Date: 20090116

Docket: A-484-07

Citation: 2009 FCA 8

CORAM: **LÉTOURNEAU J.A.**
NOËL J.A.
BLAIS J.A.

BETWEEN:

APOTEX INC.

Appellant
(Respondent)

and

PFIZER CANADA INC. and
PFIZER IRELAND PHARMACEUTICALS

Respondents
(Applicants)

and

THE MINISTER OF HEALTH

Respondent
(Respondent)

Heard at Toronto, Ontario, on December 17 and 18, 2008.

Judgment delivered at Ottawa, Ontario, on January 16, 2009.

REASONS FOR JUDGMENT BY: NOËL J.A.

CONCURRED IN BY: LÉTOURNEAU J.A.
BLAIS J.A.

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REASONS FOR JUDGMENT

NOËL J.A.

[1] This is an appeal from the decision of Justice Mosley (the Federal Court Judge) allowing the application brought by Pfizer Canada Inc. and Pfizer Ireland Pharmaceuticals (the respondents)

to prohibit the Minister of Health (the Minister) from issuing a Notice of Compliance (NOC) to Apotex (the appellant or Apotex) in accordance with subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (PM(NOC) Regulations) for its sildenafil tablets until after the expiration of the respondents' Canadian Patent No. 2,163,446 (the '446 patent).

[2] In the Memorandum filed in support of its appeal, the appellant pursued the issues of faulty disclaimer, claims broader than the invention made and disclosed, patent ineligibility, obviousness and anticipation. Two days prior to the scheduled hearing, the appellant wrote to advise that it would only pursue the appeal in respect of the issue of obviousness, intending to rely upon the decision of the Supreme Court of Canada in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 (*Sanofi-Synthelabo*) released November 6, 2008.

THE RELEVANT FACTS

[3] The respondents market a drug for the treatment of Erectile Dysfunction (ED), under the brand name VIAGRA.

[4] The respondents obtained patent protection for the use of the compound sildenafil for this purpose. They obtained the '446 patent on July 7,1998 from an application filed in Canada on May 13, 1994 claiming priority from Great Britain Patent Application No. 9311920.4 filed on June 9, 1993. The '446 patent will expire on May 13, 2014.

[5] The respondents submitted a patent list to the Minister pursuant to subsection 4(1) of the PM(NOC) Regulations in connection with NOCs for 25 mg, 50 mg and 100 mg oral tablets of the drug sildenafil citrate (sildenafil). The ‘446 patent was added to the Patent Register in respect of the above NOCs.

[6] The appellant delivered its Notice of Allegation (NOA) on June 16, 2005 to the respondents (i.e., specifically, Pfizer Canada Inc.) in relation to the ‘446 patent. In its NOA, the appellant claims to have filed with the Minister a submission for sildenafil citrate tablets for oral administration in strengths of 25, 50 and 100 mg tablets for the treatment of ED in men, arguing that the ‘446 patent is invalid for several reasons, notably that the use of sildenafil for the treatment of ED in men was obvious in light of the state of the art, and that it should therefore, be allowed to market its own generic version.

[7] The respondents filed their Notice of Application on July 28, 2005 and it was amended on February 5, 2007.

THE PATENT AT ISSUE

[8] The ‘446 patent relates to the use of a series of pyrazolo[4,3-d] pyrimidin-7-ones compounds and their pharmaceutically acceptable salts for the treatment of ED. Sildenafil is one such compound and has the formula 5-[2-ethoxy-5-(4-methyl-1-piperazinylsulphonyl)phenyl]-1-methyl-3-n-propyl-1,6-dihydro-7Hpyrazolo[4,3-d]pyrimidin-7-one].

[9] Each of the claims in issue is specific to the treatment of ED with sildenafil, or its salt, sildenafil citrate, which is the active ingredient in the appellant's proposed products. For ease of reference, the relevant claims are reproduced below:

> **Claim 1**
> The use of a compound of formula (I) *[which is then defined*] or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition containing either entity, for the manufacture of a medicament for the curative or prophylactic treatment of erectile dysfunction in man.
>
> *Claims 2-4 in essence claim "The use according to claim 1" and give more narrow definitions for formula (I).*
>
> **Claim 7**
> The use according to claim 4 wherein the compound of formula (I) is 5-[2-ethoxy-5-(4-methyl-1-piperazinylsulphonyl)phenyl]-1-methyl-3-n-propyl-1,6-dihydro-7Hpyrazolo[4,3-d]pyrimidin-7-one] or a pharmaceutically acceptable salt thereof.
>
> **Claim 8**
> The use according to any one of claims 1 to 7 for the manufacture of a medicament for the curative or prophylactic treatment of erectile dysfunction in man.
>
> **Claim 18**
> The use of a compound of formula (I) according to any one of claims 1 to 7, or a pharmaceutically acceptable salt thereof, for the curative or prophylactic treatment of erectile dysfunction in man.
>
> **Claim 22**
> The use according to any one of claims 1 to 8 wherein the medicament is adapted for oral treatment.

