use in human and veterinary therapeutic applications. On the basis of this analysis, the Trial Judge concluded that:

> In summary, the Court concludes that the *POSITA* [Person of Ordinary Skill in the Art] would find the promise respecting the use of the invention of the '777 Patent to be a use in humans.
>
> Reasons, paragraph 175

[18] Having come to this conclusion, the Judge examined whether the utility of the invention had been demonstrated. His analysis of this question was based on a clopidogrel human study described as P-1062, a randomized double blind study comparing clopidogrel to a placebo in 10 healthy humans. This study is not referred to in the patent. The Judge found that the study was inconclusive as to the effectiveness of clopidogrel in humans. The Judge then considered whether one of the inventors of clopidogrel, Dr Daniel Fréhel, was aware of the activity of clopidogrel in humans prior the filing date. This issue turned on whether Dr. Fréhel was present at a meeting on January 28, 1988 at which time the therapeutic effect of clopidogrel in humans was discussed. The Trial Judge found the evidence on this point was also inconclusive. As a result, the Trial Judge found that the utility of clopidogrel in humans had not been demonstrated at the time of the patent application.

[19] The Judge then turned to the question of whether the inventors, as of the filing date, could soundly predict that the invention would be useful in humans. The Judge referred to the Supreme Court of Canada's decision *Apotex Inc. et al v Wellcome Foundation Ltd*, 2002 SCC 77, [2002] 4 SCR 153 (*AZT*) at paragraph 70, where the elements necessary to support a finding of sound prediction are set out: (i) a factual basis, (ii) a sound line of reasoning, and (iii) disclosure of the first two elements.

[20] After a thorough review of the history leading to the filing of the application, including prior work on the '875 Patent, work on other compounds which had been abandoned, work on the racemate, (described as PCR 4099), as well as the circumstances leading to the decision to attempt to separate the enantiomers of the racemate, the Trial Judge found that there was both a factual basis for the sound prediction (paragraphs 404-488 of the Reasons) and an articulable line of reasoning leading to the sound prediction (paragraphs 489-583 of the Reasons).

[21] The Trial Judge then asked if these two elements were sufficiently disclosed in the patent specification. He concluded that they were not as "the '777 Patent does not instruct the POSITA that there was a factual basis and a line of reasoning for the prediction that the animal studies conducted on rat models could be extrapolated to the prediction that the compound - clopidogrel - had a use in humans": see Reasons, at paragraph 570. In particular, the Judge found that the inventors' "track record" in the development of clopidogrel was crucial to enable the POSITA "to make the leap to predict use of the compound in humans" and that it had not been disclosed.: see Reasons at paragraph 573. As a result, he found that the '777 Patent was "invalid for lack of sound prediction": see Reasons, paragraph 585. To be more precise, the patent was invalid

because the utility of the invention had neither been demonstrated nor soundly predicted as of the date of the filing of the patent application.

[22] Having found the patent to be invalid for lack of utility, the Trial Judge nonetheless went on to consider obviousness, the other ground of invalidity advanced by Apotex. He began by setting out the four step framework for the obviousness analysis set down by the Supreme Court in *Plavix*:

> (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?
>
> *Plavix*, cited above, at paragraph 67, quoted at Reasons, paragraph 589

[23] The Judge reiterated the Supreme Court's teaching that the "obvious to try" test may be appropriate at the fourth step of the analysis, particularly in fields in which advances come as a result of experimentation.

[24] The Trial Judge identified the common general knowledge of the person skilled in the art. He then restated the inventive concept of the patent. The Trial Judge concluded that there was more disclosed in the '777 Patent than was in the common general knowledge: Reasons at

paragraph 656. This then led to the last step in the analysis: was the invention simply the result of taking steps that were "obvious to try"?

[25] Since the claimed invention relates to the dextro-rotary isomer of a racemic mixture, the question which the Judge asked himself was whether it was obvious to separate the racemic mixture and thereby isolate the isomer which is the subject of the '777 Patent. The Trial Judge concluded that it was.

[26] The Judge's conclusion focused on the racemic mixture identified in Sanofi's laboratory documents as PCR 4099. That compound is one of approximately 250,000 compounds which come within the terms of the '875 Patent. The patent itself describes 21 specific examples of compounds coming within the terms of the patent, one of which is PCR 4099. The Judge found that there were, at the relevant time, two relevant known methods of separating racemic mixtures of the type described in the '875 Patent, and in particular, PCR 4099, though it was not self evident that either of them "ought to work". In addition, he concluded that there was a well known and well established method of obtaining salts of the compounds resulting from such separation, including the isomers of PCR 4099.

[27] The Judge then asked whether there was a motive provided in the prior art to attempt to resolve compounds covered by the '875 Patent into their optical isomers. He identified factors which were known prior to the date of invention which would have led a person skilled in the art to separate the enantiomers of PCR 4099. Those factors were:

> a- the "thalidoimide disaster" which sensitized regulators to the differential effects of isomers contained in a racemic mixture.

> b- guidelines issued by Japanese regulators which "directed sponsors of applications for racemic drugs to separate and characterize the enantiomers": Reasons, paragraph 727.
>
> c- a speech given by senior official of the United States Food and Drug Administration (FDA) at the 1986 Annual Meeting of the American Pharmaceutical Association in which it was stated that sponsors of applications for racemic drugs would be expected to investigate the properties of the enantiomers of such racemic mixtures.
>
> d- the adoption in 1987 by the FDA of guidelines relating to applications for racemic drugs and the establishment in 1989 of a stereoisomers committee by the FDA.
>
> e- the awareness among leading chemists in the area of drug discovery that prior to 1989, there was already regulatory pressure toward separation of racemic mixtures.

[28] In summary, the Trial Judge found that, at the relevant time, the PCR 4099 compound, though not its properties was part of the common general knowledge and was featured in the '875 Patent, that the POSITA would have known of the method available to resolve PCR 4099 into its constituent enantiomers, that the methodology for salt selection was well known at that time, and that there was motivation to separate PCR 4099 into its enantiomers. He therefore found, on a balance of probabilities, that the "invention of the '777 Patent 'was obvious to try'" so that the patent was invalid for obviousness: see Reasons at paragraph 784.

[29] At trial, the issue of infringement was a live issue as were certain defences to infringement raised by Apotex. Those conclusions were overtaken by the Trial Judge's conclusions as to the validity of the '777 Patent. For the purposes of readability, I will deal with the analysis of the issues of validity and then deal with the issues of infringement separately.

ANALYSIS OF THE VALIDITY OF THE PATENT

Issues

[30] In my view, the critical issue with respect to utility arises from the Trial Judge's construction of the '777 Patent. Did the Trial Judge err in reading into the patent an explicit promise that the invention could be used in humans?

[31] As to obviousness, the issue is whether the Trial Judge erred in holding that the invention was obvious based on the fact that the resolution of the racemate PCR 4099 was "obvious to try"?

Standard of review

[32] This is an appeal of a decision reached by a Trial Judge after a 26 day trial. The standard of review is that set out in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235 (*Housen*). Findings of fact are to be reviewed on a standard of palpable and overriding error: *Housen*, cited above, at paragraph 10. The Trial Judge's conclusions on questions of law are subject to review on a standard of correctness: *Housen*, cited above, at paragraph 6. A question of mixed fact and law is also to be reviewed on a standard of palpable and overriding error unless the error involves an extricable error of law, in which case the standard of correctness applies.

[33] The construction of the patent is a question of law: *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 (*Whirlpool*), at paragraph 76. The Trial Judge must interpret the

patent as it would be understood by a person skilled in the art to which it pertains. This requires the judge to take into account the evidence as to how persons skilled in the art would understand certain words and phrases used in the patent, but it is for the judge to decide what the patent means: *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504, (*Consolboard*) at pages 521-525.

Utility and the promise of the patent

[34] In Canadian law, patent law is purely statutory: *Plavix* at paragraphs 12, 13; *Commissioner of Patent v. Fabwerks Hoechst Aktiengeselschaft Vormals Meister Lucius and Bruning* (1963), [1964] S.C.R. 49. While the Courts have added to the fabric of patent law in Canada, the starting point for any analysis is the *Patent Act* R.S.C. 1985 c. P-4 (the *Act*), as it read at the material time. Since the application for the '777 Patent was filed in Canada on February 2, 1988, this dispute is governed by the terms of the *Act* as it read immediately before October 1, 1989 (the *Old Act*).

[35] The following two provisions of the *Old Act* are relevant to the issue of utility. The first is the definition of "invention":

"invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter; (my emphasis)	*« invention »* Toute réalisation, tout procédé, toute machine, fabrication ou composition de matières, ainsi que tout perfectionnement de l'un d'eux, présentant le caractère de la nouveauté et de l'utilité. (Je souligne)

[36] The second relevant statutory provision is s. 34(1) [now 27(3)] which read as follows at the material time:

34(1) An applicant shall in the specification of his invention (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;	34. (1) Dans le mémoire descriptif, le demandeur: (a) décrit d'une façon exacte et complète l'invention et son application ou exploitation, telles que les a conçues l'inventeur;
(b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most closely connected, to make, construct, compound or use it;	(b) expose clairement les diverses phases d'un procédé, ou le mode de construction, de confection, de composition ou d'utilisation d'une machine, d'un objet manufacturé ou d'un composé de matières, dans des termes complets, clairs, concis et exacts qui permettent à toute personne versé dans l'art ou la science dont relève l'invention, ou dans l'art ou la science qui s'en rapproche le plus, de confectionner, construire, composer ou utiliser l'objet de l'invention;
(c) in the case of a machine, explain the principle thereof and the best mode in which he has contemplated the application of that principle;	(c) s'il s'agit d'un machine, en explique le principe et la meilleure manière dont il a conçu l'application de ce principe;:
(d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other invention; and.	(d) s'il s'agit d'un procédé, explique la suite nécessaire, le cas échéant, des diverses phases du procédé, de façon à distinguer l'invention d'autres inventions,
(e) particularly indicate and distinctly claim the part, improvement or combination that he claims as his invention	(e) indique particulièrement et revendique distinctement la partie, le perfectionnement ou la combinaison qu'il réclame comme son invention.
(2) The specification referred to in (1) shall end with a claim or claims stating	(2) Le mémoire descriptif se termine par une ou plusieurs revendications

distinctly and in explicit terms the things or combinations that the applicant regards as new and in which he claims an exclusive privilege or property is claimed.	exposant distinctement et en termes explicites les choses ou combinaisons que le demandeur considère comme nouvelles et dont il revendique la propriété ou le privilège exclusif.

[37] These provisions are important because they frame the issue of what must be disclosed in the patent itself which, in turn, is relevant to the construction of the promise of the patent.

[38] Given the fact that an invention must be new and useful, must the demonstration of novelty and utility appear in the patent itself?

[39] In *Consolboard*, the Supreme Court considered this very question and held that an inventor need not describe the utility of his invention in his patent.

> In my respectful opinion the Federal Court of Appeal erred also in holding that s. 36(1) requires distinct indication of the real utility of the invention in question.
> ....
>
> Although (i) s. 36(1) [now s.27(3)] requires the inventor to indicate and distinctly claim the part, improvement or combination which he claims as his invention and (ii) to be patentable an invention must be something new and useful (s. 2), and not known or used by any other person before the applicant invented it (s. 28(1)(a)), I do not read the concluding words of s. 36(1) as obligating the inventor in his disclosure or claims to describe in what respect the invention is new or in what way it is useful. He must say what it is he claims to have invented. He is not obliged to extol the effect or advantage of his discovery, if he describes his invention so as to produce it.
>
> *Consolboard*, cited above at pages 525, 526 (my emphasis)

[40] The Supreme Court of Canada has consistently followed this reasoning: see, e.g., *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902, at paragraph 18; *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067, at paragraph 52

(*Whirlpool*); *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623, at page 1636 and, most recently, *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] S.C.J. No. 60, at paragraphs 49-52.

[41] Are selection patents subject to the same rules? The nature of selection patents was explained *Plavix*, cited above, which makes frequent reference to the English case of *In re I.G. Farbenindustrie A.G.'s Patents* (1930), 47 R.P.C. 289 (Ch. D.) (*I.G. Farbenindustrie*):

> At p. 321, he [Maugham J. the trial judge in *I.G. Farbenindustrie*] 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".
>
> *Plavix*., cited above at paragraph 9 (my emphasis).

[42] Maugham J. specified that the "unexpected character" is "a substantial advantage to be secured or disadavantage to be avoided by the use of the selected members": see *I.G. Farbenindustrie*, cited above, at pages 322, 323.

[43] The same concepts can be found in *E. I. Du Pont de Nemours & Co. (Witsiepe's) Application*, [1982] F.S.R. 303 (H.L.) where Lord Wilberforce stated, at page 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.

[44] In *Plavix*, cited above, the Supreme Court, at paragraph 11, accepted that a selection patent is like any other patent. As a result, it must satisfy the requirements of the *Act*, including the requirement that the invention be new and useful. The element of novelty is satisfied by the fact that the selected compounds have not previously been made. The element of utility is usually satisfied by the presence of a special property of an unexpected character, consisting in the advantage secured or the disadvantage avoided by the selection and which is at the heart of the inventive steps (*Plavix* above at paragarphs 9-10). Were it not so, no selection would meet the statutory criteria for patentability.

[45] A selection patent must also satisfy the disclosure requirements found in s. 34 of the *Old Act*. It does so by setting out in the specification "in clear terms the nature of the characteristic which the patentee alleges to be possessed by the selection for which he claims a monopoly": see *Plavix*, at paragraph 114. See also *Eli Lilly Canada Inc. v. Novopharm Ltd*, 2010 FCA 197, [2012] 1 F.C.R. 349 (*Olanzapine*) at paragraph 78.

[46] A patent holder whose patent is challenged on grounds of lack of utility must be able to show that, at the time of the patent was applied for, the utility of the invention could either be demonstrated or soundly predicted: see *AZT*, at paragraph 46. The sticking point, in this case as in others, is to determine what it is that must be demonstrated or soundly predicted. This is where the notion of the promise of the patent comes into play.