THE FEDERAL COURT DECISION

[10] The Federal Court Judge concluded that, based on the evidence, the respondents' discovery was truly inventive and that none of the appellant's attacks on the patent should succeed.

He held that the respondents met their legal burden to establish the validity of the ‘446 patent on a balance of probabilities and that the application to prohibit the Minister from issuing an NOC to the appellant until after the expiry of the ‘446 patent should be granted.

[11] More specifically, with respect to the issue of obviousness, which is the only one left to be considered in the present appeal, the Federal Court Judge held that the core question in the case was whether the person of ordinary skill in the art, in the light of the state of the art and of common general knowledge as at the claimed date of invention, would have found the solution taught by the patent. The “solution taught by the patent” that he used for this inquiry was consistent with his claim construction, namely “the appreciation that the oral administration of sildenafil, as a potent PDE5 inhibitor, would be useful in the treatment of [ED] in men” (Reasons, para. 57).

[12] On the basis of the scientific literature and the experts’ opinions tendered in evidence, the Federal Court Judge defined the notional skilled person for the ‘446 patent as a trained and experienced scientist working in drug development with a knowledge of penile physiology and erectile response.

[13] In considering the relevant prior art, the Federal Court Judge referred in particular to the National Institute of Health Consensus Statement resulting from the Consensus Conference on Impotence held in December 1992. While he noted that the document did not purport to be an exhaustive review of the literature, it was useful as a reference to what was commonly known and was not known at the time by the highly trained physicians and scientists experienced in the field of

ED research and therapy. He held that what was clear from the document was that important information was lacking and that more work needed to be done to fully understand penile physiology. In his view, the content of the document could not be reconciled with what the appellant's experts claimed to be the state of the art at the time.

[14] The Federal Court Judge also considered the specific literature references relied on by the appellant in support of its claim of obviousness, in particular three papers written by Drs. Rajfer, Murray and Bush (Reasons, para. 87). He concluded that based on an analysis of the expert testimony, none of the literature references would have led a skilled person directly and without difficulty to the invention of the '446 patent.

[15] In concluding his obviousness analysis, the Federal Court Judge held that what emerged from the prior art was a picture of a field of rapidly advancing science which led to the discovery, but which did not point directly to it. He specifically noted that, in 1993, none of the scientists who had speculated that PDE inhibition might be a factor in erectile tissue physiology, arrived at the solution of using oral administration of sildenafil as a PDE5 inhibitor in the treatment of ED. He therefore concluded that the evidence did not establish that the solution taught by the patent was obvious at the time. At best, the Federal Court Judge noted that there was speculation, which in hindsight proved to be correct, that PDE5 inhibitors might treat impotence.

[16] In addition to his findings on the state of the art, the Federal Court Judge also considered the other factors for analyzing obviousness as set out in *Novopharm Ltd. v. Janssen-Ortho Inc.*

2007 FCA 217, aff'g 2006 FC 1234 (*Novopharm*). He found that there was a strong motivation to come up with a convenient drug treatment for ED, and genuine surprise when the respondents did so. He also noted the cumulative effect of the secondary indicia such as the commercial success of VIAGRA®, its wide use, and the surprise that accompanied its first publication, all of which he found to further support his conclusion that the use of sildenafil to treat ED was not obvious.

ORAL SUBMISSIONS OF THE APPELLANT AT THE HEARING

[17] The appeal was argued on the basis of the revised grounds first announced by the appellant two days before the hearing. No advance submissions were provided, so that the exact nature of the issues only became clear as the hearing progressed.

[18] The appellant argued that the Supreme Court in *Sanofi-Synthelabo* brought a fundamental change to the jurisprudential approach to obviousness in Canada by incorporating the "worth a try" test into Canadian law. The state of the law in Canada is now in line with that applicable in the United Kingdom (U.K.) so that U.K. precedents become highly relevant. The "worth a try" test must now be conducted in cases involving advances won by experimentation (*Sanofi-Synthelabo, supra*, para. 68). This is such a case and the Federal Court Judge erred in failing to apply this test.