[47] The promise of the patent is the standard against which the utility of the invention described in the patent is measured. The source of the concept is found in the decision of the Supreme Court of Canada in *Consolboard*:

> There is a helpful discussion in Halsbury's Laws of England, (3rd ed.), vol. 29, at p. 59, on the meaning of "not useful" in patent law. It means "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do".
>
> *Consolboard*, cited above at p. 525

[48] While an inventor need not describe the utility of his invention in his patent, if he does so, he will be held to the promise which he has made. This was set out as follows in *Olanzapine*, cited above, at paragraph 76:

> Where the specification does not promise a specific result, no particular level of utility is required; a "mere scintilla" of utility will suffice. However, where the specification sets out an explicit "promise", utility will be measured against that promise: *Consolboard*; *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2009] 1 F.C.R. 253, 2008 FCA 108 (*Ranbaxy*). The question is whether the invention does what the patent promises it will do.(emphasis in the original)

[49] If the inventor does not make an explicit promise of a specific result, the test for utility is a "mere scintilla" of utility. If, on the other hand, the inventor makes an explicit promise of a specific result, then utility will be assessed by reference to the terms of the explicit promise.

[50] When this Court said at paragraph 80 of *Olanzapine*, cited above, that the promise of the patent must be ascertained, it should not be taken to have assumed that every patent contains an explicit promise of a specific result since, subject to what is said below with respect to selection patents, there is no obligation on the part of the inventor to disclose the utility of his invention in the patent. In *Olanzapine*, the Court was simply indicating that the firs step in assessing utility

was to determine the standard against which utility will be measured. This requires the Court to construe the patent to determine if a person skilled in the art would understand it to contain an explicit promise that the invention will achieve a specific result. If so, the inventor will be held to that promise. If there is no explicit promise of a specific result, then a mere scintilla of utility will do.

[51] In the case of selection patents, as we have seen, the novelty of the selection and its advantages (including disadvantages to be avoided) are the invention and must be described in the patent. The Trial Judge's description of the invention is framed in terms of its advantages over the genus patent as was the Supreme Court's description of the same invention in *Plavix*, cited above at paragraph 78. For ease of reference, I reproduce his description of the invention (Reasons at paragraph 140):

> …a compound which is useful in inhibiting platelet aggregation, has greater therapeutic effect and less toxicity than the other compounds of the '875 Patent, has the advantages of the salts (crystallize easily, not hygroscopic, and sufficiently water soluble) and the methods for obtaining that compound.

[52] The Trial Judge turned his mind to whether the invention of the '777 Patent worked as described above. He examined toxicological tests in rats, mice and baboons, as well as studies of base activity, and concluded that the studies demonstrated the existence of the advantages which the inventors identified for the selection:

> 392 In terms of persuasive evidence given on this point, the Court notes that a Sanofi study (D-136, Tab-122 - SA361) demonstrated a differential LD50 and LD10 and that convulsions were a problem with PCR 4099 and the levo-rotatory enantiomer but not with clopidogrel. On this basis, it can be concluded that there was a differential toxicity as well as the better tolerability of clopidogrel.

> 395 On the basis of this evidence [the tests described at paragraph 394], the Court finds that Sanofi has demonstrated the differential toxicity as well as the better tolerability of clopidogrel.
>
> 399 Based on the evidence above, the Court accordingly finds that Sanofi has demonstrated the differential activity of clopidogrel.
>
> Reasons, at paragraphs 392, 395, 399.

[53] Had the analysis ended here, the Trial Judge would have found that the compound of the '777 Patent had the advantages over the compounds of the '875 Patent which were described in the patent and whose existence had been demonstrated at the time of the filing of the application for the patent. To that extent, the promise of the patent had been met.

[54] An inventor whose invention is described in a patent which would otherwise be valid can nonetheless promise more for his invention than required by the *Act* so as to render his patent invalid. If he does so, so be it; it is a self-inflicted wound: see *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024, at paragraph 51. But Courts should not strive to find ways to defeat otherwise valid patents. As the Supreme Court said in *Consolboard*, cited above, and reiterated some twenty years later in *Whirlpool*, cited above, at paragraph 49(g):

> We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance, (*Noranda Mines Limited v. Minerals Separation North American Corporation* ([1950] S.C.R. 36])being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and public. There is no occasion for being too astute or technical in the matter of objections to either title or specification for, as Duff C.J.C. said, giving the judgment of the Court in *Western Electric Company, Incorporated, and Northern Electric Company v. Baldwin International Radio of Canada* [[1934] S.C.R. 570], at p. 574, "where the language of the specification, upon a reasonable view of it, can be so read as to afford the inventor protection for that which he has actually in good faith invented, the court, as a rule, will endeavour to give effect to that construction". (my emphasis)

[55] While the construction of the patent is reserved to the Trial Judge, he is to read it and understand it as would the person skilled in the art. To that end, he has the evidence of experts as to how a person skilled in the art would understand the patent. In this case, only Apotex's expert, Dr. Hirsh, a haemotologist, read the patent as promising that the invention would be effective in humans. Dr. Hirsh came to this conclusion on the basis of inferences which he drew from particular expressions used in the patent.

[56] Dr. Hirsh first noted that some of the diseases referred to in the patent are clearly human diseases and conditions (Expert Report of Dr. Hirsh (Confidential), Appeal Book, Tab 20 at paragraphs. 25, 68; Trial Transcripts, Vol. 2, Appeal Book, page 386, lignes 4, 5, 24-26; page 387, lines 1-5).

[57] Second, he noted that the high end of the daily dosage used to effect platelet aggregation was based on 10mg/kg, a dosage that would correspond with that needed by a human of average weight, approx. 50kg (Expert Report of Dr. Hirsh (Confidential), Appeal Book, Tab 20 at paragraph. 69).

[58] Third, the invention is described as being a "medicine and 'active medicinal[s]' for therapeutic purposes". According to Dr. Hirsh, a haemotologist would understand from these words that this is a medecine that can be used in humans (Expert Report of Dr. Hirsh (Confidential), Appeal Book, Tab 20 at paragraph 68).

[59] Sanofi's experts on the other hand recognized that the patent invites the person skilled in the art to understand that the invention has potential use in humans, but all expressed the view that the person skilled in the art would understand that no promise of a specific result is made in that regard.

[60] Dr. Byrn, a chemist said that:

> "...any pharmaceutical chemist would interpret the '777 Patent as telling the world that very interesting results had been obtained and thus one might expect similar results would be achieved in humans but no clear promise or guarantee that such results would be achieved in humans."
>
> Reasons, at paragraph 150

[61] Dr. Rodricks, a toxicologist, testified to the effect that:

> "the combination of platelet aggregating inhibiting activity and reduced toxicity...would suggest that the dextro-rotatory enantiomer holds promise as a useful human drug...however...the '777 Patent does not guarantee that the enantiomer would be a successful human drug.."
>
> Reasons, at paragraph 151

[62] Finally, Dr. Shebuski, a cardiovascular pharmacologist, was of the view that

> "..it would be understood that clopidogrel had potential to be used as an antithrombotic medicine...a person in the art would not understand the teachings of the '777 Patent to be promising a specific result in humans."
>
> Reasons, at paragraph 152

[63] The Trial Judge was not persuaded by the evidence of Dr.'s Byrn, Rodricks and Shebuski. Relying on the expert testimony of Dr. Hirsh, he came to the conclusion that the words of the patent contained "an explicit promise" for use in humans (Reasons at paragraph 163).

[64] In this context, the Trial Judge needed to clearly explain why he saw an "explicit promise" for use in humans when Dr. Hirsh did not point to any explicit promise. It appears that Dr. Hirsh's opinion is that the person skilled in the art would infer from the high end of the dosage set out in the patent, the diseases and conditions to which it refers and the phrase "medecines and 'active medicinal[s]' for the therapeutic purposes" that the invention promises use in humans. These inferences are all equivocal. Dosage is often expressed in terms of units of medicine per unit of weight. Animals, like humans, come in a wide range of weights. Similarly, practicitioners of veterinary medicine have their "patients" to whom they administer "medicines" for "therapeutic purposes".