[19] The appellant urges us to apply the "worth a try" test and suggests that the decision of Mr. Justice Laddie of the Chancery Division in *Lilly Icos Ltd. v. Pfizer Ltd.*, [2001] F.S.R. 16 (*Pfizer Ltd.*), confirmed by the English Court of Appeal in *Lilly Icos Ltd. v. Pfizer Ltd.*, [2002] EWCA Civ 1

(*Lilly Icos Ltd.*), provides the "blue print" for the application of this test. In these decisions the U.K. Courts concluded that the relevant claims of the patent in issue in the present appeal were invalid on the ground of obviousness.

[20] The appellant further argues that the previously published patent application EP-0463756A1 (the '756 patent, also referred to as the Bell application) was a crucial element in the obviousness analysis conducted by the U.K. Courts. It identifies sildenafil (the active ingredient in VIAGRA) as one of five compounds useful in the treatment of cardiovascular disorders (Appeal Book, Vol. 4, pp. 1343 to 1349). This patent was referred to by Apotex in its NOA in order to establish that the relevant claims were made obvious by the state of the prior art. According to the appellant, the '756 patent was an essential component of the prior art and the Federal Court Judge erred in law in failing to consider this patent in his obviousness analysis.

[21] Counsel for the appellant confirmed in the course of his argument that his appeal rests solely on these two grounds, and that if the Court should come to the conclusion that the Federal Court Judge applied the proper test, and did not ignore the '756 patent as alleged, the appeal should be dismissed. To be clear, the construction of the patent and the findings of fact made by the Federal Court Judge are no longer in issue.

ANALYSIS AND DECISION

[22] The first ground of appeal is based on the appellant's understanding of the decision of the Supreme Court in *Sanofi-Synthelabo* and in particular the test that was adopted in that case. The appellant views this decision as establishing that the "worth a try" test is now part of the law of Canada. As the Federal Court Judge did not apply this test, the appellant invites us to do so.

[23] Before considering whether the Federal Court Judge failed to apply the appropriate test, as is being alleged by Apotex, the test in question must first be identified. In *Sanofi-Synthelabo,* Rothstein J. writing for the Court began his obviousness inquiry by noting that the Federal Court Judge in that case (Shore J.) conducted his analysis on the basis that the test set out by this Court in *Beloit Canada Ltd. v. Valmet Oy*, [1986] F.C.J. No. 87, 8 C.P.R. (3d) 289 (*Beloit*) at page 294 would not accommodate the "worth a try" test (para. 52). Rothstein J. identified the position of Apotex in that case as follows (para. 55):

> 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.

[24] Rothstein J. first looked to the United States and U.K. case law. He concluded that a test described as the "obvious to try" test has been accepted in both of these jurisdictions (paras 56 to 59). Given the state of the law in these other jurisdictions, Rothstein J. says (para. 60):

> … the restrictiveness with which the *Beloit* test has been interpreted in Canada should be re-examined.

[25] Under the heading “Approach to Obviousness in Canada”, Rothstein J. notes that until now Canadian Courts have tended to treat the *Beloit* test as a statutory prescription that limits the obviousness inquiry (para. 61). The “obvious to try” test can have a useful role under Canadian law (para. 64).

[26] Rothstein J. then focuses on the scope of this test. After noting that the factors set forth in the passage adopted by Lord Hoffmann in *Generics (UK) Ltd. v. H. Lundbeck A/S*, [2008] R.P.C. 19, [2008] EWCA Civ 311, which he quotes at paragraph 59, provide useful guidance, he says (para. 64):

> … 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.

[27] Rothstein J. then hones in on the precise test. At paragraph 66, he says:

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

In the prior paragraph, he made it clear that the word “obvious” in the phrase “obvious to try” is to be given its primary meaning of “very plain”.

[28] I take it from this that the test adopted by the Supreme Court is not the test loosely referred to as “worth a try”. After having noted Apotex’ argument that the “worth a try” test should be accepted (para. 55), Rothstein J. never again uses the expression “worth a try” and the error which he identifies in the matter before him is the failure to apply the “obvious to try” test (para. 82).