[65] Beyond adopting the inferences drawn by Dr. Hirsh or, as he put, it the "indications" that the patent promises use in humans, the Trial Judge drew additional inferences of his own: Reasons, at paragraph 163. First, he inferred from the fact that clopidogrel is to be administered by oral, rectal or parenteral administration that human use is contemplated. He drew the same inference from the use of the word "patient" and from the phrase "the patent indicates that the dosage depends on the age of the patient and the severity of the disorder to be treated".The Trial Judge was also influenced by the fact that the active ingredient is formulated into "tablets, capsules and other dosage forms that are useful for administration". This exercise in the

construction of a document, familiar as it is to lawyers, is an unreliable guide to the skilled person's reading of such a document.

[66] While these "indications" are consistent with human use, they are not inconsistent with other uses. Although Dr. Hirsh was entitled to form an opinion on the basis of the inference which he drew, the Trial Judge was held to a higher standard. He erred in law in reading into the '777 patent a promise for use in humans on the basis of inferences, in the absence of language at least as clear and unambiguous as that used to establish the advantages of the selection over the compouds of the genus patent.

[67] The frailty of the Trial Judge's conclusion is even more apparent when the distinction drawn in the jurisprudence between the potential use of an invention and an explicit promise to achieve a specific result is considered. As Dr. Byrn made clear, the inventive step was in the differential activity and tolerability of clopidogrel as demonstrated in rats. The pharmaceutical industry's interest of the invention obviously lay in its potential use in humans which the invention foreshadowed. The person skilled in the art would understand that in alluding to this possibility, the inventors were not promising that this result had been or would be achieved. As was held in *AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023 at paragraph 61:

> 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. (my emphasis)

> *AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023, [2011] F.C.J. No. 1262 (Q.L.) at paragraph 139. For other examples of this distinction, see *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, 2012 FCA 103, [2012] F.C.J. No. 386, at paragraph 61, *Mylan Pharmaceuticals ULC v. Canada (Minister of Health)*, 2012 FCA 109, [2012] F.C.J. No. 422, at paragraphs 32-33.

[68] The Trial Judge justified his conclusion on another ground. He reasoned that since the genus patent (the '875Patent) contained a reference to use in humans, the '777 Patent would fail as a selection patent unless an explicit promise for use in humans was also read into it (Reasons at paragraphs. 169-171). In the Judge's words, "the '777 selection patent cannot promise less than the '875 genus patent":Reasons at paragraph 172).

[69] This reasoning is problematic for at least two reasons. First and foremost, it is improper to construe a patent with an eye to its validity (*Whirlpool Corp. V. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 at paragraph 49(a) (*Whirlpool*); *Dableh v. Ontario Hydro*, [1996] 3 F.C. 751 at paragraph 26 (C.A.); *Allergan Inc. v. Apotex Inc.*, 2012 FCA 308, [2012] F.C.J. No. 1467 (QL) at paragraph 65; *American Cyanamid co. V. Berk Pharmaceuticals Ltd.*, [1976] R.P.C. 231 at page 234 (Ch. D.); *Xerox of Canada Ltd. Et al. V. IBM Canada Ltd.*, (1977), 33 C.P.R. (2d) 234 at page 43 (F.C.T.D.)). The Trial Judge erred when he read into the patent a promise of use in humans in order to validate the patent as a selection patent, then used this promise in order to invalidate it for lack of utility.

[70] Second, the Trial Judge found that the '777 Patent described the advantages of the compound of the '777 Patent over the compounds of the '875 Patent, and that the inventor was able to demonstrate the existence of those advantages as of the date of the filing of the patent

application. On that basis, the '777 Patent is a valid selection patent when measured against the genus patent, the '875 Patent, regardless of the fact that it makes no promise for use in humans. A selection patent describes a compound which has an unexpected advantage over the compounds of the genus patent. That unexpected advantage need not be an improvement on every aspect of the invention described in the genus patent, though it may be. It is sufficient that it is a new and useful improvement on some aspect of that invention.

[71] Having regard to all of the above, I am of the view that the Trial Judge erred in law in his construction of the promise of the patent. The '777 Patent described a compound having advantages (including the absence of disadvantages) over the compounds of the'875 Patent and those advantages were clearly disclosed in the patent specification. The Trial Judge found that those advantages were demonstrated at the time of the patent application. The Trial Judge erred in construing the patent as specifically promising a result when the invention was used in humans and then assessing the utility of the patent against that specific promise. Properly construed, the '777 Patent made no such promise. As a result, the allegation that the patent was invalid for lack of utility ought to have been dismissed.

Obviousness

[72] The Trial Judge's analysis of obviousness turned on the "obvious to try" analysis set out in the Supreme Court's decision in *Plavix*. It is worth remembering that the issue of obviousness was raised and rejected in *Plavix*. The Supreme Court's reasoning turned on a few key facts:

> 1- "…there were five well known methods to separate this racemate into its isomers": *Plavix*, cited above, at paragraph 75.

> 2- " …the relative advantage of the dextro-rotatory isomer would not have been known by the skilled person": *Plavix*, ibid.
>
> 3- "Nothing distinguishes the racemate in this case from other compounds disclosed or tested in terms of therapeutic effect or toxicity": Plavix, cited above, at paragraph 79

[73] With these facts in mind, the Supreme Court articulated why the separation of the racemate was not obvious to try. It held that just because the methods of separating a racemate into its isomers are known, it does not follow that a person skilled in the art would necessarily apply them. The Supreme Court explained:

> 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.
>
> *Plavix*, cited above, at paragraph 85
>
> 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.
>
> *Plavix*, cited above, at paragraph 90

[74] What emerges from this review of the Supreme Court's decision in *Plavix*, cited above, is that the key factor in its "obvious to try" analysis was the lack of knowledge of the properties of the enantiomers of the compounds of the '875 Patent, including the racemate from which clopidogrel was obtained. Absent that knowledge, it was not obvious to try to resolve the racemate, or any other compound, so as to obtain the enantiomer having those advantageous properties.

[75] In his analysis of obviousness, the Trial Judge focused exclusively on the question of whether it was obvious to try to resolve PCR 4099: Reasons, at paragraphs, 663, 668, 672, 675, 679, 681, 692, 712, 724, 730 and 750. He found that the existence of PCR 4099, though not its properties, was part of the common general knowledge at the relevant time: Reasons, at paragraphs 614, 647. He found as well that the possible methods of separation were within the common general knowledge: Reasons, at paragraph 665. The Trial Judge concluded there was motivation to resolve PCR 4099: Reasons, at paragraph 750.

[76] All of these factors led the Trial Judge to conclude that the resolution of PCR 4099 was obvious to try. Apotex supports this conclusion by pointing to evidence which it says was before the Trial Judge and which was not before the Supreme Court in *Plavix*,cited above, notably that PCR 4099 was the "lead" drug in the '875 Patent and the most potent of the compounds whose test results were reported in that patent. These distinctions are not supported by the evidence and, even if they were, they do not detract from the key fact that the properties of the enantiomers of PCR 4099 were not known.