[29] The test recognized is “obvious to try” where the word “obvious” means “very plain”. According to this test, an invention is not made obvious because the prior art would have alerted the person skilled in the art to the possibility that something might be worth trying. The invention must be more or less self-evident. The issue which must be decided in this appeal is whether the Federal Court Judge failed to apply this test.

[30] In my respectful view, he did not. While the Federal Court Judge does not use the phrase “obvious to try”, his reasons show that he conducted his analysis along the dividing line drawn in *Sanofi-Synthelabo*. Specifically, he rejected the contention that the invention was obvious based on mere possibilities or speculation and looked for evidence that the invention was more or less self-evident.

[31] A review of the Federal Court Judge’s assessment of the experts’ opinions and the literature references tendered in evidence supports this conclusion. More specifically, it is apparent that he turned his mind to the question of whether the patented invention was more or less self-

evident in examining this evidence. Indeed, the following excerpts show that he found, based on the expert evidence, that the invention was not self-evident:

> [76] In Dr. Brock's view, the discovery of the ability of a selective PDE5 inhibitor, such as sildenafil, to be an effective and safe oral agent to enhance erectile function in man was fortuitous and insightful. The fact that hundreds of active investigators had studied ED for decades without this realization, in his opinion, strongly supports this conclusion.
>
> [83] Dr. Christ was actively researching erectile physiology and mechanisms of erectile dysfunction in the late 1980s and early 1990s. He states that prior to the publication of Pfizer's positive results with sildenafil citrate, it was not obvious to scientists working in the field that a PDE5 inhibitor could be used to treat ED and it also was not obvious that oral administration of a PDE5 inhibitor would work. Indeed, he says, many remained skeptical even after publication of the Pfizer results. The focus was on intracavernous drug injections and other therapies. It was counterintuitive and surprising that a PDE5 inhibitor administered orally could have a localized effect …
>
> [84] … In [Dr. Palmer's] affidavit he recounts the history of the physiology of NO and its role as a chemical messenger. Palmer says that while by the early 1990s much was known about this, the surrounding complexity tended to blur what now appears clear in hindsight. He states that it was not commonly and generally accepted at the relevant time that the NANC pathway was the right pathway to target for treatment of impotence, citing a compilation of abstracts from the first meeting of the European Society for Impotence Research in September 1995. In particular, Palmer refers to an abstract of research by a leading group at the Hanover Medical School (Taher, Stief et al.,) which describes the continuing controversy regarding the involvement of cyclic nucleotide monophosphates in the process of penile erection in males. The research of the Hanover group into the potential of inhibiting PDEs as a treatment for impotence led them away from PDE5 to PDE3.
>
> [85] Dr. Heaton was conducting research on neural stimulation of the NANC pathway for ED from about 1990 and attended an international impotence research conference at Singapore in 1994 where developments in the field were presented. He describes his first reaction when he heard that Pfizer had an oral PDE inhibitor compound for ED as "real surprise and skepticism". He and many other scientists at the time doubted that the selectivity of sildenafil would be enough to avoid significant systemic effects at clinically useful doses. They found it surprising and "revolutionary" that sildenafil worked when an

> erection was wanted and worked through oral administration as opposed to local injection. He saw this development as a paradigm shift in the field of ED treatment.
>
> [My emphasis]

[32] In the same vein, it is also apparent that the Federal Court Judge was looking for more than mere possibilities in examining the primary literature references relied upon by the appellant. With respect to the Rajfer and Trigo-Rocha papers, he found that they did not disclose, or even suggest, that a cGMP PDE5 inhibitor, like sildenafil, would treat ED:

> [101] In the view of the applicants' experts, and as supported by cross-examination of the respondent's experts, what the 1992 Rajfer article did was essentially to confirm further previous work that the NO/cGMP pathway in the corpus cavernosum was involved in penile erection. It did not suggest the use of cGMP inhibitors for the treatment of ED. This conclusion is not altered by the subsequent Trigo-Rocha studies from the same group. They do not, as Apotex argues, disclose that the solution to ED is to use a cGMP PDE inhibitor. Rather they present an *in vivo* parallel of the Rajfer findings in healthy dogs, not what might be expected in either impotent dogs or impotent men. They do not point specifically to, or even suggest, the use of cGMP PDE inhibitors as a therapeutic remedy but provide further evidence for the involvement of the NO pathway *in vivo*.
>
> [My emphasis]

[33] With respect to the Murray paper, while it identified some cGMP PDE5 inhibitors, their relationship to smooth muscle relaxation and their potential uses as a drug therapy, the Federal Court Judge found that (Reasons, para. 105) "… at best, [the paper could] be taken to suggest that there [was] a possibility that cGMP PDE5 inhibitors could be developed for ED, subject to human testing, but that, in any event, [it] point[ed] to the potential utility of zaprinast, not sildenafil."