[77] The Trial Judge found that "the '875 Patent does not directly or indirectly point to PCR 4099 or to clopidogrel": Reasons, at paragraph 612, (my emphasis). As noted above, the Trial Judge also noted that "PCR 4099 (not its properties) would form part of the common general knowledge that a person skilled in the art could find by making a reasonably diligent search of patent applications": Reasons, at paragraph 614. Furthermore, the properties of PCR 4099 would not have been discoverable by means of a reasonably diligent patent search: Reasons, at paragraph 645-647.

[78] As a result, the Trial Judge found himself in exactly the same position as did the Supreme Court when it decided Plavix,cited above. The focus of the obviousness analysis in *Plavix* was not the difficulty in seperating the racemates covered by the '875 genus Patent – which included PCR 4099 – but the unknown properties of the resulting enantiomers. :

> The method 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 would be and therefore that what was being tried ought to work.
>
> *Plavix*, cited above, at paragraph 92

[79] The reasons of the Trial Judge make it clear that, as was the case in *Plavix*, it was not possible to predict the properties of the separated enantiomers: Reasons, at paragraphs 673 and 676. The lack of knowledge as to these properties is precisely what led the Supreme Court in *Plavix*, cited above, to hold that it was not self-evident that what was being tried ought to work (*Plavx*,at paragraph 92, quoted above). Simply put, the person skilled in the art would not think of separating PCR 4099 and testing its enantiomers in order to obtain the benefit of its properties when the existence and nature of those properties were unknown.

[80] It follows that although the resolution of PCR 4099 was part of the common general knowledge, nothing turns on this as it is the unknown nature of the properties of the enantiomers which explains why the invention was not "obvious to try".

[81] Given that the Trial Judge applied the test for obviousness set out in *Plavix*, and given that he applied it to the same material facts as the Supreme Court, he ought to have come to the same conclusion. His error lay in failing to recognize that the unknown nature of the properties of the enantiomers of PCR 4099, or of any of the other compounds of the '875 Patent, was fatal to the "obvious to try" analysis. Put another way, the distance between the common general knowledge and the inventive concept of the '777 Patent could not be bridged by routine experimentation since the results to be obtained were unknown. On the facts, this was confirmed by the fact that the inventors, who had more knowledge that the person of ordinary skill in the art, attempted to resolve a number of other compounds before finally trying PCR 4099: see Reasons, at paragraphs 752-759.

[82] As a result, the Trial Judge erred in finding that the invention of the '777 Patent was obvious.

Conclusion on invalidity

[83] For the reasons set out above, I believe that the judgment of the Federal Court erred in finding that the '777 Patent was invalid. The Court's conclusion that the patent was invalid for lack of utility was based on a flawed interpretation of the patent. The Trial Judge erred in construing the patent as containing an explicit promise that the invention of the '777 Patent could be used in humans with beneficial effects .

[84] I am also of the view, for the reasons expressed above, that the Court's conclusion that the invention of the '777 Patent was obvious was in error.

INFRINGEMENT

Facts and trial decision

[85] Sanofi alleged that Apotex infringed the '777 Patent by importing, offering for sale, selling, making, possessing for commercial purposes, using and exporting clopiodgrel tablets, all of which are acts which deprive it of the benefit of the monopoly conferred by the '777 Patent and the *Act*. Specific instances of infringement consisted of:

> - arranging for the manufacture of bulk clopidogrel in Mexico and its importation into Canada;
>
> - the formulation of bulk clopidogrel into tablets in Canada which were then exported to the United States, and other countries such as Australia, New Zealand, Hong Kong, Malaysia, Singapore, Hungary, the Phillipines, Malta, and Iran;and
>
> - the possession for commercial purposes of large amounts of bulk clopidogrel in Canada, some of which was said to have been exported back to Mexico.
>
> Reasons, at paraphraphs 207, 208, 210

[86] The Trial Judge found that Apotex contracted with Apotex Pharmacem Inc. (Pharmachem), an Apotex subsidiary, to have the latter develop "the Apotex product and the process of manufacture": see Reasons at paragraph 198. Pharmacem then entered into a Technology Transfer and Custom Manufacturing Agreement by which Pharmachem transferred to a Mexican company, Signa S.A. de CV, the process and manufacturing information it had developed. Signa manufactured clopidogrel according to Pharmacem's specification and sold it

in bulk to Apotex. Signa agreed to supply only Apotex (in respect of Canada and the U.S.) while Apotex agreed to by exclusively from Signa. To the date of trial, Apotex received approximately 80,000 kilograms of clopidogrel from Signa.

[87] Signa shipped clopidogrel to Apotex at Pearson International Airport in Toronto via Air Canada usually under a waybill issued in Montreal. All customs documentation showed Apotex as the importer. Once the bulk clopidogrel cleared customs, it was trucked to Apotex's manufacturing plant where it was formulated into tablets for resale. Apotex then exported the tablets to various markets in accordance with agreements with Apotex subsidiaries.

[88] In this appeal, Apotex does not contest the Trial Judge's conclusion that it infringed Claims 1, 3, 6, 7, 8, 9, 10, and 11 the '777 Patent: see paragraph 112 of Apotex's Memorandum of Fact and Law. Instead, it raises a number of issues which, if successful, would preclude Sanofi from recovering any damages for the infringement. Those issues include the appropriate limitation period, the possession of clopidogrel for experimental and regulatory use, and settlement and estoppel based on an agreements settling litigation between the parties in the U.S.

[89] Sanofi did not challenge Apotex's right to claim the exemption for experimental and regulatory use but questioned its application in this case. The Trial Judge found that Apotex failed to provide the Court with evidence as to the ultimate destination of the material said to have been developed for regulatory purposes. The Trial Judge was clearly of the view that the experimental and regulatory use exception in subsection 55.2(1) of the *Act* did not apply if the regulatory samples were sold subsequent to their use for regulatory purposes. Since Apotex

could not produce records showing the destruction of the disputed lots of clopidogrel, the Trial Judge concluded that it had not demonstrated that the experimental and regulatory use exemption applied to those lots.

[90] Apotex's argument with respect to limitation periods flows from section 39 of the *Federal Courts Act*, R.S.C. 1985 c. F-7:

> **39.** (1) Except as expressly provided by any other Act, the laws relating to prescription and the limitation of actions in force in a province between subject and subject apply to any proceedings in the Federal Court of Appeal or the Federal Court in respect of any cause of action arising in that province.
>
> (2) A proceeding in the Federal Court of Appeal or the Federal Court in respect of a cause of action arising otherwise than in a province shall be taken within six years after the cause of action arose.
>
> **39.** (1) Sauf disposition contraire d'une autre loi, les règles de droit en matière de prescription qui, dans une province, régissent les rapports entre particuliers s'appliquent à toute instance devant la Cour d'appel fédérale ou la Cour fédérale dont le fait générateur est survenu dans cette province.
>
> (2) Le délai de prescription est de six ans à compter du fait générateur lorsque celui-ci n'est pas survenu dans une province.

[91] The Trial Judge examined the question of where Sanofi's cause of action arose in order to determine whether subsection (1) or (2) of section 39 applied to the facts of this case. Relying on *Apotex Inc. v. Pfizer Canada Inc*, 2004 FC 190, [2004] F.C.J. No. 230 (Q.L.) (*Apotex v. Pfizer)* and the cases cited in the latter, he found that "both the damages suffered as well as the act that caused the damage" must have occurred in the same province in order for subsection 39(1) to apply: see Reasons, paragraph 250.

[92] The Trial Judge found that the importation from Mexico and subsequent exportation to other countries was a sufficient basis for concluding that the cause of action (infringement) was

not limited to a single province. In addition the Trial Judge relied on a number of other factors, such as the fact that Apotex conducts business in many provinces, accepts orders for its product from foreign entities and that it retained an Indian manufacturer to asssist in the sale of its clopidogrel in India, to conclude that the damages suffered as a result of Apotex's infringement were not limited to a single province. As a result, he found that subsection 39(2) of the *Federal Courts Act* applied, so that the applicable limitation period was 6 years. In the result, no part of Sanofi's claim was statute barred.

[93] Apotex also argued before the Trial Judge that Sanofi was precluded from seeking damages for infringement by reason of a settlement agreement reached between Sanofi and Apotex in the context of a U.S. patent infringement action brought by Sanofi with respect to its U.S. patent (the '265 patent) for clopidogrel. Two settlement agreements were entered into because the settlement required regulatory approval. For the purposes of this appeal, the relevant provisions are those which would come into effect if the settlement agreement was not approved by the U.S. authorities.

[94] The Trial Judge summarized the situtation as follows:

> However, during the negotiations, Sanofi/BMS advised Apotex that they were under consent decrees with the Federal Trade Commission (FTC) and the Attorneys General of some of the states in the U.S. that prevented them from entering into patent settlements without prior approval. As a result of this, Apotex demanded and Sanofi/BMS agreed to concessions to Apotex if the settlement was submitted to the regulators but was not approved by them. The concessions were, first, that, in the event of regulatory denial, Apotex would have a period of time within which to sell off its inventory (i.e. without facing the prospect of a motion for an interlocutory injunction) and, second, that, in the event that the action proceeded to trial with Apotex having launched at risk, Apotex would be

> guaranteed a profit in respect of its sales by way of an agreement to a fixed level of damages that would be less than Apotex' profits.
>
> Reasons, at paragraph 267 (my emphasis)

[95] The first settlement agreement was not approved by the U.S. authorities, so Apotex and Sanofi renegotiated their agreement in an attempt to obtain that approval. At the same time, the clauses which came into effect if the settlement was not approved were also amended so as to reduce the amount of the Liability Exposure Provision (the fixed level of damages referred to above) from 70% of net sales to 50% of net sales. The second agreement, dated May 26, 2006, did not obtain regulatory approval either. As a result, the U.S. litigation proceeded. The validity of the '265 patent was upheld and Apotex was found to have infringed it. However, in keeping with the Liability Exposure Provision, Apotex's liability for damages was limited to 50% of U.S. sales, or U.S. $442,209,362.

[96] Before the Trial Judge, Apotex argued that the Liability Exposure Provision which limited Apotex' liability for damages (and therefore Sanofi's right of recovery) prevented Sanofi from claiming damages for any U.S. sales since it had already agreed to limit its recovery in the May 26, 2006 agreement. While the Trial Judge does not expressly say so, one assumes from Apotex's argument that all of the clopidogrel sold in the U.S. by Apotex originated in Canada.

[97] The Trial Judge reviewed the May 26, 2006 agreement and found that it was limited to the U.S. litigation with respect to the '265 patent. The words "'777 Patent" or "Canada" did not appear in the agreement which was expressly limited to "…litigation …involving the U.S. Patent No. 4, 847, 265.02CV-2255 and 05CV-3965": see Reasons at paragraph 280. As a result, the

Trial Judge concluded that the May 26, 2006 agreement did not limit Sanofi's ability to recover damages for infringement of the '777 Patent.

[98] Apotex then argued that Sanofi was estopped from pursuing a second claim for compensation in respect of the very same manufacture and sale of clopidogrel imported from Mexico and exported to the U.S. Apotex claimed that it had acted in reliance on May 26 agreement and therefore, Sanofi was estopped from claiming damages in respect of U.S. sales. The Trial Judge found that the estoppel argument did not apply because the U.S. litigation and the May 26, 2006 agreement "simply did not deal with the infringement or validity of the '777 Patent." As a result, the issue in that litigation was not the issue in this litigation so that there was no basis for estoppel.

[99] Apotex also argued that Sanofi's claim for damages arising from U.S. sales was an abuse of process. The Trial Judge dismissed this argument out of hand.

[100] As a result, the Trial Judge found that the '777 Patent had been infringed and that there was no restriction on Sanofi's right to seek damages.

ANALYSIS WITH RESPECT TO THE ISSUE OF INFRINGEMENT

[101] As noted, Apotex did not seek to set aside the Trial Judge's finding that the '777 Patent had been infringed. Its entire argument on appeal was that the limitation defence, the May 26,

2006 settlement agreement and the exemption in favour of experimental and regulatory use limited Sanofi's right of recovery.

[102] In my view, the Trial Judge came to the correct conclusion though in the case of the limitation defence, perhaps for the wrong reasons.

[103] Apotex claims that the Trial Judge erred in failing to give it the benefit of the expiremental and regulatory use exemption found at section 55.2(1) of the *Act*. It will be recalled that the Trial Judge denied Apotex the benefit of this exemption on the ground that Apotex had not shown that the clopidogrel used for regulatory purposes was destroyed once its regulatory use was completed. It is true that Apotex was entitled to the benefit of section 55.2(1) for clopidogrel so long as it was used for the purposes permitted by that provision. But clopidogrel is a valuable and highly profitable product. To the extent that Apotex was unable to account for the clopidogrel used for regulatory purposes after it was no longer required for those purposes, it was a reasonable inference that the product had been sold, a use which fell outside the protection of section 55.2(1). I can see no basis for interfering with the Trial Judge's conclusion on this issue.

[104] Before turning to the limitation issue, I note that this issue in unlikely to recur very often in the form in which it arises here, given that the *Act* now provides a 6 year limitation for all applications filed and patents issued after October 1, 1989: see section 55.1.

[105] That said, in order for section 39(1) of the *Federal Courts Act* to apply, all the elements of the cause of action must have occurred in the same province: see *Canada v. Maritime Group Inc.*, [1995] 3 F.C. 124 (*Maritime Group*), at paragraph 9.

[106] In *Apotex v. Pfizer*, cited above, the Federal Court held that the place where damage occurred is to be taken into account in determining whether a cause of action arose in a particular province. It is implicit in this proposition that damages are an element of the cause of action of patent infringement. In my view, this is incorrect. The cases referred to *Apotex v. Pfizer*, are either cases where the damages are an element of the cause of action (tort, in the case of *Maritime Group*, cited above, at paragraph 7) or where *Maritime Group* has been misapplied (*Kirkbi A.G. v. Ritvik Holdings Inc*, 2002 FCT 585, [2002] F.C.J. No. 793 (Q.L.) at paragraph 161).