[34] Similarly, the Federal Court Judge noted that a similar conclusion could be drawn from the Bush paper, namely that it was not a given that a specific cGMP PDE inhibitor would be clinically effective in treating ED and that it was a possibility to be considered and further researched:

> [121] In Dr. Brock's opinion, when a skilled person read [the summary and conclusion section of the Bush paper] in context, he would not have understood that a specific cyclic GMP PDE inhibitor would successfully treat erectile dysfunction. It was a possibility to be considered and further researched, which is consistent with the views of the other experts at the time such as Rajfer and Trigo-Rocha.
>
> [122] For Dr. Heaton, the Bush thesis showed just how much remained unknown that could be the subject of future research projects. It was not a given that a cGMP PDE inhibitor would be clinically effective as a treatment for ED and there is no suggestion in the thesis that such a drug could be administered orally. On cross examination, Dr. Corbin agreed with the suggestion that what Dr. Bush was saying is that understanding the mechanism for relaxation will establish a basis for future research into not only the mechanism of erection but also for treatment of impotence. But that does not, in my view, point directly to the invention claimed by the '446 patent.
>
> [My emphasis]

[35] The Federal Court Judge goes on to confirm that the most that he could gather from the prior art at the priority date was that using orally administered sildenafil to treat ED was "worth a try":

> [126] Even if the person of ordinary skill had arrived, based on the art, at oral administration of sildenafil, and being mindful of the caution stated in *Novopharm* above about the use of catchphrases, the most that could have been said at the priority date is that it would be "worth a try". Indeed that is essentially how Dr. Ringrose characterized his view when he suggested that sildenafil be tried out as a treatment for impotence by the Urogenitals Group at Pfizer in January, 1992. …
>
> [My emphasis]

In so saying, the Federal Court Judge equates the expression “worth a try” with “a possibility worth exploring” as Dr. Ringrose had characterized the matter when he suggested that sildenafil be tried as a treatment for impotence (Reasons, para. 61).

[36] It is apparent from the above review that the Federal Court Judge throughout his analysis looked for more than possibilities understanding that mere possibilities were not enough, and that the prior art had to show more than that. His appreciation of the matter is summed up and further demonstrated by his concluding remarks (Reasons, para. 125):

> Although there was a significant amount of evidence indicating that cGMP PDE inhibitors should be further explored with regards to the treatment of ED in the months leading up to the Pfizer discovery, the evidence does not in my view establish that the solution taught by the patent was obvious at the time. At best there was speculation, which in hindsight proved to be correct, that PDE5 inhibitors might treat impotence. Experiments with zaprinast, a cGMP PDE inhibitor, had been performed but in an effort to understand how the erectile process works, not how to treat ED.
>
> [My emphasis]

[37] In so holding, the Federal Court Judge drew the line precisely where the Supreme Court drew it in *Sanofi-Synthelabo* when it held that (para. 66) “the mere possibility that something might turn up is not enough”.

[38] The other alleged error is that the Federal Court Judge failed to consider the ‘756 patent in his obviousness analysis. The ‘756 patent was relied upon by Apotex in the Federal Court to show that by 1993, it had been disclosed that sildenafil was a potent and selective cGMP PDE inhibitor

that could be orally-administered for the treatment of ailments involving the need to relax smooth muscle (Apotex' Memorandum, para. 29). Had the Federal Court Judge considered this element of the prior art, he would have been bound to conclude that the skilled person had the means to obtain the invention.

[39] In this respect, Counsel for Apotex pointed to the decision of Mr. Justice Laddie in the U.K. case who began his analysis by referring to the '756 patent (*Pfizer Ltd.*, *supra*, para. 23). This, according to Apotex, highlights the importance of the '756 patent and the extent of the error committed by the Federal Court Judge in failing to give it any consideration.

[40] Although the Federal Court Judge does not refer to the '756 patent by name in his obviousness analysis (he does so in his anticipation analysis), it is clear that he had this patent in mind. The issue before the Federal Court Judge, based on the way in which he construed the patent, was whether the skilled person would be led to use sildenafil orally to treat ED. The '756 patent identified sildenafil as an antihypertensive. The Federal Court Judge did not give the '756 the significance which Apotex contends it should have because he found as a fact that it would have been counterintuitive to use a drug that lowers blood pressure to treat ED when ED is associated with low blood pressure (Reasons, paras 68, 78, 83, 85, 95 and 98). While Apotex disagrees with this factual assessment, it cannot be seriously argued that the '756 patent was not considered.