[107] In *Precision Metalsmiths Inc. v. Cercast Inc.*, [1967] 1 Ex.C.R. 214, President Jackett had to consider the elements of the cause of action of patent infringement. He held that:

> 10 In an action for infringement of a patent under the Patent Act, there must therefore be in the Statement of Claim allegations
>
> > (a) of facts from which it follows as a matter of law that the plaintiff has, by virtue of the Patent Act, the exclusive right to do certain specified things, and
> >
> > (b)that the defendant has done one or more of the specified things that the plaintiff has the exclusive right to do

[108] This flows from section 42 of the *Act* (section 46 in the *Old Act*) which grants the patent holder "the exclusive right, privilege and liberty of making, constructing and using the invention

and selling it to others to be used.": see *Beloit Canada Ltd. v. Valmet-Dominion Inc.*, [1997] 3 F.C. 497, [1997] F.C.J. No. 48, at paragraph 31. Damages, accounting, or an injunction are the remedies which may be obtained from the Court once infringement has been proved but it is not necessary to prove that the patent holder has suffered a loss of some kind in order to succeed in an action for patent infringement. As a result, to the extent that the Trial Judge based his conclusion on the place where the cause of action arose or the place where damages occurred, he erred.

[109] That said, the Trial Judge found that the acts of infringement consisted of the importation and exportation of clopidogrel from Mexico into Canada and then to the United States. Apotex argues that since the ports of entry and departure were located in Ontario, the cause of action arose in Ontario.

[110] In my view, the essential aspect of importation and exportation is the movement of goods into or out of Canada. Since a patent confers monopoly rights across Canada, the movement of goods across provincial boundaries is not an infringement of the patent. The port at which goods enter or leave the country is not determinative of the place where the cause of action arose since it is the movement of goods into or out of Canada which is the act of infringement.

[111] To that extent, this case is akin to *Markevich v. Canada*, 2003 SCC 9, [2003] 1 S.C.R. 94. The issue in that case was the place where a tax debt arose. The argument was made that the debt arose in the province of the debtor. The Supreme Court held, at paragraph 39 of its decision:

> 39 Tax debts created under the ITA arise pursuant to federal legislation and create rights and duties between the federal Crown and residents of Canada or those who have earned income within Canada. The debt may arise from income earned in a combination of provinces or in a foreign jurisdiction. The debt is owed to the federal Crown, which is not located in any particular province and does not assume a provincial locale in its assessment of taxes. Consequently, on a plain reading of s. 32, the cause of action in this case arose "otherwise than in a province".

[112] In the same way, Canada is indivisible for the purposes of importation and exportation of infringing goods. Goods are imported or exported when they enter or leave Canada, regardless of the port of entry or departure. To that extent, the infringing acts of importing and exporting clopidogrel took place other than in a province so that subsection 39(2) of the *Federal Courts Act* applies. As a result, none of Sanofi's claim is statute barred.

[113] The final issue is the effect of the settlement reached in the U.S. Apotex argues, as it did before the Trial Judge, that this agreement was intended to settle all claims which the parties had or could have against each other in relation to clopidogrel. The Trial Judge found that given the explicit references to settlement of the litigation involving the '265 patent, Apotex's position was not credible. Had it been intended to settle all possible claims involving clopidogrel, it would have been easy enough for these sophisticated parties, advised as they were by top quality lawyers, to say so in their settlement agreement. They failed to do so. I can see no basis on which this finding ought to be disturbed.

[114] Apotex's arguments based on the May 2006 Agreement seek to shelter it from Sanofi's claim for damages or profits arising from its infringement of the '777 Patent. Apotex argues that since the subject matter of the May 2006 agreement and the Liability Exposure Provision was

Apotex's risk from the sale of the clopidogrel which it imported into the U.S. from Canada, those contractual provisions should be read as extending to the risk Apotex ran in exporting the same clopidogrel from Canada. In essence, Apotex says that Sanofi is trying to recover the same loss twice.

[115] I would agree that the equitable rule against double recovery would prevent Sanofi from recovering the same loss twice. To the extent that the sale of clopidogrel in the U.S. in breach of the '265 patent is the same loss as that incurred by Sanofi from Apotex's exportation of clopidogrel to the U.S. for sale there, Sanofi could only recover that loss once. I point out, however, that it has not been established to this point that the infringement of the '265 and '777 Patent by the exportation of clopidogrel to the U.S. are, in fact or in law, the same loss. Since the matter must be returned to the Trial Judge on the question of remedies, I will say no more about that question.

[116] However, even if the loss from the infringement of the '265 and '777 Patents are the same loss, it does not follow that the Liability Exposure Provision would prevent Sanofi from recovering the remaining 50% of that loss as a result of the infringement of the '777 Patent. I do not come to this conclusion as a result of a construction of the May 2006 Agreement and the Liability Exposure Provision in the context of the factual matrix in which those provisions were negotiated, though I do not disagree with the Trial Judge's construction of those documents. I come to that conclusion on the basis that even if the Liability Exposure Provision would otherwise have the effect proposed by Apotex, Apotex lost the benefit of that provision when it chose to attack Sanofi's Canadian patent.

[117] It is inconceivable that Apotex could retain immunity from the consequences of its infringement of the '777 Patent while at the same time seeking a declaration of invalidity of that patent. If terms are to be implied into the Liability Exposure Provision to give it business efficacy, surely one of the implied terms would be that the parties would accept the decision of the U.S. court as binding on them for the purposes of their dealings in Canada. Apotex would retain 50% of its net U.S. sales even though it infringed the '265 patent but in return Apotex would respect Sanofi's Canadian monopoly. In commencing an action seeking a declaration of invalidity of the '777 Patent, Apotex breached the implied term and lost the benefit which it would otherwise have enjoyed under the Liability Exposure Provision.

[118] As a result, I would reject Apotex's argument based on the May 2006 Agreement and the Liability Exposure Provision. Since Apotex's arguments with respect to estoppel and *res judicata* are simply aspects of the argument against double recovery, I need not say anything more about them.

[119] As a result, I find that none of Apotex's alternate grounds for supporting the Trial Judge's conclusions have merit.

CONCLUSION

[120] For the reasons set out above, I would set aside the judgment of the Federal Court and, rendering the judgment which it should have rendered, I would allow Sanofi-Aventis' action for

infingement of the Canadian Patent No.1,366,777 and declare that Apotex has infringed claims 1, 3, 6, 7, 8, 9, 10, and 11 of that patent. I would dismiss Apotex's action seeking a declaration that Canadian Patent No.1,366,777 is invalid. I would return the matter to the Federal Court to deal with the issue of remedies and award Sanofi its costs, to be assessed, both in this court and in the Federal Court.

[121] As the Trial Judge made no findings of infringement against Apotex Pharmachem Inc. and Signa SA de CV, I would dismiss Sanofi's claims against them. Since these entities were represented by counsel representing Apotex Inc. and since their representation did not add to Apotex Inc's cost of defence, I would make no order as to costs in their favour.

"J.D. Denis Pelletier"
J.A.

"I agree
Marc Noël J.A."

GAUTHIER J.A. (Concurring reasons)

[122] I agree that this appeal should be allowed for the reasons given by my colleague, Pelletier J.A.

[123] Although it is not necessary to dispose of this appeal, I wish to add further brief comments on some issues raised in this case in respect of utility and obviousness.

[124] First, as noted by Pelletier J.A., not every patent contains a promise of a specific result within the meaning of *Consolboard*, cited above. However, one may wonder why an inventor would include comments relating to a practical purpose to which an invention may be applied when such statements are not necessary under Canadian law.