[41] The assessment made by the Federal Court Judge is different than that made by Mr. Justice Laddie of the Chancery Division and confirmed by the English Court of Appeal in the U.K.

case. The Federal Court Judge was aware of these decisions (Reasons, para. 119). However, he was entitled, indeed obliged to draw his own conclusions.

[42] Furthermore, a review of Mr. Justice Laddie's decision suggests that the issue of obviousness was determined on the basis of a broader test than that adopted by the Supreme Court in *Sanofi-Synthelabo*. In his decision, Mr. Justice Laddie says (*Pfizer Ltd., supra*, paras. 106 and 107):

> [106] … Where something is obvious to try depends to a large extent on balancing the expected rewards if there is success against the size of the risk of failure. Here it was apparent that the rewards for finding an oral treatment would be substantial. The risk was not, as indicated above, the risk of killing anyone, but the risk that trying oral administration would not work so that the research would be unproductive. In considering this, it is worth bearing in mind the approach adopted by the EPO Technical Board of Appeal in case T0379/96, a case concerned with attempts to replace ozone damaging aerosol propellants with non-damaging ones. The Board said:
>
> > Moreover, having regard to the degree of pressure put on industry by existing or imminent legislation and by the public interest, to try to replace P12 [i.e. a damaging propellant], in the Board's view, it is a minor matter whether or not there was a particularly high degree of expected success before starting experimental work with HFC 134a.
>
> [107] I have come to the conclusion that the skilled team would not have been put off trying oral administration of a PDE inhibitor. On the contrary, on balance there is much in the evidence which suggests that trying oral administration was a worthwhile, and perhaps the first, avenue to pursue. …
>
> [My emphasis]

The English Court of Appeal in confirming the decision of Mr. Justice Laddie expressed the view that he properly identified the test (*Lilly Icos Ltd., supra*, paras 67 and 68).

[43] The reasoning advanced by Mr. Justice Laddie and approved by the English Court of Appeal is that where the motivation to achieve a result is very high, the degree of expected success becomes a minor matter. In such circumstances, the skilled person may feel compelled to pursue experimentation even though the chances of success are not particularly high.

[44] This is no doubt the case. However, the degree of motivation cannot transform a possible solution into an obvious one. Motivation is relevant in determining whether the skilled person has good reason to pursue "predictable" solutions or solutions that provide "a fair expectation of success" (see respectively the passages in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) at page 1742 and *Angiotech Pharmaceuticals Inc. v. Conor Medsystems Inc.*, [2008] UKHL 49, at paragraph 42, both of which are referred to with approval in *Sanofi-Synthelabo, supra*, at paragraphs 58 and 59).

[45] In contrast, the test applied by Mr. Justice Laddie appears to be met if the prior art indicates that something may work, and the motivation is such as to make this avenue "worthwhile" to pursue (*Pfizer Ltd., supra*, para. 107, as quoted at para. 42 above). As such, a solution may be "worthwhile" to pursue even though it is not "obvious to try" or in the words of Rothstein J. even though it is not "more or less self-evident" (*Sanofi-Synthelabo, supra*, para. 66). In my view, this approach which is based on the possibility that something might work, was expressly rejected by the Supreme Court in *Sanofi-Synthelabo*, at paragraph 66.

[46] The Federal Court Judge rendered his decision on the basis that more than possibilities were required. He concluded based on the evidence before him that Apotex had failed to establish more than that. In so doing, he applied the correct test.

[47] The appellant having failed to establish that either of the two alleged errors was committed, I would dismiss the appeal with costs. The respondents sought increased costs by reason of the late change in the appellant's position on appeal. I agree that if proper attention had been given to the matter, the change in approach would have been communicated earlier, and the respondents would have been in a position to reflect on their response. I would order that costs be computed in accordance with the mid-range of column V of Tariff B.

"Marc Noël"
J.A.

"I agree.
Gilles Létourneau J.A."

"I agree.
Pierre Blais J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-484-07
(APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE MOSLEY DATED SEPTEMBER 27, 2007, NO. T-1314-05.)	
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DATED:	January 16, 2009

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