[125] Although such statements may be made in a disclosure, for example, to support a specific result included in the claims or an advantage that is necessary to support the invention described in the claim, there are other cases where the reasons for including them have little to do with an intent to promise a result within the meaning of *Consolboard*. For example, when Canadian applications are filed on the basis of European applications (priority date), it is useful to know that under European Union patent law, an invention must be capable of industrial application, which is a wide concept. Because of this, European applications will often contain some statements in that respect. In this context, and considering that no such requirement exists in our law, one must be careful not to treat each reference to a practical purpose as a promise of a specific result within the meaning of *Consolboard*.

[126] Moreover, in my view, statements of or references to a specific result in a claim, which are part of the specification as expressly noted in *Consolboard* (such as one dealing with a new use/new utility (See *AZT*, cited above)) and statements in respect of a claimed new process to make an old product to obtain a specific result (See, for example, *Re Alsop's Patent* (1907), 24 R.P.C. 733) ought to be distinguished from expressly qualified statements as to what practical applications can be expected to flow from the demonstrated properties and advantages of a new product (such as the new compound in this case).

[127] Thus, even if I were to assume that the Trial Judge was correct to construe the last part of the long sentence on page 21 of the '777 patent as referring to human use ("...the medicine of the invention *can* be usefully administered in the treatment and prevention of platelet disorders due to extracorporeal blood circuits or the consequence of complications in artheroma [Emphasis added]."), I could not construe this statement as a promise of a specific result within the meaning of *Consolboard*.

[128] I understand the Trial Judge to have found that a person skilled in the art would know at the relevant time that one cannot reasonably predict any useful use of clopidogrel in humans from the properties and advantages demonstrated in the patent (See, for example, paragraphs 572, 573 & 580 of the Reasons). Thus, the person skilled in the art would recognize that the mechanism and the properties specifically identified in the first part of the statement found on page 21 of the '777 patent ("On account of its interesting inhibitory properties towards platelet aggregation and its interference in the mechanism of formation of arterial and venous

thromboses...") are insufficient to make the leap to the conclusion that a practical application in humans will indeed be achieved.

[129] In this context, it is difficult, if not impossible, in my view, to construe the statement at the end of the sentence at page 21 of the '777 patent as a promise (i.e., effectively, a guarantee) that any specific result will be achieved in humans. The word "can" must mean that, as a pro-drug, clopidogrel has the prerequisite inhibitory properties before ingestion (i.e., the power) to allow a practical application to occur in humans; it is "potentially capable of" such application (See *The Oxford Canadian Dictionary*, 2d ed., *s.v.* "can").

[130] As patent disclosures are addressed to persons skilled in the art, a patentee should be able to assume that the specific limits of his or her statement will be properly understood. This, in my view, is perfectly in line with the approach to construction mandated in *Consolboard* and referred to at paragraph 54 of Pelletier J.A.'s reasons.

[131] The Supreme Court of Canada's comments in *Consolboard* with respect to a promise of specific result were made in a case raising issues of demonstrated utility. I believe that one must be particularly prudent when one seeks to extend *Consolboard*'s principles to statements clearly based on expectations. In fact, in my view, even if one were to adopt the Trial judge's construction, the promise has been met as clopidogrel is indeed useful in humans.

[132] If this is not so, then this case demonstrates the seriousness of some of the criticisms set out in Professor Norman Siebrasse's article "Must the Factual Basis for Sound Prediction be

Disclosed in the Patent?" (2012) 28 C.I.P.R. 39. In that article, Professor Siebrasse argues that Binnie J.'s brief statement at paragraph 70 of *AZT* is not a proper basis for the heightened level of disclosure applied in recent case law, especially in cases where no use or specific result is referred to in claims where the inventor defines the invention for which he is seeking a monopoly, or where a specific advantage/utility is required to support the right to claim a particular invention (selection).

[133] It is clear that the Trial Judge was satisfied that the patent application was not filed on the basis of mere speculation. The patentee had a solid track record based on an extensive research program and a reasonably sound line of reasoning. It is not challenged here that the invention is indeed useful and extensively used. Thus, neither the description of the invention (per s. 34 of the *Act*) nor the policy reasons discussed in the *AZT* decision at paragraph 69 are at issue.

[134] In contradistinction with the situation in *AZT*, where the invention claimed was the new use/utility and thus the *quid pro quo* for the grant of the monopoly was a full disclosure in respect of such utility, the public here received all the information necessary to make and use clopidogrel, the invention claimed in the '777 Patent. The Trial Judge found, and this is no longer challenged, that the advantages necessary to make the selection inventive and thus justify the grant of a monopoly on clopidogrel were fully and properly described and demonstrated in the patent.

[135] In such a case, the level of disclosure required by law should be lower. If again I were to assume that the Trial Judge's construction was correct, the clear indication in the statement at

page 21 of the ‘777 Patent that use in humans was predicted as opposed to demonstrated should be sufficient at law to meet the test for sound prediction. Indeed, this is enough to enable the public to know that such practical application was not demonstrated at the time the patent application was filed. Therefore, the public would have the ability to challenge the monopoly based on whether it was granted on mere speculation, and determine whether the inventor in fact had the required factual basis and sound line of reasoning to support this statement at the relevant time.

[136] Turning now to obviousness, I add to the reasons given by my colleague, Pelletier J.A. that, in my view, the analysis of the Trial Judge is incomplete because it only focused on the resolution of PCR 4099.

[137] The Trial Judge believed that the evidence before him with respect to the separation of the enantiomers was significantly different from the evidence before the Supreme Court of Canada in *Plavix* because: i) he found that a line had been drawn in the sand at the time the application was filed, and that as part of the process of developing a racemic drug a sponsor would be motivated to separate the enantiomers to get information to pre-empt expected new regulatory requirements (See Reasons at paragraphs 748-749); and ii) in his view, the separation itself did not involve substantial difficulties and was routine. However, Rothstein J. made it clear in *Plavix* that whether the separation or resolution of the enantiomers was routine or involved arduous work would assume small significance in this case when one considers the whole course of conduct that led to the decision to separate (See *Plavix* at paragraph 89).

[138] It appears to me that the Trial Judge did not really weigh the extent, nature, and amount of efforts required to arrive at a decision to actually develop PCR 4099, as opposed to any other racemic compound covered by the '875 Patent to the point that separation will become relevant. As mentioned by Pelletier J.A. above at paragraph 73, Rothstein J. found in *Plavix* that the '875 Patent did not differentiate between the efficacy and toxicity of any of the compounds it covered. The Trial Judge essentially agreed and held that the '875 Patent did not point either directly or indirectly to PCR 4099, even if PCR 4099 itself was known as one of the 21 compounds used in the examples of the '875 Patent.

[139] The Trial Judge did not find that the person skilled in the art would obviously start a development project based on the '875 Patent compound with PCR 4099 as opposed to any other compound, including the 21 compounds expressly used in the examples. In fact, Sanofi's actual course of action militates against such a conclusion.

[140] Thus, for the reasons given by my colleague, Pelletier J.A., and considering the additional comments above, I agree that the conclusion in respect of obviousness cannot stand.

"Johanne Gauthier"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-7-12
STYLE OF CAUSE:	SANOFI-AVENTIS and APOTEX SANOFI-AVENTIS and BRISTOL-MYERS SQUIBB SANOFI PARMACEUTICALS HOLDINGS PARTNERSHIP
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	January 28 and 29, 2013
REASONS FOR JUDGMENT BY:	PELLETIER J.A.
CONCURRED IN BY:	NOËL J.A..
CONCURRING REASONS BY:	GAUTHIER J.A
DATED:	July 24, 2013

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